



Federal Register

12-22-00

Vol. 65 No. 247

Pages 80733-81320

Friday

Dec. 22, 2000



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Federal Register

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DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 929

[Docket No. FV00-929-6 FIR]

Cranberries Grown in the States of Massachusetts, et al.; Temporary Suspension of Provisions in the Rules and Regulations

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: The Department of Agriculture (Department) is adopting, as a final rule, without change, the provisions of an interim final rule that suspended certain sections in the rules and regulations to shorten the appeals procedure for growers who disagree with their sales history determination made by the Cranberry Marketing Committee (Committee) for the 2000/2001 marketing season. Due to the lateness of the season, and the numerous appeals received, the Committee recommended that review of the subcommittee's determination by the full Committee be suspended to shorten the appeal process during the current season. This time savings allowed the Committee to inform growers more timely how many cranberries handlers could purchase under this season's volume regulation and facilitated grower harvesting decisions.

EFFECTIVE DATE: January 22, 2001.

FOR FURTHER INFORMATION CONTACT: Patricia A. Petrella or Kenneth G. Johnson, DC Marketing Field Office, Fruit and Vegetable Programs, AMS, USDA, Suite 2A04, Unit 155, 4700 River Road, Riverdale, Maryland 20737, telephone: (301) 734-5243, Fax: (301) 734-5275; or George Kelhart, Technical Advisor, Marketing Order

Administration Branch, Fruit and Vegetable Programs, AMS, USDA, room 2525-S, PO Box 96456, Washington, DC 20090-6456; telephone: (202) 720-2491, Fax: (202) 720-5698. Small businesses may request information on complying with this regulation by contacting Jay Guerber, Marketing Order Administration Branch, Fruit and Vegetable Programs, AMS, USDA, P.O. Box 96456, room 2525-S, Washington, DC 20090-6456; telephone: (202) 720-2491, Fax: (202) 720-5698, or E-mail: Jay.Guerber@usda.gov.

SUPPLEMENTARY INFORMATION: This rule is issued under Marketing Order No. 929, as amended (7 CFR part 929), regulating the handling of cranberries grown in Massachusetts, Rhode Island, Connecticut, New Jersey, Wisconsin, Michigan, Minnesota, Oregon, Washington, and Long Island in the State of New York, hereinafter referred to as the order. The marketing order is effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601-674), hereinafter referred to as the Act.

The Department of Agriculture (Department) is issuing this rule in conformance with Executive Order 12866.

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule is not intended to have retroactive effect. This rule will not preempt any State or local laws, regulations, or policies, unless they present an irreconcilable conflict with this rule.

The Act provides that administrative proceedings must be exhausted before parties may file suit in court. Under section 608c(15)(A) of the Act, any handler subject to an order may file with the Secretary a petition stating that the order, any provision of the order, or any obligation imposed in connection with the order is not in accordance with law and request a modification of the order or to be exempted therefrom. Such handler is afforded the opportunity for a hearing on the petition. After the hearing the Secretary would rule on the petition. The Act provides that the district court of the United States in any district in which the handler is an inhabitant, or has his or her principal place of business, has jurisdiction to review the Secretary's ruling on the petition, provided an action is filed not

later than 20 days after the date of the entry of the ruling.

This rule finalizes an interim final rule that temporarily suspended, through November 15, 2000, provisions in § 929.125 of the rules and regulations (65 FR 42598, July 11, 2000) to shorten the sales history appeal process for the 2000/2001 marketing season. The Committee is responsible for calculating each grower's sales history on an annual basis. The appeals process includes three levels of review, a review by the appeals subcommittee of the Committee, the full Committee, and finally the Secretary of Agriculture. Due to the lateness of the season, and the numerous appeals received from growers, the Committee unanimously recommended that the review by the Committee be suspended for the 2000/2001 season. This allowed growers to take their appeals directly to the Secretary for a final decision. The Committee unanimously recommended this action at its August 28, 2000, meeting.

Section 929.48 of the order and § 929.149 of the rules and regulations describe how the Committee computes a sales history for each grower. There are different computations used depending on the number of years a grower has been producing on such acreage. The Committee has been updating growers' sales histories each season. The Committee accomplishes this by using information submitted by the grower on a production and eligibility report filed with the Committee. The Committee established a review procedure in § 929.125 of the rules and regulations for growers who disagree with the Committee's computation.

Currently, § 929.125 (65 FR 42598; July 11, 2000) provides that a grower may appeal to an appeals subcommittee within 30 days of receipt of the Committee's determination of his/her sales history. If the grower is not satisfied with the subcommittee's decision, the grower may further appeal to the full Committee. Such grower must notify the full Committee of his or her appeal within 15 days after notification of the subcommittee's decision. The Committee has 15 days to review the appeal. The grower may further appeal to the Secretary, within 15 days after notification of the full Committee's findings, if the grower is not satisfied

with the Committee's decision. All decisions by the Secretary are final.

A volume regulation has been implemented for the 2000–2001 cranberry crop to address an oversupply situation currently being experienced by the industry. The Committee determined the best method of volume control to be the producer allotment program which provides for an annual marketable quantity and allotment percentage. Marketable quantity is defined as the number of pounds of cranberries needed to meet total demand and to provide for an adequate carryover into the next season. The allotment percentage equals the marketable quantity divided by the total of all growers' sales histories. The Committee is responsible for calculating each grower's sales history on an annual basis.

The appeals procedure described above could take 60 or more days to complete, and the number of appeals received for the season was large. At the Committee meeting on August 28, 2000, the appeals committee reviewed about 150 grower appeals, and more needed to be reviewed at this level.

Due to the lateness of the season, and the numerous appeals received, the Committee recommended that the review by the full Committee be suspended from the procedures to shorten the process. This was intended to allow growers to take their appeals directly to the Secretary for a final decision if they were not satisfied with the appeals subcommittee's determinations. To date all such appeals have been reviewed by the appeals subcommittee and reviewed and acted upon by the Secretary, if warranted.

The Committee recommended that the full Committee review step be temporarily suspended through November 15, 2000, to expedite the process for the current harvest. The complete procedures will be available to growers next season, if needed.

The Regulatory Flexibility Act and Effects on Small Businesses

Pursuant to requirements set forth in the Regulatory Flexibility Act (RFA), the Agricultural Marketing Service (AMS) has considered the economic impact of this action on small entities. Accordingly, AMS has prepared this final regulatory flexibility analysis.

The purpose of the RFA is to fit regulatory actions to the scale of business subject to such actions in order that small businesses will not be unduly or disproportionately burdened. Marketing orders issued pursuant to the Act, and rules thereunder, are unique in that they are brought about through

group action of essentially small entities acting on their own behalf. Thus, both statutes have small entity orientation and compatibility.

There are approximately 20 handlers of cranberries who are subject to regulation under the order and approximately 1,100 producers of cranberries in the regulated area. Small agricultural service firms, which include handlers, are defined by the Small Business Administration (13 CFR 121.201) as those having annual receipts of less than \$5,000,000, and small agricultural producers are defined as those having annual receipts of less than \$500,000. The majority of cranberry handlers and producers may be classified as small businesses.

This rule finalizes an interim final rule that temporarily suspended provisions in § 929.125 of the rules and regulations regarding the appeals procedure for growers who disagree with their sales history determination made by the Cranberry Marketing Committee. The Committee is responsible for calculating each grower's sales history on an annual basis. The appeals process includes a review by the appeals subcommittee, the full Committee, and finally the Secretary. Due to the lateness of the season, and the numerous appeals received, the Committee recommended that the review by the full Committee be suspended from the procedures to shorten the process.

This suspension action allowed growers, who filed appeals, to know their sales histories and annual allotments sooner. Handlers need this information to plan their acquisitions throughout this crop year under volume regulation. In addition, the Committee received over 200 appeals and needed to act on them quickly to render decisions as soon as possible. To date all such appeals have been reviewed by the appeals subcommittee and reviewed and acted upon by the Secretary, if warranted.

The Committee discussed the alternative of delegating the Committee's review to the appeals subcommittee, however, such action is not authorized under the rules and regulations. The Committee also discussed not revising the rules and regulations, however, this would not have allowed growers to know their sales histories and annual allotment as promptly as possible.

This action imposes no additional reporting or recordkeeping requirements on either small or large cranberry handlers. As with all Federal marketing order programs, reports, and forms are periodically reviewed to reduce

information requirements and duplication by industry and public sector agencies.

The Department has not identified any relevant Federal rules that duplicate, overlap, or conflict with this rule.

Further, the Committee's meeting was widely publicized throughout the cranberry industry and all interested persons were invited to attend the meeting and participate in Committee deliberations on all issues. Like all Committee meetings, the August 28, 2000, meeting was a public meeting and all entities, both large and small, were able to express views on this issue. Finally, interested persons were invited to submit information on the regulatory and informational impacts of this action on small businesses.

An interim final rule concerning this action was published in the **Federal Register** on September 14, 2000. Copies of the rule were mailed by the Committee's staff to all Committee members and handlers. In addition, the rule was made available through the Internet by the Office of the Federal Register. That rule provided for a 60-day comment period which ended November 13, 2000. No comments were received.

A small business guide on complying with fruit, vegetable, and specialty crop marketing agreements and orders may be viewed at: <http://www.ams.usda.gov/fv/moab.html>. Any questions about the compliance guide should be sent to Jay Guerber at the previously mentioned address in the **FOR FURTHER INFORMATION CONTACT** section.

After consideration of all relevant material presented, including the information and recommendation submitted by the Committee and other available information, it is hereby found that finalizing the interim final rule, without change, as published in the **Federal Register** (65 FR 55436, September 14, 2000) will tend to effectuate the declared policy of the Act.

List of Subjects in 7 CFR Part 929

Cranberries, Marketing agreements, Reporting and recordkeeping requirements.

PART 929—CRANBERRIES GROWN IN THE STATES OF MASSACHUSETTS, RHODE ISLAND, CONNECTICUT, NEW JERSEY, WISCONSIN, MICHIGAN, MINNESOTA, OREGON, WASHINGTON, AND LONG ISLAND IN THE STATE OF NEW YORK

Accordingly, the interim final rule amending 7 CFR part 929 which was published at 65 FR 55436 on September

14, 2000, is adopted as a final rule without change.

Dated: December 19, 2000.

Robert C. Keeney,

Deputy Administrator, Fruit and Vegetable Programs.

[FR Doc. 00-32715 Filed 12-21-00; 8:45 am]

BILLING CODE 3410-02-P

FEDERAL RESERVE SYSTEM

12 CFR Part 203

[Regulation C; Docket No. R-1093]

Home Mortgage Disclosure

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Final rule; staff commentary.

SUMMARY: The Board is publishing a final rule amending the staff commentary that interprets the requirements of Regulation C (Home Mortgage Disclosure). The Board is required to adjust annually the asset-size exemption threshold for depository institutions based on the annual percentage change in the Consumer Price Index for Urban Wage Earners and Clerical Workers. The present adjustment reflects changes for the twelve-month period ending in November 2000. During this period, the index increased by 3.4 percent; as a result, the threshold is increased to \$31 million. Thus, depository institutions with assets of \$31 million or less as of December 31, 2000, are exempt from data collection in 2001.

EFFECTIVE DATE: January 1, 2001. This rule applies to all data collection in 2001.

FOR FURTHER INFORMATION CONTACT: Kathleen C. Ryan, Senior Attorney, Division of Consumer and Community Affairs, at (202) 452-3667; for users of Telecommunications Device for the Deaf (TDD) only, contact Janice Simms at (202) 872-4984.

SUPPLEMENTARY INFORMATION: The Home Mortgage Disclosure Act (HMDA; 12 U.S.C. 2801 *et seq.*) requires most mortgage lenders located in metropolitan areas to collect data about their housing-related lending activity. Annually, lenders must file reports with their federal supervisory agencies and make disclosures available to the public. The Board's Regulation C (12 CFR part 203) implements HMDA.

Provisions of the Economic Growth and Regulatory Paperwork Reduction Act of 1996 (codified at 12 U.S.C. 2808(b)) amended HMDA to expand the exemption for small depository

institutions. Prior to 1997, HMDA exempted depository institutions with assets totaling \$10 million or less, as of the preceding year end. The statutory amendment increased the asset-size exemption threshold by requiring a one time adjustment of the \$10 million figure based on the percentage by which the Consumer Price Index for Urban Wage Earners and Clerical Workers (CPIW) for 1996 exceeded the CPIW for 1975, and provided for annual adjustments thereafter based on the annual percentage increase in the CPIW. The one-time adjustment increased the exemption threshold to \$28 million for 1997 data collection.

Section 203.3(a)(1)(ii) of Regulation C provides that the Board will adjust the threshold based on the year-to-year change in the average of the CPIW, not seasonally adjusted, for each twelve-month period ending in November, rounded to the nearest million. Pursuant to this section, the Board raised the threshold to \$30 million for 1999 data collection, and kept it at that level for data collection in 2000.

During the period ending November 2000, the CPIW increased by 3.4 percent. As a result, the threshold is increased to \$31 million. Thus, depository institutions with assets of \$31 million or less as of December 31, 2000, are exempt from data collection in 2001. An institution's exemption from collecting data in 2001 does not affect its responsibility to report the data it was required to collect in 2000.

The Board is amending comment 3(a)-2 of the staff commentary to implement the increase in the exemption threshold. Under the Administrative Procedure Act, notice and opportunity for public comment are not required if the Board finds that notice and public comment are unnecessary or would be contrary to the public interest. 5 U.S.C. 553(b)(B). Regulation C establishes the formula for determining adjustments to the exemption threshold, if any, and the amendment to the staff commentary merely applies the formula. This amendment is technical and not subject to interpretation. For these reasons, the Board has determined that publishing a notice of proposed rulemaking and providing opportunity for public comment are unnecessary and would be contrary to the public interest. Therefore, the amendment is adopted in final form.

List of Subjects in 12 CFR Part 203

Banks, Banking, Federal Reserve System, Mortgages, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Board amends 12 CFR part 203 as follows:

PART 203—HOME MORTGAGE DISCLOSURE (REGULATION C)

1. The authority citation for part 203 continues to read as follows:

Authority: 12 U.S.C. 2801-2810.

2. In Supplement I to part 203, under Section 203.3—Exempt Institutions, under 3(a) *Exemption based on location, asset size, or number of home-purchase loans*, paragraph 2 is revised to read as follows:

Supplement I to Part 203—Staff Commentary

* * * * *

Section 203.3 Exempt Institutions

3(a) *Exemption based on location, asset size, or number of home-purchase loans.*

* * * * *

2. *Adjustment of exemption threshold for depository institutions.* For data collection in 2001, the asset-size exemption threshold is \$31 million. Depository institutions with assets at or below \$31 million are exempt from collecting data for 2001.

* * * * *

By order of the Board of Governors of the Federal Reserve System, acting through the Director of the Division of Consumer and Community Affairs under delegated authority, December 19, 2000.

Jennifer J. Johnson,

Secretary of the Board.

[FR Doc. 00-32749 Filed 12-21-00; 8:45 am]

BILLING CODE 6210-01-P

FEDERAL RESERVE SYSTEM

12 CFR Part 225

[Regulation Y; Docket No. R-1078]

Bank Holding Companies and Change in Bank Control

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Final rule.

SUMMARY: The Board of Governors of the Federal Reserve System, in consultation with the Secretary of the Treasury and after seeking public comment, has determined by rule that acting as a finder is an activity that is incidental to a financial activity and therefore permissible for a financial holding company. The Board's final rule amends Subpart I of Regulation Y by adding acting as a finder to the list of activities that a financial holding company may conduct using the streamlined post-

transaction notice procedure authorized by the Gramm-Leach-Bliley Act.

The final rule allows a financial holding company to bring together buyers and sellers of products and services for transactions that the buyers and sellers themselves negotiate and consummate. The rule provides examples of specific services that a financial holding company may and may not perform when acting as a finder under the rule. The rule also requires a financial holding company that acts as a finder to provide appropriate disclosures to distinguish products and services that are offered by the financial holding company from those that are offered by a third party using the financial holding company's finder service.

DATES: Effective January 22, 2001.

FOR FURTHER INFORMATION CONTACT:

Scott G. Alvarez, Associate General Counsel (202/452-3583), Kieran J. Fallon, Senior Counsel (202/452-5270), or Adrienne G. Threatt, Senior Attorney (202/452-3554), Legal Division; Betsy Cross, Assistant Director (202/452-2574), Division of Banking Supervision and Regulation, Board of Governors of the Federal Reserve System, 20th Street and Constitution Avenue, N.W., Washington, D.C., 20551. For users of Telecommunications Device for the Deaf ("TDD"), contact Janice Simms at 202/452-4984.

SUPPLEMENTARY INFORMATION:

Background

The Gramm-Leach-Bliley Act (Pub. L. 106-102, 113 Stat. 1338 (1999)) ("GLB Act") amended the Bank Holding Company Act (12 U.S.C. § 1841 *et seq.*) ("BHC Act") to allow a bank holding company or foreign bank that qualifies as a financial holding company to engage in a broad range of activities that the GLB Act defined as financial in nature or incidental to a financial activity. The GLB Act also provides that the Board, in consultation with the Secretary of the Treasury ("Secretary"), may determine that additional activities are financial in nature or incidental to a financial activity and, thus, permissible for a financial holding company.¹

Earlier this year, the Board, after consulting with the Secretary, requested public comment on a proposal to determine that acting as a finder is an activity that is incidental to a financial activity and, therefore, permissible for a financial holding company.² Under the proposal, a financial holding company could act as a finder that brings together one or more buyers and sellers of any type of products and services for transactions that the parties themselves negotiate and consummate. The proposed rule noted that the services provided by a finder could include: (1) identifying potential parties to a transaction, making inquiries as to interest, introducing and referring potential parties to each other, and arranging contacts between and meetings of interested parties; (2) conveying between interested parties expressions of interest, bids, offers, orders, and confirmations relating to a transaction; and (3) transmitting information concerning products and services to potential parties in connection with the activities described in items (1) and (2) above. To illustrate some of the services of a finder, the proposed rule included examples of specific services that a finder could provide under the proposed rule, including hosting an Internet marketplace on the finder's web site, hosting the Internet web site of a seller, and operating an Internet web site that allows multiple buyers and sellers to enter into transactions between themselves.

The proposed rule also included specific parameters designed to ensure that a finder did not engage in any nonfinancial activity. In addition, the proposed rule required a finder to use disclosures or other means to distinguish the products and services offered by the financial holding company from those offered by a third party through the finder service.

Overview of Public Comments

The Board received 18 public comments on the proposal. Commenters included financial holding companies and other bank holding companies; trade associations representing the banking, securities, and real estate industries; a state banking and insurance department; and a law firm.

efficiently deliver financial information and services through technological means, and offer customers any available or emerging technological means for using financial services or for the document imaging of data. The Board also may consider other information that it considers relevant to its determination.

² See 65 FR 47696 (August 3, 2000).

Nearly all of the commenters supported the proposal. Many of these commenters praised the scope of the proposed rule or stated that adoption of the proposal would increase the ability of financial holding companies to compete effectively with other financial service providers in a manner consistent with the purposes of the GLB Act. Some commenters that supported the proposal suggested that the Board determine acting as finder to be a financial activity, rather than an activity that is incidental to a financial activity. Two commenters opposed the proposal, contending that it would allow financial holding companies to engage in commercial activities and would expose financial holding companies to additional risks.

Commenters also requested that the Board make certain changes to the proposed rule. For example, some commenters requested that the Board expand, modify, or clarify the examples of permissible finder services included in the proposed rule. In addition, while some commenters supported the limitations included in the proposed rule on the finder activities of financial holding companies, other commenters requested that the Board modify or eliminate some of these limitations, including the limitations that prevent a financial holding company from binding a buyer or seller to a specific transaction, negotiating the terms of a specific transaction on behalf of a buyer or seller, or engaging in any activity that would cause the company to register or obtain a license as a real estate agent or broker. One commenter urged that the limitations on real estate agency and brokerage activities be retained.

Some commenters asked the Board to provide additional guidance concerning how a financial holding company could comply with the disclosure requirements of the proposed rule. A few commenters also asked that the Board clarify that the proposed limitations on the finder activities do not apply to other activities that a financial holding company is authorized to conduct.

Final Rule

National banks and many state banks are permitted to act and have acted as a finder in nonfinancial transactions for many years. Opportunities to provide finder services and interest in acting as a finder have grown dramatically with advances in technology and the increased use of the Internet. Thus, banking organizations, which in the past largely have served as a finder by providing statement stuffers and other marketing materials of sellers of various products and services or by helping to

¹ See 12 U.S.C. 1843 (k)(2). In determining whether to authorize an additional activity, the GLB Act directs the Board to consider: (1) the purposes of the GLB and BHC Acts; (2) the changes or reasonably expected changes in the marketplace in which financial holding companies compete; (3) the changes or reasonably expected changes in technology for delivering financial services; and (4) whether the proposed activity is necessary or appropriate to allow a financial holding company to compete effectively with companies seeking to provide financial services in the United States,

identify service providers as an accommodation to customers, have begun to explore the opportunity to act as a finder electronically on a broader scale. Financial holding companies have argued that acting as a finder, particularly electronically, offers increased opportunities for financial holding companies to cross sell financial products and services or to enhance the attractiveness to customers of the financial holding company's own electronic web site. Commenters asserted that authorizing FHCs to act as a finder as proposed would facilitate competition between FHCs and nonbanking companies to provide customers with a wide range of financial services. One commenter stated that the new authority particularly would benefit FHCs affiliated with community banks, which often are knowledgeable about the business interests of third parties with whom they deal. In this way, finder services have become incidental to financial activities.

After carefully reviewing the public comments on the finder proposal, the Board has adopted a final rule that provides that acting as a finder, as defined in the rule, is an activity that is incidental to a financial activity and therefore permissible for financial holding companies to conduct. Under the GLB Act, the Board may not determine that an activity is financial in nature or incidental to a financial activity if the Secretary notifies the Board in writing that the Secretary believes the activity is not financial in nature, incidental to a financial activity, or otherwise permissible under section 4 of the BHC Act. The Secretary must notify the Board of the Secretary's determination within 30 days of receiving notice from the Board, or within such longer period as the Board may allow under the circumstances. The Board has provided the Secretary with notice of the proposed activity as required by the GLB Act and the Secretary has informed the Board in writing that the Secretary does not object to the final rule as adopted.

The Board has made a number of changes to the rule to respond to public comments and to clarify the scope of the proposed rule. These changes and the comments on particular aspects of the rule are discussed below.

Detailed Description of Final Rule

The rule adds "acting as finder" to the list of activities in section 225.86 of Subpart I of the Board's Regulation Y that are financial in nature or incidental to a financial activity and, thus, permissible for a financial holding company. Bank holding companies and

foreign banks that qualify as financial holding companies may engage in finder activities by using the post-transaction notice procedure described in section 225.87 of Regulation Y. Bank holding companies and foreign banks that do not qualify as financial holding companies may not engage in finder activities under the rule.

Section 225.86(d)(1)(i)—What Is the Scope of Finder Activities?

The activity of a finder is defined under the rule as bringing together one or more buyers and sellers of any product or service for transactions that the parties themselves negotiate and consummate. A financial holding company may act as a finder under the rule for financial and nonfinancial products or services that are offered or sold by third-party buyers and sellers.³

As the Board noted in the proposal, the actual services provided by a finder in a particular transaction may vary. Under current practices, however, finders perform two principal functions—(1) locating and matching third parties that are interested in engaging in a business transaction between themselves, and (2) acting as a conduit for transaction-related information between parties that may be or are interested in conducting a business transaction between themselves.

Accordingly, the final rule provides that the services provided by a finder may include—

- (1) Identifying potential parties that may be interested in engaging in a transaction between themselves;
- (2) Making inquiries of third parties as to their interest in engaging in a transaction with another party;
- (3) Introducing and referring potential parties to each other;
- (4) Arranging contacts and meetings between interested parties;
- (5) Conveying expressions of interests, bids, offers, orders, and confirmations relating to a transaction between third parties; and
- (6) Transmitting information concerning products and services to potential parties in connection with the activities described in paragraphs (1) through (5) above, such as transmitting to a buyer information concerning the products and services offered by a seller

³ The Board notes that a financial holding company is permitted to act as a finder for financial products and services as part of other permissible financial activities. For example, a financial holding company may act as a finder in the purchase and sale of securities under authority to act as a securities broker under § 225.86(a) of Regulation Y, or act as a finder in the purchase and sale of insurance products as an insurance agent under § 225.86(c) of Regulation Y.

or transmitting to a seller the product preferences of a buyer.

Some commenters requested that the Board clarify that a finder may act through a variety of media, including through electronic means (such as the Internet) or non-electronic means. The final rule explicitly provides that a finder may act through any means and also clarifies that a finder may perform one, all, or any combination of the permissible finder services described in the rule.

A few commenters contended that the Board should expand the rule to allow a finder to transmit or exchange any type of information between any parties. The final rule authorizes financial holding companies to transmit any type of information between potential parties to a transaction, including information about the buyer and seller and the products and services sought or offered by the buyer or seller, so long as the information is related to the proposed transaction. The Board believes that it is not appropriate to expand this authority to allow a finder to transmit between parties information that is not related to a proposed transaction. Allowing financial holding companies to provide information without limit goes beyond what is necessary to bring transacting parties together and could be interpreted to allow a financial holding company to engage in nonfinancial activities, such as operating a newspaper.

Section 225.86(d)(1)(ii)—What Are Some Examples of Finder Services?

As noted above, the proposed rule included examples of specific services that a finder may provide under the rule. Commenters generally favored the Board's decision to include examples of permissible finder services in the rule but were divided on the issue of whether additional examples of permissible finder services should be provided. A number of commenters requested that the Board modify or clarify certain examples included in the proposed rule, and several commenters requested assurance that the examples included in the rule were not exhaustive.

In light of these comments, the Board has revised and reorganized the examples of permissible finder activities included in the rule to illustrate more fully the breadth of the rule. The examples included in the final rule illustrate that a finder may:

- Host an electronic marketplace Internet web site that provides hypertext or similar links to the web sites of third party buyers or sellers;

- Host the Internet web site of a buyer (or seller) that provides information concerning the buyer (or seller) and the products or services it seeks to buy (or sell) and allows sellers (or buyers) to submit expressions of interest, bids, offers, orders, and confirmations relating to such products or services;

- Host the Internet web site of a government or government agency that provides information concerning the services or benefits made available by the government or government agency, assists persons in completing applications to receive such services or benefits from the government or agency, and allows persons to transmit their applications for services or benefits to the government or agency;

- Operate an Internet web site that allows multiple buyers and sellers to exchange information concerning the products and services that they are willing to purchase or sell, locate potential counterparties for transactions, aggregate orders for goods or services with those made by other parties, and enter into transactions between themselves; and

- Operate a telephone call center that provides permissible finder services.

The rule states that the examples of permissible finder services included in the rule are illustrative and not exclusive. Furthermore, while the Board expects that financial holding companies likely will engage in finder activities through electronic means, such as over the Internet or other electronic networks, a finder may act through any means available so long as the activity complies with the requirements of the rule. Financial holding companies that are uncertain whether a proposed activity is within the scope of the rule may contact Federal Reserve staff to discuss the proposal.

Section 225.86(d)(1)(iii)—What Limitations Are Applicable to a Financial Holding Company Acting as a Finder?

The rule prevents a finder from becoming a principal in the underlying transaction. In particular, a finder may not negotiate for or bind third parties; acquire or take title to, or provide distribution services for, products and services offered or sold through the finder service; or own or operate real property used to manufacture, store, transport, or assemble products offered or sold by a third party.

Several commenters requested that the Board modify or eliminate certain of these limitations. For example, some commenters requested that the Board remove the restrictions on binding

parties or negotiating transactions or, alternatively, allow a financial holding company to take such actions within parameters established by the buyer or seller. A few commenters also contended that the Board should allow a finder to acquire an ownership interest in products as a “riskless principal.” In addition, some commenters asked the Board to confirm that the restrictions included in the rule would not prevent a financial holding company from operating an electronic exchange that provides finder services and that automatically matches bids and offers submitted to the exchange, and that these restrictions would not apply to the conduct of financial activities that a financial holding company is authorized to engage in under other provisions of Regulation Y.

The Board has carefully reviewed the limitations included in the proposed rule in light of the comments received. As a general matter, the Board continues to believe that the restrictions included in the proposed rule are appropriate to ensure that a finder acts only as an intermediary in providing finder services and does not otherwise become involved in impermissible commercial activities. The Board recognizes, however, that technological developments in communications, computing, and the Internet have made the intermediary function more important and that further developments in these areas may alter the methods and manner of providing finder services. The Board intends to monitor future developments in technology, the financial services industry, and the market for finder services and to review periodically the limits in the rule to determine whether such limits continue to be necessary or appropriate.

For the foregoing reasons, the final rule continues to provide that a finder may act only as an intermediary and may not bind any buyer or seller to the terms of a specific transaction or negotiate the terms of a specific transaction on behalf of a buyer or seller. In response to comments, the final rule clarifies that these restrictions do not prevent a finder from establishing rules of general applicability governing the use and operation of the finder service. These operating rules may, for example, establish the parameters under which buyers and sellers may submit bids and offers to the finder service and the circumstances under which the finder service will match bids and offers submitted by buyers and sellers. Similarly, the finder may establish rules of general applicability that govern the

manner in which buyers and sellers bind themselves to the terms of a specific transaction entered into through the finder service. Under these provisions, a financial holding company may establish and operate an electronic exchange that assists buyers and sellers to locate potential counterparties, matches buyers and sellers that submit bids and offers within specified ranges established by the rules of the exchange, and requires buyers and sellers to accept transactions matched through the exchange.

The proposed rule also stated that the proposal did not prevent a financial holding company from arranging for buyers that use its finder services to receive preferred terms from sellers so long as the terms are not negotiated as part of any individual transaction, are made available to broad categories of customers, and are provided by the seller and not the financial holding company. Commenters generally supported this provision and it is retained in the final rule.

The final rule does not authorize a financial holding company to take title to, or acquire or hold an ownership interest in, any product or service offered or sold through the finder service or provide distribution services for physical products or services offered or sold through such service. In addition, a financial holding company may not own or operate any real or personal property that is used for the purpose of manufacturing, storing, transporting, or assembling physical products offered or sold by third parties, or that serves as a physical location for the physical purchase, sale, or distribution of products or services offered or sold by third parties. These limitations are consistent with the limited role of a finder as an intermediary and distinguish a finder, for example, from a company that owns or operates a physical shopping mall, retail store, a manufacturing plant, a product distribution center, or a transport or trucking company.

Acting As a Real Estate Agent or Broker

The proposed rule did not authorize a financial holding company to engage in any activity that would require the company to register or obtain a license as a real estate agent or broker under applicable law. While some commenters supported this provision, others requested that the Board remove the provision from the rule or amend the rule to only prohibit financial holding companies from engaging in “general” real estate agency or brokerage activities under the rule.

The Board has not to date determined whether real estate agency or brokerage activities are financial in nature or incidental to financial activities and, thus, permissible for financial holding companies. The Board has received a request to determine that real estate agency and brokerage services are financial in nature and separately has requested public comment on a proposal that would find those activities to be financial in nature or incidental to a financial activity.⁴ Accordingly, the final rule retains the limitation that prohibits a financial holding company from engaging in activities that require licensing or registration as a real estate broker.⁵

Other Authorities Not Affected

As noted above, several commenters were uncertain whether the limits included in the rule applied to or restricted the conduct of other financial activities that a financial holding company is authorized to conduct. The Board confirms that authorization to act as a finder is in addition to, and separate from, the authority that a financial holding company has under other provisions of Regulation Y to conduct other financial activities. The restrictions contained in § 225.86(d)(1)(iii) apply only to the finder activities conducted by a financial holding company under § 225.86(d) of Regulation Y. These limitations do not restrict or otherwise limit the manner in which a financial holding company may conduct other activities that are permissible for a financial holding company, such as securities brokerage, insurance agency, investment advisory, or leasing activities.

In this regard, a financial holding company that acts as a finder for a buyer or seller may also provide the buyer or seller any combination of other services that are permissible under Regulation Y so long as the finder and other services are provided in accordance with any applicable limitations under the rule and Regulation Y. For example, a finder for a merchant may, in addition to acting as finder, make, acquire, broker, or service loans or other extensions of

credit to or for the merchant or the merchant's customers; provide the merchant with check verification, check guaranty, collection agency and credit bureau services; provide financial investment advice to the merchant or the merchant's customers within the parameters of Regulation Y; act as a certification authority for digital signatures and thereby authenticate the identity of persons conducting business with the merchant over electronic networks; and process and transmit financial, economic, and banking data on behalf of the merchant, such as by processing the merchant's accounts receivables and debit and credit card transactions, providing the merchant with bill payment and billing services, and processing order, distribution, accounting, settlement, collection and payment information for the merchant's transactions.⁶

Furthermore, a financial holding company may market and provide its own financial products and services in conjunction with acting as a finder for buyers and sellers of nonfinancial products and services. For example, a financial holding company may use its finder service to promote the company's own products and services and, in connection with that activity, may negotiate on its own behalf and bind itself to transactions.

Section 225.86(d)(1)(iv)—What Disclosures Are Required?

The proposed rule required a finder to distinguish the products and services offered by the financial holding company from the products and services offered through the finder service by a third party. A number of commenters supported this disclosure requirement as an appropriate means of limiting potential customer confusion and reputational risk to financial holding companies. Some commenters requested that the Board provide additional guidance, such as sample disclosure clauses, illustrating how a financial holding company could comply with the rule's disclosure requirements.

The final rule continues to require that a finder distinguish the products or services offered by the financial holding

company from those offered by a third party through the finder service. Because a financial holding company may act as a finder for third parties through varied technological means and in a wide variety of circumstances, the Board has determined not to identify specific disclosures that must or could be provided by financial holding companies. The Board expects financial holding companies to provide disclosures that, given the medium employed and type of buyers and sellers using the service (e.g., consumers or corporations), are reasonably designed to ensure that users are not led to believe that the financial holding company is providing the products or services offered or sold by third parties through the finder service. A financial holding company could provide such notice by identifying through appropriate means those products or services that are offered or sold by the financial holding company (with a corresponding notice that all other products or services are provided by third parties), or by identifying those products or services that are offered and sold by third parties and not by the financial holding company. Financial holding companies are encouraged to tailor the content and presentation of their disclosures to suit the specific type of finder service they are providing. The Board intends to monitor the disclosure practices of financial holding companies and may provide additional guidance, such as identifying best practices in this area, as it gains experience with the finder activities of financial holding companies.

Regulatory Flexibility Act

In accordance with the Regulatory Flexibility Act, the Board is required to conduct an analysis of the effect this final rule would have on small institutions. The rule authorizes all financial holding companies regardless of their size to engage in a new activity—that of acting as a finder. Moreover, the rule enables such companies to commence the new activity by using the streamlined post-transaction notice procedure authorized by the GLB Act, which is the least burdensome notice procedure available to a financial holding company. This rule therefore should enhance the ability of financial holding companies, including small ones, to compete with other providers of financial services in the United States and to respond to technological and other changes in the marketplace in which financial holding companies compete. Moreover, the comments received by the Board did not indicate that the rule would impose a

⁴ Published in the December 21, 2000, issued of the **Federal Register**.

⁵ One commenter requested that the Board clarify that the rule does not preempt any applicable state insurance or mortgage solicitation licensing requirements. This rule represents a determination that finder activities are permissible activities for financial holding companies and does not represent an attempt by the Board to preempt applicable state law. This rule does not address whether other federal law, such as section 104 of the GLB Act (15 U.S.C. § 6701), may limit the applicability of state law in specific situations.

⁶ See 12 CFR 225.28(b)(1) (extending credit and servicing extensions of credit); (b)(2)(iii), (iv), and (v) (credit bureau, check guaranty, check verification, collection agency and credit bureau services); (b)(6) (financial and investment advice); 12 CFR 225.86(a)(2) (certification authority for digital signatures); and 12 CFR 225.28(b)(14), *Banc One Corporation, Inc.*, 83 Federal Reserve Bulletin 602 (1997); *Royal Bank of Canada*, 83 Federal Reserve Bulletin 135 (1997); *Compagnie Financière de Paris*, 82 Federal Reserve Bulletin 348 (1996) (financial data processing and data transmission services).

burden on financial holding companies of any size.

Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3506; 5 CFR 1320 Appendix A.1), the Board reviewed the rule under authority delegated to the Board by the Office of Management and Budget ("OMB"). The Board may not conduct or sponsor, and an organization is not required to respond to, this information collection unless it displays a currently valid OMB control number. The OMB control number is 7100-0292.

A financial holding company may engage in the finder activities authorized by this rule by providing a post-transaction notice in accordance with § 225.87 of Regulation Y. This information is mandatory to evidence compliance with the requirements of the GLB Act and Regulation Y, and the burden of the post-transaction notice requirement was reviewed in connection with the Board's adoption of § 225.87.

In addition, this rule requires a finder to distinguish the products and services offered by the financial holding company from those offered by a third party through the finder service. Provision of such disclosures, although not contained in a submission to the Board, does constitute a collection of paperwork under the Paperwork Reduction Act. Financial holding companies, of which there are approximately 450, are the respondents/recordkeepers. Board staff anticipates that the majority of the burden on financial holding companies will be a one-time burden in the first year a company engages in the finder activity, when the financial holding company must develop a mechanism to distinguish the products and services offered by the financial holding company from those offered by a third party through the finder service. The estimated one-time burden to develop such disclosures is one hour. Although financial holding companies may update their disclosures periodically, this will be a negligible burden on them. It is estimated that there will be 50 financial holding companies required to comply with the post-transaction notice with an average of 1 update per respondent each year. Therefore the total amount of annual burden is estimated to be 50 hours.

Board staff estimates that there would be nominal start up costs associated with modifying the operations of the financial holding company's finder service to provide this notice. Thus,

there is estimated to be no annual cost burden over the annual hour burden.

Because the disclosures would be maintained at and provided by financial holding companies and the disclosures are not submitted to the Federal Reserve System, no issue of confidentiality arises under the Freedom of Information Act. The Board has a continuing interest in the public's opinions of its collections of information. At any time, comments regarding the burden estimate, or any other aspect of this collection of information, including suggestions for reducing the burden, may be sent to: Jennifer J. Johnson, Secretary, Board of Governors of the Federal Reserve System, 20th and C Streets, NW., Washington, DC 20551; and to the Office of Management and Budget, Paperwork Reduction Project (7100-0292), Washington, DC 20503.

List of Subjects in 12 CFR Part 225

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

Authority and Issuance

For the reasons set out in the preamble, the Board amends 12 CFR part 225 as follows:

PART 225—BANK HOLDING COMPANIES AND CHANGE IN BANK CONTROL (REGULATION Y)

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

Authority: 12 U.S.C. 1817(j)(13), 1818, 1828(o), 1831i, 1831p-1, 1843(c)(8), 1843(k), 1844(b), 1972(l), 3106, 3108, 3310, 3331-3351, 3907, and 3909.

2. Section 225.86 is amended by adding a new paragraph (d) to read as follows:

§ 225.86 What activities are permissible for financial holding companies?

* * * * *

(d) *Activities determined to be financial in nature or incidental to financial activities by the Board*—(1) *Acting as a finder*—Acting as a finder in bringing together one or more buyers and sellers of any product or service for transactions that the parties themselves negotiate and consummate.

(i) *What is the scope of finder activities?* Acting as a finder includes providing any or all of the following services through any means—

(A) Identifying potential parties, making inquiries as to interest, introducing and referring potential parties to each other, and arranging

contacts between and meetings of interested parties;

(B) Conveying between interested parties expressions of interest, bids, offers, orders and confirmations relating to a transaction; and

(C) Transmitting information concerning products and services to potential parties in connection with the activities described in paragraphs (d)(1)(i)(A) and (B) of this section.

(ii) *What are some examples of finder services?* The following are examples of the services that may be provided by a finder when done in accordance with paragraphs (d)(1)(iii) and (iv) of this section. These examples are not exclusive.

(A) Hosting an electronic marketplace on the financial holding company's Internet web site by providing hypertext or similar links to the web sites of third party buyers or sellers.

(B) Hosting on the financial holding company's servers the Internet web site of—

(1) A buyer (or seller) that provides information concerning the buyer (or seller) and the products or services it seeks to buy (or sell) and allows sellers (or buyers) to submit expressions of interest, bids, offers, orders and confirmations relating to such products or services; or

(2) A government or government agency that provides information concerning the services or benefits made available by the government or government agency, assists persons in completing applications to receive such services or benefits from the government or agency, and allows persons to transmit their applications for services or benefits to the government or agency.

(C) Operating an Internet web site that allows multiple buyers and sellers to exchange information concerning the products and services that they are willing to purchase or sell, locate potential counterparties for transactions, aggregate orders for goods or services with those made by other parties, and enter into transactions between themselves.

(D) Operating a telephone call center that provides permissible finder services.

(iii) *What limitations are applicable to a financial holding company acting as a finder?*

(A) A finder may act only as an intermediary between a buyer and a seller.

(B) A finder may not bind any buyer or seller to the terms of a specific transaction or negotiate the terms of a specific transaction on behalf of a buyer or seller, except that a finder may—

(1) Arrange for buyers to receive preferred terms from sellers so long as the terms are not negotiated as part of any individual transaction, are provided generally to customers or broad categories of customers, and are made available by the seller (and not by the financial holding company); and

(2) Establish rules of general applicability governing the use and operation of the finder service, including rules that—

(i) Govern the submission of bids and offers by buyers and sellers that use the finder service and the circumstances under which the finder service will match bids and offers submitted by buyers and sellers; and

(ii) Govern the manner in which buyers and sellers may bind themselves to the terms of a specific transaction.

(C) A finder may not—

(1) Take title to or acquire or hold an ownership interest in any product or service offered or sold through the finder service;

(2) Provide distribution services for physical products or services offered or sold through the finder service;

(3) Own or operate any real or personal property that is used for the purpose of manufacturing, storing, transporting, or assembling physical products offered or sold by third parties; or

(4) Own or operate any real or personal property that serves as a physical location for the physical purchase, sale or distribution of products or services offered or sold by third parties.

(D) A finder may not engage in any activity that would require the company to register or obtain a license as a real estate agent or broker under applicable law.

(iv) *What disclosures are required?* A finder must distinguish the products and services offered by the financial holding company from those offered by a third party through the finder service.

(2) [Reserved]

December 19, 2000.

By order of the Board of Governors of the Federal Reserve System.

Jennifer J. Johnson,

Secretary of the Board.

[FR Doc. 00-32747 Filed 12-21-00; 8:45 am]

BILLING CODE 6210-01-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2000-SW-19-AD; Amendment 39-12049; AD 2000-26-02]

RIN 2120-AA64

Airworthiness Directives; Eurocopter Deutschland Model EC135 P1 and T1 Helicopters

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

SUMMARY: This amendment supersedes an existing airworthiness directive (AD) that applies to Eurocopter Deutschland Model EC135 P1 and T1 helicopters. That AD currently requires visual and dye-penetrant inspections for a cracked stator blade of the fenestron tail rotor (tail rotor). That AD also requires either stop drilling a cracked blade or, as necessary, replacing an unairworthy stator blade with an airworthy stator blade. This amendment requires replacing the existing stator blade assembly with a new stator blade assembly that incorporates a reinforced base and modified riveting and limits the applicability to certain serial numbered tail booms. This amendment is prompted by additional reports of cracked stator blades of the tail rotor. The actions specified by this AD are intended to prevent failure of the tail rotor and subsequent loss of control of the helicopter.

EFFECTIVE DATE: January 26, 2001.

FOR FURTHER INFORMATION CONTACT: Richard Monschke, Aviation Safety Engineer, FAA, Rotorcraft Directorate, Rotorcraft Standards Staff, 2601 Meacham Blvd., Fort Worth, Texas 76137, telephone (817) 222-5116, fax (817) 222-5961.

SUPPLEMENTARY INFORMATION: A proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) by superseding AD 97-20-13, Amendment 39-10240 (62 FR 65198), which is applicable to Eurocopter Deutschland Model EC135 P1 and T1 helicopters, was published in the **Federal Register** on September 18, 2000 (65 FR 56276). That action proposed to require replacing any stator blade assembly, part number (P/N) L 535A4201 052, with a stator blade assembly, P/N L 535A4201 053, that incorporates a reinforced base and modified riveting. That action also proposed limiting the applicability to certain serial numbered tail booms.

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

The FAA estimates that 25 helicopters of U.S. registry will be affected by this AD, that it will take approximately 12 work hours per helicopter to accomplish the required actions, and that the average labor rate is \$60 per work hour. The manufacturer states in its service bulletin that parts and labor will be furnished at no cost. Based on that information, there is no cost impact from the AD on U.S. operators.

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

For the reasons discussed above, I certify that this action (1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A final evaluation has been prepared for this action and it is contained in the Rules Docket. A copy of it may be obtained from the Rules Docket at the FAA, Office of the Regional Counsel, Southwest Region, 2601 Meacham Blvd., Room 663, Fort Worth, Texas.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

2. Section 39.13 is amended by removing Amendment 39-10240 (62 FR 65198, December 11, 1997), and by adding a new airworthiness directive (AD), Amendment 39-12049, to read as follows:

2000-26-02 Eurocopter Deutschland:

Amendment 39-12049, Docket No. 2000-SW-19-AD. Supersedes AD 97-20-13, Amendment 39-10240, Docket No. 97-SW-46-AD.

Applicability: Model EC135 P1 and T1 helicopters, with tail boom serial number EVL 001 through EVL 045, installed, certificated in any category.

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

Compliance: Required within 90 days, unless accomplished previously.

To prevent failure of the stator blades of the fenestron tail rotor and subsequent loss of control of the helicopter, accomplish the following:

(a) Replace stator blade assembly, part number (P/N) L 535A4201 052, with stator blade assembly, P/N L 535A4201 053.

(b) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Regulations Group, Rotorcraft Directorate. Operators shall submit their requests through an FAA Principal Maintenance Inspector, who may concur or comment and then send it to the Manager, Regulations Group.

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

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

(d) This amendment becomes effective on January 26, 2001.

Issued in Fort Worth, Texas, on December 11, 2000.

Henry A. Armstrong,

Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 00-32553 Filed 12-21-00; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION**Federal Aviation Administration****14 CFR Part 39**

[Docket No. 99-SW-65-AD; Amendment 39-12048; AD 2000-26-01]

RIN 2120-AA64

Airworthiness Directives; Eurocopter Deutschland GMBH Model BO-105CB-5 and BO-105CBS-5 Helicopters

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

SUMMARY: This amendment supersedes an existing airworthiness directive (AD) that applies to Eurocopter Deutschland GMBH (ECD) Model BO-105CB-5 and BO-105CBS-5 helicopters. That AD currently requires, before further flight, creating a component log card or equivalent record and determining the calendar age and number of flights on each tension-torsion (TT) strap. This amendment requires before further flight, establishing a life limit for certain main rotor TT straps. This amendment is prompted by a need to establish a life limit for certain TT straps because of an accident in which a main rotor blade (blade) separated from an ECD Model MBB-BK 117 helicopter due to fatigue failure of a TT strap. The same part-numbered TT strap is used on the ECD Model BO-105 helicopters. The actions specified by this AD are intended to prevent fatigue failure of a TT strap, loss of a blade, and subsequent loss of control of the helicopter.

DATES: Effective January 26, 2001.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of January 26, 2001.

ADDRESSES: The service information referenced in this AD may be obtained from American Eurocopter Corporation, 2701 Forum Drive, Grand Prairie, Texas 75053-4005, telephone (972) 641-3460, fax (972) 641-3527. This information may be examined at the FAA, Office of the Regional Counsel, Southwest Region, 2601 Meacham Blvd., Room 663, Fort Worth, Texas; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT:

Charles Harrison, Aviation Safety Engineer, FAA, Rotorcraft Directorate, Rotorcraft Standards Staff, Fort Worth, Texas 76193-0110, telephone (817) 222-5128, fax (817) 222-5961.

SUPPLEMENTARY INFORMATION: A proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) by superseding AD 99-24-05, Amendment 39-11429 (64 FR 62973, November 18, 1999), applicable to ECD Model BO-105CB-5 and BO-105CBS-5 helicopters, was published in the **Federal Register** on March 13, 2000 (65 FR 13251). That action proposed to require establishing a life limit effective January 1, 2001, for the TT straps of 120 months or 25,000 flights, whichever occurs first.

After the issuance of that Notice of Proposed Rulemaking (NPRM), the FAA reevaluated the proposed requirements and determined that establishing a life limit on the TT straps should be accomplished before further flight and not by January 1, 2001, as earlier indicated. The FAA also determined that the graduated inspection criteria and the accompanying TT strap life limits specified in the current AD are no longer necessary if the proposed life limit is established.

Since those changes expanded the scope of the original NPRM, the FAA determined that it was necessary to reopen the comment period to provide additional opportunity for public comment and published a Supplemental NPRM (SNPRM) on September 20, 2000 (65 FR 56817). The SNPRM revised the NPRM by proposing to require that you establish a life limit for certain main rotor TT straps before further flight instead of by January 1, 2001, as indicated in the previous proposal. The SNPRM also proposed removing some of the requirements that were proposed previously.

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

The FAA estimates that 200 helicopters of U.S. registry will be affected by this AD, that it will take approximately 16 work hours per helicopter to accomplish the required actions, and that the average labor rate is \$60 per work hour. Required parts will cost approximately \$10,400 per helicopter. Based on these figures, the total cost impact of the AD on U.S. operators is estimated to be \$2,272,200.

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

levels of government. Therefore, it is determined that this final rule does not have federalism implications under Executive Order 13132.

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

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

2. Section 39.13 is amended by removing Amendment 39-11429 (64 FR 62973, November 18, 1999), and by adding a new airworthiness directive (AD), Amendment 39-12048, to read as follows:

2000-26-01 Eurocopter Deutschland

GMBH: Amendment 39-12048. Docket No. 99-SW-65-AD. Supersedes AD 99-24-05, Amendment 39-11429, Docket No. 99-SW-58-AD.

Applicability: Model BO-105 CB-5, and BO-105CBS-5 helicopters, certificated in any category.

Note 1: This AD applies to each helicopter identified in the preceding applicability provision, regardless of whether it has been otherwise modified, altered, or repaired in the area subject to the requirements of this AD. For helicopters that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (d) of this AD. The request should include an assessment of the effect of the modification, alteration, or

repair on the unsafe condition addressed by this AD; and if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required as indicated, unless accomplished previously.

To prevent fatigue failure of a tension-torsion (TT) strap, loss of a main rotor blade (blade), and subsequent loss of control of the helicopter, accomplish the following:

(a) Before further flight:

(1) Remove TT straps, part number (P/N) 2604067 (Bendix) or J17322-1 (Lord), from service or re-identify them as P/N 117-14110 or 117-14111, respectively, in accordance with the Accomplishment Instructions, paragraph 2.B.1.2., Eurocopter Deutschland GMBH Alert Service Bulletin BO 105 No. ASB-BO 105-10-113, Revision 2, dated November 16, 1999 (ASB). TT straps, P/N 2604067 (Bendix) or J17322-1 (Lord), are no longer eligible for installation.

(2) Create a component log card or equivalent record for each TT strap.

(3) Review the history of the helicopter and each TT strap. Determine the age since initial installation on any helicopter (age) and the number of flights on each TT strap. Enter both the age and the number of flights for each TT strap on the component log card or equivalent record. When the number of flights is unknown, multiply the number of hours time-in-service (TIS) by 5 to determine the number of flights.

(4) Remove any TT strap from service if the total hours TIS or number of flights and age cannot be determined.

(b) Before further flight, remove any TT strap, P/N 117-14110 or 117-14111, that has been in service 120 months since initial installation on any helicopter or accumulated 25,000 flights (a flight is a takeoff and a landing). Replace the TT strap with an airworthy TT strap.

(c) This AD revises the Airworthiness Limitations Section of the maintenance manual by establishing a life limit for the TT strap, P/N 117-14110 and 117-14111, of 120 months or 25,000 flights, whichever occurs first.

(d) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Regulations Group, Rotorcraft Directorate, FAA. Operators shall submit their requests through an FAA Principal Maintenance Inspector, who may concur or comment and then send it to the Manager, Regulations Group.

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

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

(f) The modification shall be done in accordance with the Accomplishment Instructions, paragraph 2.B.1.2., Eurocopter Deutschland GMBH Alert Service Bulletin BO 105 No. ASB-BO 105-10-113, Revision 2, dated November 16, 1999. 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 American Eurocopter Corporation, 2701 Forum Drive, Grand Prairie, Texas 75053-4005, telephone (972) 641-3460, fax (972) 641-3527. Copies may be inspected at the FAA, Office of the Regional Counsel, Southwest Region, 2601 Meacham Blvd., Room 663, Fort Worth, Texas; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(g) This amendment becomes effective on January 26, 2001.

Note 3: The subject of this AD is addressed in the Luftfahrt Bundesamt (Federal Republic of Germany) AD 1999-289/2, dated September 1, 1999.

Issued in Fort Worth, Texas, on December 11, 2000.

Henry A. Armstrong,

Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 00-32552 Filed 12-21-00; 8:45 am]

BILLING CODE 4910-13-U

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Parts 121,125,135, and 145

[Docket No. FAA-2000-7952; Amendment Nos. 121-279, 125-35, 135-77, and 145-23]

RIN 2120-AF71

Service Difficulty Reports

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule; delay of effective date.

SUMMARY: The Federal Aviation Administration (FAA) is delaying the effective date of a final rule that amends the reporting requirements for air carriers and certificated domestic and foreign repair station operators concerning failures, malfunctions, and defects of aircraft, aircraft engines, systems, and components. This action was prompted by questions being raised by the aviation industry on the implementation of the new requirements. The delay will allow the FAA to develop appropriate guidance materials and disseminate that information to the aviation industry.

EFFECTIVE DATE: The effective date (January 16, 2001) of the rule amending 14 CFR parts 121, 125, 129, and 145 published at 65 FR 56191, September 15, 2000, is delayed until July 16, 2001.

FOR FURTHER INFORMATION CONTACT: Jose Figueroa, AFS-300, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591, telephone 202-267-3797.

SUPPLEMENTARY INFORMATION:**Background**

The FAA requested that comments on the information collection requirements of the Service Difficulty Reporting final rule (65 FR 56191, September 15, 2000) be submitted by November 14, 2000. The FAA has received written comments from the Air Transport Association, American Airlines, Evergreen International Airlines, and Pratt & Whitney, raising questions on some of the SDR reporting requirements and indicating the potential for duplicate reporting of certain failures, malfunctions, and defects.

Also one commentator has requested that the FAA delay the effective date of the final rule until the FAA has resolved these concerns.

The SDR rule, as published, has an effective date of January 16, 2001. The FAA has determined that it will need more time to review the commenter's concerns and to develop and disseminate guidance that will assist the industry in complying with the new rule. Therefore the FAA has delayed the effective date of the final rule until July 16, 2001. The existing rules will remain in effect until the new effective date.

Since this delay of the effective date is not a new requirement and does not impose any additional burden, I find that notice and public procedure thereon are unnecessary and that good cause exists for extending the effective date on less than 30 days notice.

Issued in Washington, DC, on December 15, 2000.

Jane F. Garvey,

Administrator.

[FR Doc. 00-32510 Filed 12-21-00; 8:45 am]

BILLING CODE 4910-13-M

DEPARTMENT OF STATE**22 CFR Part 42**

[Public Notice 3515]

Bureau of Consular Affairs; Visas: Immigrant Religious Workers

AGENCY: Bureau of Consular Affairs, DOS.

ACTION: Final rule.

SUMMARY: This rule amends the Department of State's existing regulation regarding the validity of an immigrant visa issued to an alien worker coming to the United States to perform work in a religious occupation or vocation. The current regulation permits validity of those visas only until September 30, 2000. This rule amends the regulation to

extend the program until September 30, 2003. The amendment is necessitated by a change in the authorizing statute.

EFFECTIVE DATE: December 22, 2000.

FOR FURTHER INFORMATION CONTACT: H. Edward Odom, Legislation and Regulations Division, Visa Services, (202) 663-1204.

SUPPLEMENTARY INFORMATION:**What Is the Background of This Regulation?***Immigration Act of 1990*

Sec. 151 of the Immigration Act of 1990 (IMMACT 90), Pub. L. 101-649, amended INA 101(a)(27)(C) by adding a new category of special immigrant visas for aliens who will work in a religious occupation or vocation for a religious organization in a professional or other capacity. Unlike the provision for special immigrant ministers of religion, which does not contain a sunset provision, the provisions for religious workers (as defined under INA 101(a)(27)(C)(ii)(II) and (III)), as originally enacted, required religious workers to seek to enter the United States before October 1, 1994.

Immigration and Nationality Technical Corrections Act of 1994

On October 25, 1994, sec. 214 of the Immigration and Nationality Technical Corrections Act of 1994 (Pub. L. 103-416) amended INA 101(a)(27)(C)(ii) to extend the sunset date to before October 1, 1997.

Religious Workers Act of 1997

Sec. 1 of the Religious Workers Act of 1997, Pub. L. 105-54 further extended the deadline for special immigrant religious workers to enter the United States until before October 1, 2000.

Religious Workers Act of 2000

On November 1, 2000, the President signed the Religious Workers Act of 2000 (Pub. L. 106-409), extending the program for three additional years through September 30, 2003.

Final Rule**How Is the Department Amending Its Regulation?**

This rule amends 22 CFR 42.32(d)(1)(ii) by changing the date from September 30, 2000 to September 30, 2003 to conform to the statutory requirements of the Religious Workers Act of 2000.

Administrative Procedure Act

The Department's implementation of this regulation as a final rule is based upon the "good cause" exceptions found at 5 U.S.C. 553(b)(B) and (d)(3).

As the amendment to the regulation provides a benefit to aliens by extending the special immigrant religious worker program for an additional three years, the Department has determined that it is unnecessary to publish a proposed rule or to solicit comments from the public. In view of this benefit and since the current validity date has already expired, the rule will be made effective immediately upon publication in the **Federal Register**.

Regulatory Flexibility Act

The Department of State, in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), has reviewed this regulation and, by approving it, certifies that this rule will not have a significant economic impact on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by state, local and tribal governments, in the aggregate, or by the private sector, of \$100 million or more in any year and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Small Business Regulatory Enforcement Fairness Act of 1996

This rule is not a major rule as defined by section 804 of the Small Business Regulatory Enforcement Act of 1996. This rule will not result in an annual effect on the economy of \$100 million or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

Executive Order 12866

The Department of State does not consider this rule, to be a "significant regulatory action" under Executive Order 12866, section 3(f), Regulatory Planning and Review, and the Office of Management and Budget has waived its review process under section 6(a)(3)(A).

Executive Order 13132

This regulation 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 section 6 of Executive

Order 13132, it is determined that this rule does not have sufficient federalism implications to warrant the preparation of a federalism summary impact statement.

Paperwork Reduction Act

This rule does not impose any new reporting or record-keeping requirements. The information collection requirement (Form OF-156) contained by reference in this rule was previously approved for use by the Office of Management and Budget (OMB) under the Paperwork Reduction Act.

List of Subjects in 22 CFR Part 42

Aliens, Immigration, Passports and visas.

In view of the foregoing the Department amends 22 CFR Chapter I as follows:

PART 42—[AMENDED]

1. The authority citation for Part 42 continues to read as follows:

Authority: 8 U.S.C. 1104.

2. In § 42.32, revise paragraph (d)(1)(ii) to read as follows:

§ 42.32 Employment based preference immigrants.

* * * * *

(d) * * *

(ii) *Timeliness of application.* An immigrant visa issued under INA 203(b)(4) to an alien described in INA 101(a)(27)(C), other than a minister of religion, who qualifies as a "religious worker" as defined in 8 CFR 204.5, shall bear the usual validity except that in no case shall it be valid later than September 30, 2003.

* * * * *

Dated: November 13, 2000.

Mary A. Ryan,

Assistant Secretary for Consular Affairs.

[FR Doc. 00-32740 Filed 12-21-00; 8:45 am]

BILLING CODE 4710-06-P

DEPARTMENT OF JUSTICE

Bureau of Prisons

28 CFR Parts 524 and 550

[BOP-1034-F; BOP-1052-F; BOP-1070-F]

RIN 1120-AA36; RIN 1120-AA66

Drug Abuse Treatment and Intensive Confinement Center Programs: Early Release Consideration

AGENCY: Bureau of Prisons, Justice.

ACTION: Finalization of interim rules.

SUMMARY: In this document, the Bureau of Prisons (Bureau) finalizes three interim final rules, published in 1995, 1996 and 1997, on Drug Abuse Treatment Programs. These rules allow for consideration of early release of eligible inmates who complete a residential drug abuse treatment program. This document also finalizes the conforming amendment to the criteria for possible sentence reduction under the intensive confinement center program.

EFFECTIVE DATE: December 22, 2000.

ADDRESSES: Rules Unit, Office of General Counsel, Bureau of Prisons, HOLC Room 754, 320 First Street, NW., Washington, DC 20534.

FOR FURTHER INFORMATION CONTACT: Sarah Qureshi, Office of General Counsel, Bureau of Prisons, phone (202) 514-6655.

SUPPLEMENTARY INFORMATION: The Bureau finalizes its interim rules on Drug Abuse Treatment Programs (28 CFR part 550, subpart F). These interim rules implemented the Bureau's discretion under Section 32001 of the Violent Crime Control and Law Enforcement Act of 1994 (codified at 18 U.S.C. 3621(e)) to reduce the period of custody for inmates who successfully complete the treatment program.

We published the first interim rule in the **Federal Register** on May 25, 1995 (60 FR 27692) and we amended it by a second interim rule published on May 17, 1996 (61 FR 25122). We then published a third interim rule on this subject on October 15, 1997 (62 FR 53690). This last interim rule also made conforming amendments to the criteria for possible sentence reduction under the intensive confinement program (28 CFR 524.31(a)(3)).

On September 9, 2000, BOP published at 65 FR 56840 a proposed rule regarding "Drug Abuse Treatment Program". By that rule, BOP proposes changes to its existing regulations concerning participation in the drug abuse education course and the residential drug abuse treatment program, part of which had been codified by the three earlier interim rules which we finalize in this document. This document, therefore, does not affect comments to the proposed rule document published at 65 FR 56840. We will consider all comments we receive on the proposed rule before we finalize it. This document only discusses comments we received on the three interim final rules we previously published in 1995, 1996 and 1997.

Changes Made by the First Interim Rule

The first interim rule established the procedures which we would use to determine (1) eligibility for early release under 18 U.S.C. 3621(e) and (2) the length of the reduction in sentence.

To conform with the statutory provisions that possible reduction in sentence applies to an inmate convicted of a nonviolent offense, the procedures in our interim final rule stated that an inmate whose current offense falls under the definition in 18 U.S.C. 924(c)(3) of a crime of violence is excluded from early release.

Under section 924(c)(3), a crime of violence means an offense that is a felony and has as an element the use, attempted use, or threatened use of physical force against the person or property of another, or that by its nature, involves a substantial risk that physical force against the person or property of another may be used in the course of committing the offense. Staff use information in the Judgment and Commitment Order and the Presentence Investigation Report to determine if the inmate's committed offense meets this definition of crime of violence.

In exercising the Bureau's discretion to reduce a sentence, we also review the inmate's criminal history in the Presentence Investigation Report. We preclude early release for any inmate with an adult prior federal and/or state conviction for homicide, forcible rape, robbery, or aggravated assault. We selected the above categories of crimes, which are reported under the FBI Violent Crime Index, due to the extensive variations in statutes between states.

Inmates in our custody who are not serving a sentence for a federal offense (for example, INS detainees, pretrial inmates, or contractual boarders) are not eligible for early release. An inmate eligible for parole is not eligible for early release by the Bureau; however, information concerning the successful completion of a residential drug abuse treatment program by a parole-eligible inmate will be transmitted to the Parole Commission for consideration of a Superior Program Achievement Award (see 28 CFR 2.60).

Summary of Public Comments on First Interim Rule

Fifteen commenters objected on the grounds that the interim regulations did not extend early release to inmates serving a sentence for a non-parolable offense.

Four commenters objected to using prior convictions as a disqualifying criterion. Two of these commenters

requested that if we used prior convictions as a disqualifying criterion, we should limit such use to convictions within the last fifteen years. These commenters stated that the fifteen year time limit was used in the Sentencing Commission Criminal History Category.

Two commenters recommended that inmates who completed or were in Bureau drug abuse treatment programs between the time it became known that Congress was considering the amendment to 18 U.S.C. 3621(e) and the publication of the interim rule be granted consideration regardless of any disqualifying criterion.

These commenters stated that inmate participation in the Bureau's drug abuse treatment program was motivated by the expectation that the inmate would subsequently be eligible for early release. One of these commenters recommended that some offenses should not be included under the prior conviction category, but recommended that others be included.

One commenter, the American Psychiatric Association, agreed that the program was a good idea, but expressed concern about the adequacy of transitional drug treatment programming provided at Bureau institutions. The Bureau's regulations in 28 CFR 550.59(a) required minimum participation of one hour per month for such transitional services. The Association stated that this minimum was probably not of sufficient intensity to facilitate a good outcome and recommended enhanced psychiatric consultation and the availability of a broad array of services. The comment by the American Psychiatric Association on the adequacy of transitional services became the basis for the second interim rule.

Agency Response to Public Comment on the First Interim Rule

We do not have statutory authority under 18 U.S.C. 3621(e) to grant early release to an inmate who is serving a sentence for an offense committed before November 1, 1987 (commonly referred to as an "old-law" sentence).

Section 3621(e) applies to inmates serving sentences determined by Sentencing Guidelines (commonly referred to as "new-law" sentences). Some inmates with "old-law" sentences may be eligible for parole. We provide information concerning a parole-eligible inmate's satisfactory participation in our drug abuse treatment programs to the United States Parole Commission for the Commission's use in making determinations under its own regulations (see 28 CFR 2.60) on an inmate's superior program achievement.

Information regarding prior convictions is in the Presentence Investigation Report (PSI). The PSI is a court document and is subject to review by the defendant and defense counsel. In general, information in the PSI about prior convictions may be limited to the fifteen year period covered in the Sentencing Commission Criminal History Category.

If, however, the PSI contains information on prior convictions beyond the period covered in the Criminal History Category, we believe that we are acting in accordance with Congressional intent when we use the listed prior conviction as a disqualifying criterion.

We do not agree with the contention that inmates who participated in drug abuse treatment before the publication of the first interim rule should be granted early release regardless of disqualifying criteria. We must predicate early release on our implementing regulations. The regulations implement our statutory authority by defining successful completion of the drug abuse treatment program and by qualifying the exercise of the Director's discretion to reduce the sentence.

We issued the regulations as interim rules to extend the early release incentive to eligible inmates as quickly as practicable. Inmates who participate in our drug abuse treatment program clearly benefit from the program's objective of equipping the individual with the cognitive, emotional, and behavior skills necessary to choose and maintain a drug-free and crime-free lifestyle, even if they are not eligible for early release.

Changes Made by the Second Interim Rule

We recognize the importance of transitional services in drug treatment programming and agree with the American Psychiatric Association that an enhanced transitional program, such as is available in a community-based program, increases the opportunity for a good outcome. Transitional services offered within the institution are a minimum of one hour per month. Even so, we believe that successful completion of the program must include both the institutional and the community-based component.

While we may be able to increase the availability of certain transitional services at an institution, we cannot duplicate within the institution the environment of community-based transitional services (i.e., the evaluation of the inmate in conditions where the

inmate is reintegrating into the community).

We therefore further amended the interim regulations to require that early release be contingent upon the inmate's completion of transitional services in a community-based program (i.e., in a Community Corrections Center or on home confinement).

One result of the revision was that an inmate who we do not place in community-based programs because of community safety or custodial considerations would not be eligible for early release. The Warden, in her/his professional discretion, decides whether to place an inmate in a community corrections center. The Warden makes the decision based on factors such as the presence of a detainee or the possibility that the inmate's placement in a community-based program would pose a danger to the public.

In implementing the second interim rule, we chose to waive the new requirement with respect to inmates with a detainee participating in the drug abuse treatment program on or before August 17, 1995. These inmates could therefore complete transitional services within the institution before being turned over to the detaining authority.

Summary of Public Comment on the Second Interim Rule

We received three comments on the second interim rule. One commenter agreed with the change being made, but objected to excluding inmates serving a sentence for a non-parolable offense.

Another commenter objected to any exclusion, stating that exclusions were not authorized under 18 U.S.C. 3621(e).

A third commenter objected on the grounds that the statute did not require transitional services. This commenter argued that we moved beyond the intent of Congress in a number of ways.

The commenter objected to the program's name (drug abuse treatment program), stating that it was offensive and contrary to the clear wording of Congress (substance abuse treatment program). The commenter argued that the statute provides for aftercare services when the participant leaves the custody of the Bureau of Prisons rather than for transitional services. The commenter maintained that requiring transitional services delayed or limited possible sentence reductions and consequently resulted in greater costs to the government. The commenter also maintained that variations in individual sentences resulted in inconsistent benefits to eligible inmates.

In June 2000, the American Psychiatric Association submitted a clarification to its original comment. In

this clarification, the Association agrees with the Bureau's contention that it cannot duplicate within a prison institution the environment of community-based transitional services.

The Association, however, does think that transitional services can be established within a prison setting that can improve the outcome related to successful completion of a residential drug treatment program. The Association believes that this can be done by increasing the minimum requirement for transitional services within the institution from the original minimum of one hour per month. The Association does not mean to present an either/or choice of one hour per month within the institution or full participation in the community-based program.

The Association recommends that the rule be reviewed with respect to the importance of providing substance abuse treatment to prisoners requiring external incentives for participation.

Agency Response To Comments on the Second Interim Rule

As noted above in the response to the first interim rule, we do not have statutory authority under 18 U.S.C. 3621(e) to grant early release to an inmate who is serving a sentence for an offense committed before November 1, 1987 (commonly referred to as an "old-law" sentence).

We disagree with the assertion that 18 U.S.C. 3621(e) does not allow for exclusions. By statute, the Director of the Bureau is responsible for determining what constitutes successful completion of the program and for making the decision to reduce the period of custody. The interim rules established procedures, including qualifying criteria, for these purposes.

As for the concerns raised by the third commenter, we wish to emphasize the significance of the nomenclature change with respect to the basis for the transitional services requirement. We have statutory authority under 18 U.S.C. 3621(b) to place inmates in community-based programs such as a community corrections center. Such inmates are technically still in the custody of the Bureau. Furthermore, because the transitional services component is critical to the success of the treatment, successful completion of the "residential substance abuse treatment" program as determined by the Director of the Bureau of Prisons, per 18 U.S.C. 3621(e)(2)(A), includes both the unit-based program and the following transitional services component.

The provisions pertaining to "aftercare" in the statute are separate.

Transitional services in a community-based program are an essential component of the residential substance abuse program envisioned by the statute. As for questions of cost, we do not believe that reducing costs for the government outweighs our responsibility to protect the public.

Finally, inconsistent results cited by the third commenter largely depend upon the circumstances of inmates present at the initial implementation of the interim regulations. In summary, our regulations represent our judgment as to successful completion of the program and the subsequent discretionary granting of a reduction of the time an inmate remains in custody.

As for the clarification by the American Psychiatric Association, we do not believe that it is practicable to enhance transitional services within the institution sufficiently to ensure the intended results. We acknowledge the importance of providing incentives to inmates to participate in drug abuse treatment program. To this purpose, the Bureau published a separate proposed rulemaking in the **Federal Register** (published in proposed form on September 20, 2000 at 65 FR 56840) to address incentives for inmates who would not receive an early release benefit.

Summary of Changes in the Third Interim Rule

The first interim rule attempted to define the term "crime of violence" pursuant to 18 U.S.C. 924(c)(3). Due to varying interpretations of the regulation and caselaw, the Bureau could not apply the regulation in a uniform and consistent manner.

The third interim rule sought to resolve this complication. In the third interim rule, we used the discretion allotted to the Director for granting a sentence reduction to exclude inmates whose current offense is a felony (a) that has as an element, the actual, attempted, or threatened use of physical force against the person or property of another, or (b) that involved the carrying, possession, or use of a firearm or other dangerous weapon or explosives (including any explosive material or explosive device), or (c) that by its nature or conduct, presents a serious potential risk of physical force against the person or property of another, or (d) that by its nature or conduct involves sexual abuse offenses committed upon children. Thus, even as the Bureau concedes that offenses related to this regulation are "non-violent" offenses, the implementing statute does not mandate that all "non-violent" offenders must receive an early

release. The statute merely indicates that the sentence may be reduced by the Bureau of Prisons.

As a conforming amendment, the third interim rule correspondingly revised the criteria for possible sentence reduction under the intensive confinement center program (28 CFR 524.31(a)(3)).

In the third interim rule, we also addressed the Community Corrections Regional Administrator's authority under section 550.58(c)(3) to disallow any portion of the maximum 12 month reduction for an inmate in a community-based program due to a disciplinary finding or due to program needs (for example, the inmate has not established an adequate release plan).

Summary of Public Comment on the Third Interim Rule

We received comments from approximately 150 individuals and organizations. One hundred thirty-eight individuals submitted identical comments. These commenters stated that we were using sentencing factors to label non-violent inmates as violent offenders rather than relying only on the offense of conviction.

These commenters urged that the courts should determine whether an offense was violent. The commenters also argued that inmates were being subjected to double jeopardy because an element used in the court's determination of sentence (for example, a gun enhancement) was also being used to exclude the inmates from the early release benefit.

Five other commenters objected to the requirement that transitional services must be provided in a community-based program, stating that this discriminated against aliens with INS detainers. These commenters asserted that denying the early release benefit resulted in excessive costs to the government. One of these commenters recommended that transitional services be offered in the institution, noting that the terms of an INS detainer are not intended to affect classification, work, quarters assignments, or other treatment an inmate would otherwise receive.

One commenter objected to the rulemaking on the grounds that differing circuit court decisions had resulted in inconsistent application of the policy.

Two commenters objected to the words "attempted" and "threatened" in the early release criteria (§ 550.58(a)(1)(vi)(A)). These commenters further contended that intimidation should not be considered a violent offense.

One commenter objected, arguing that the rule was an arbitrary expansion of

reasonable discretion, and that we were usurping the authority and good judgment of the courts and the legislative powers of Congress. This commenter asserted that any determination of conduct indicative of a violent offense was a matter of fact for the jury's consideration.

The commenter also maintained that our discretion was directed to the proper operation of prisons and not to the determination of the length of sentences for those inmates who successfully complete the program; that Presentence Investigation Reports were for the court's use only; that possession of a weapon or involvement in a conspiracy were not violent crimes; that the program did have an economic impact because it was specially funded by Congress; that the intent of the rule was not rehabilitative, and that the Bureau refused to execute the plain meaning of the statute.

A Public Defender's Office submitted comments stating that the regulations unduly restricted eligibility for a remedial program by inappropriately expanding the class of convictions deemed violent, by excluding prisoners with previous convictions for violent crimes, and by excluding all prisoners who were not eligible to participate in community-based programs (for example, inmates with INS detainees who would be unable to receive transitional services in a community corrections center).

The National Association of Criminal Defense Lawyers and Families Against Mandatory Minimums jointly submitted their comments. These commenters expressed their support for our stated commitment to provide drug abuse treatment services to all inmates with a documented need and/or interest. In keeping with this goal, they argued that the early release incentive should be made available to the broadest population consistent with the statute. They maintained that both the statutory language and the legislative history show that Congress intended broader application than the rule allows. They objected to the use of prior convictions and to felonies being excluded under the Director's discretion (550.58(a)(1)(vi)). They argued that some prior convictions (for example, foreign convictions) were unreliable, that prior convictions are not necessarily predictive.

Agency Response to Public Comment on the Third Interim Rule

No comments specifically addressed the conforming changes to the eligibility criteria for the intensive confinement center or for the authority of the

Community Corrections Regional Administrator.

As noted in the preamble of the third interim rule, we excluded inmates with certain felonies from receiving the early release incentive not because the offense is a "crime of violence," but as an exercise of the Director's discretion. Thus, we are no longer classifying these offenses as a "crime of violence."

We disagree with the assertion that our regulations raise the issue of double jeopardy. Our regulations do not impact the determination of the sentence or seek to impose an additional penalty, but instead pertain to the separate question of how we convey the sentence reduction incentive.

As noted in the response to the second interim rule, we believe that a residential treatment program requires participation in a community-based setting. Therefore, inmates who are not eligible to be placed in a community-based program (for example, inmates with INS detainees) are not eligible for early release.

As noted above, we do not believe that reducing costs for the government outweighs our responsibility to protect the public. Furthermore, while a detainee does not generally effect classification, work, quarters assignments, etc., due to concerns of a flight risk and community safety, detainees are always considered when deciding whether to place an inmate in the community.

As for the concerns raised over the effects of differing circuit court decisions, by implementing the third interim rule, we tried to address the concerns raised by various circuit courts of appeals. Thus, the previous caselaw did not address the revised interpretation of the statute. Accordingly, the Bureau again had a uniform national policy. As courts interpreted the new rule, there again arose a split in circuit court decisions which ultimately, of course, can only be resolved by the Supreme Court.

We disagree with the assertion that our rules are an arbitrary expansion of reasonable discretion and that they usurp the authority and good judgment of the courts and the legislative powers of Congress. Upon successful completion of the program, the statute notes only two conditions which the Bureau cannot breach: first, the early release incentive is available only to "non-violent" offenders; second, the incentive may not exceed one year. Congress imposed no other restrictions on the manner in which the incentive is granted. Specifically, Congress did not mandate that all eligible inmates must receive the early release incentive. The

reduction in sentence is an incentive to be exercised at the discretion of the Bureau of Prisons.

The assertion that the interim rules have an economic impact because the program is specially funded is without merit. Our regulations have no direct impact on small businesses.

We also take issue with assertions that the regulations intent is not rehabilitative or that they unduly restrict eligibility for a remedial program. Our drug abuse treatment program is open to all inmates with a documented need and interest in the program. The restrictions in question pertain to the conveyance of a separate incentive at our discretion. As noted above, we instituted a separate rulemaking to establish further participation incentives for inmates who are not eligible for early release.

Accordingly, upon due consideration of the comments received, we finalize the three interim rules without change.

Executive Order 12866

The Office of Management and Budget (OMB) determined that certain rules are part of a category of actions which are not "significant regulatory actions" under section 3(f) of Executive Order 12866. Because this rule falls within that category, OMB did not review it.

Executive Order 13132

This regulation will not have substantial direct effects on the States, on the relationship between the national government and the States, or on distribution of power and responsibilities among the various levels of government. Under Executive order 13132, this rule does not have sufficient federalism implications for which we would prepare a Federalism Assessment.

Regulatory Flexibility Act

The Director of the Bureau of Prisons, under the Regulatory Flexibility Act (5 U.S.C. 605(b)), reviewed this regulation. By approving it, the Director certifies that it will not have a significant economic impact upon a substantial number of small entities because: This rule is about the correctional management of offenders committed to the custody of the Attorney General or the Director of the Bureau of Prisons, and its economic impact is limited to the Bureau's appropriated funds.

Unfunded Mandates Reform Act of 1995

This rule will not cause State, local and tribal governments, or the private sector, to spend \$100,000,000 or more in any one year, and it will not

significantly or uniquely affect small governments. We do not need to take action under the Unfunded Mandates Reform Act of 1995.

Small Business Regulatory Enforcement Fairness Act of 1996

This rule is not a major rule as defined by Section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996. This rule will not result in an annual effect on the economy of \$100,000,000 or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

Plain Language Instructions

We want to make Bureau documents easier to read and understand. If you can suggest how to improve the clarity of these regulations, call or write to Sarah Qureshi at the address or telephone number listed above.

List of Subjects

28 CFR Part 524

Prisoners.

28 CFR Part 550

Prisoners.

Kathleen Hawk Sawyer,
Director, Bureau of Prisons.

Subchapter B—Inmate Admission, Classification, and Transfer

PART 524—CLASSIFICATION OF INMATES

Subchapter C—Institutional Management

PART 550—DRUG PROGRAMS

Accordingly, under the rulemaking authority vested in the Attorney General in 5 U.S.C. 552(a) and delegated to the Director, Bureau of Prisons, we adopt the interim rules amending 28 CFR parts 524 and 550 which were published on May 25, 1995 (60 FR 27692), May 17, 1996 (61 FR 25121), and October 15, 1997 (62 FR 53690) as final without change.

[FR Doc. 00-32772 Filed 12-21-00; 8:45 am]

BILLING CODE 4410-05-M

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

31 CFR Chapter V

Blocked Persons, Specially Designated Nationals, Specially Designated Terrorists, Foreign Terrorist Organizations, and Specially Designated Narcotics Traffickers: Additional Designations and Supplementary Information on Specially Designated Narcotics Traffickers

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Amendment of final rule.

SUMMARY: The Treasury Department is amending appendix A to 31 CFR chapter V by adding the names of 8 individuals and 8 entities and supplementing information concerning 16 individuals who have been designated as specially designated narcotics traffickers.

EFFECTIVE DATE: December 19, 2000.

FOR FURTHER INFORMATION CONTACT: Office of Foreign Assets Control, Department of the Treasury, Washington, D.C. 20220, tel.: 202/622-2520.

SUPPLEMENTARY INFORMATION:

Electronic and Facsimile Availability

This document is available as an electronic file on The Federal Bulletin Board the day of publication in the **Federal Register**. By modem, dial 202/512-1387 and type "/GO FAC," or call 202/512-1530 for disk or paper copies. This file is available for downloading without charge in ASCII and Adobe Acrobat® readable (*.PDF) formats. For Internet access, the address for use with the World Wide Web (Home Page), Telnet, or FTP protocol is: fedbbs.access.gpo.gov. This document and additional information concerning the programs of the Office of Foreign Assets Control are available for downloading from the Office's Internet Home Page: <http://www.treas.gov/ofac>, or in fax form through the Office's 24-hour fax-on-demand service: call 202/622-0077 using a fax machine, fax modem, or (within the United States) a touch-tone telephone.

Background

Appendix A to 31 CFR chapter V contains the names of blocked persons, specially designated nationals, specially designated terrorists, foreign terrorist organizations, and specially designated narcotics traffickers designated pursuant to the various economic sanctions

programs administered by the Office of Foreign Assets Control ("OFAC"). Pursuant to Executive Order 12978 of October 21, 1995, "Blocking Assets and Prohibiting Transactions with Significant Narcotics Traffickers" (the "Order") and § 536.312 of the Narcotics Trafficking Sanctions Regulations, 31 CFR part 536 (the "Regulations"), the following 8 individuals and 8 entities are added to appendix A as persons who have been determined to play a significant role in international narcotics trafficking centered in Colombia, to materially assist in or provide financial support or technological support for, or goods or services in support of other specially designated narcotics traffickers, or to be owned or controlled by, or to act for or on behalf of, persons designated in or pursuant to the Order (collectively "Specially Designated Narcotics Traffickers" or "SDNTs"). All real and personal property in which the SDNTs have any interest, including but not limited to all accounts, that are or come within the United States or that are or come within the possession or control of U.S. persons, including their overseas branches, are blocked. All transactions by U.S. persons or within the United States in property or interests in property of SDNTs are prohibited unless licensed by the Office of Foreign Assets Control or exempted by statute. Supplementary information is added to existing SDNT entries for 16 individuals and those entries are revised in their entirety.

Designations of foreign persons blocked pursuant to the Order are effective upon the date of determination by the Director of the Office of Foreign Assets Control, acting under authority delegated by the Secretary of the Treasury. Public notice of blocking is effective upon the date of filing with the **Federal Register**, or upon prior actual notice.

Because the Regulations involve a foreign affairs function, Executive Order 12866 and the provisions of the Administrative Procedure Act (5 U.S.C. 553), requiring notice of proposed rulemaking, opportunity for public participation, and delay in effective date, are inapplicable. Because no notice of proposed rulemaking is required for this rule, the Regulatory Flexibility Act (5 U.S.C. 601-612) does not apply.

For the reasons set forth in the preamble, and under the authority of 3 U.S.C. 301; 50 U.S.C. 1601-1651; 50 U.S.C. 1701-1706; E.O. 12978, 60 FR 54579, 3 CFR, 1995 Comp., p. 415,

appendix A to 31 CFR chapter V is amended as set forth below:

Appendix A [Amended]

1. Appendix A to 31 CFR chapter V is amended by adding the following names inserted in alphabetical order, to read as follows:

AGROVETERINARIA EL TORO (see INVERSIONES BOMBAY S.A.) [SDNT]
 AGROVETERINARIA EL TORO #2 (see INVERSIONES BOMBAY S.A.) [SDNT]
 BARRIOS, Alba Lucia, Los Alcazares Bloq. 93 Ap. 402, Cali, Colombia; c/o CREDIREBAJA S.A., Cali, Colombia; c/o POLIEMPAQUES S.A., Cali, Colombia; c/o SONAR F.M. E.U. DIETER MURRE, Cali, Colombia; c/o SONAR F.M. S.A., Cali, Colombia; Cedula No. 38853130 (Colombia) (individual) [SDNT]
 CAVIEDES DILEO Y CIA. S.C.S., Calle 21 Norte No. 3N-64, Cali, Colombia; NIT #800113437-2 (Colombia) [SDNT]
 COMUNICACION VISUAL LTDA., (a.k.a. COMVIS LTDA.), Calle 11 No. 19-44, Cali, Colombia [SDNT]
 COMVIS LTDA. (see COMUNICACION VISUAL LTDA.) [SDNT]
 CREDIREBAJA S.A., Calle 16 No. 100-88, Cali, Colombia; Calle 19 No. 2-29 of. 3001, Cali, Colombia; NIT #805001030-6 (Colombia) [SDNT]
 CUJAR DE FORERO, Claudia, c/o BONOMERCAD S.A., Bogota, Colombia; c/o DISTRIBUIDORA AGROPECUARIA COLOMBIANA S.A., Cali, Colombia; Cedula No. 20198740 (Colombia) (individual) [SDNT]
 DIAGROCOL S.A. (see DISTRIBUIDORA AGROPECUARIA COLOMBIANA S.A.) [SDNT]
 DISTRIBUIDORA AGROPECUARIA COLOMBIANA S.A., (a.k.a. DIAGROCOL S.A.), Avenida 3 Bis Norte No. 23C-69, Cali, Colombia; NIT #805011649-7 (Colombia) [SDNT]
 FORERO FERNANDEZ, Alberto Mario, c/o HAPPY DAYS S. de H., Barranquilla, Colombia; Cedula No. 8715143 (Colombia) (individual) [SDNT]
 HAPPY DAYS S. de H., Calle 78 No. 53-70, Locales 315 y 316, Barranquilla, Colombia; NIT #802003826-1 (Colombia) [SDNT]
 INVERSIONES BOMBAY S.A., (a.k.a. AGROVETERINARIA EL TORO; a.k.a. AGROVETERINARIA EL TORO #2), Transversal 29 No. 39-92, Bogota, Colombia; Calle 12B No. 28-50, Bogota, Colombia; Avenida 3 Bis Norte No. 23CN-69, Cali, Colombia; Calle 7 No. 25-69, Cali, Colombia; NIT #830019226-2 (Colombia) [SDNT]
 PALMA SAADE, Jessica Maria, Calle 78 No. 53-70, Local 202, Barranquilla, Colombia; c/o VESTIMENTA J y J S. de H., Barranquilla, Colombia; Cedula No. 32758645 (Colombia) (individual) [SDNT]
 PRIETO, Diocelina (see PRIETO, Dioselina) (individual) [SDNT]
 PRIETO, Dioselina, (a.k.a. PRIETO, Diocelina), Carrera 12 No. 2-81, Bogota, Colombia; c/o COMEDICAMENTOS S.A., Bogota, Colombia; c/o

DISTRIBUIDORA AGROPECUARIA COLOMBIANA S.A., Cali, Colombia; c/o GLAJAN S.A., Bogota, Colombia; c/o INVERSIONES BOMBAY S.A., Bogota, Colombia; Cedula No. 41760201 (Colombia) (individual) [SDNT]
 RAMOS GARBIRAS, Gerardo Alfonso, Carrera 29 No. 9-64, Cali, Colombia; c/o DISTRIBUIDORA AGROPECUARIA COLOMBIANA S.A., Cali, Colombia; c/o INVERSIONES BOMBAY S.A., Bogota, Colombia; Cedula No. 6457125 (Colombia) (individual) [SDNT]
 RODRIGUEZ ARBELAEZ, Juan Miguel, Avenida del Lago Calle Cocli Casa 19 Ciudad Jardin, Cali, Colombia; c/o CREDIREBAJA S.A., Cali, Colombia; c/o INVERSIONES ARA LTDA., Cali, Colombia; c/o INVERSIONES RODRIGUEZ ARBELAEZ Y CIA. S.C.S., Cali, Colombia; c/o M. RODRIGUEZ O. Y CIA. S.C.S., Cali, Colombia; c/o VALORES MOBILIARIOS DE OCCIDENTE S.A., Cali, Colombia; Cedula No. 94491333 (Colombia) (individual) [SDNT]
 ROJAS GALARZA, Carmen Amparo, Carrera 35 No. 10-130, Cali, Colombia; c/o CREDIREBAJA S.A., Cali, Colombia; Cedula No. 34511289 (Colombia) (individual) [SDNT]
 SORAYA Y HAYDEE LTDA., Calle 15 Norte No. 6N-34, Piso 15, Cali, Colombia; NIT #805000643-6 (Colombia) [SDNT]
 VESTIMENTA J Y J S. de H., Calle 78 No. 53-70, Local 112, Barranquilla, Colombia; NIT #802001338-8 (Colombia) [SDNT]

2. Appendix A to 31 CFR chapter V is amended by revising the following existing entries to read as follows:

ARBELAEZ PARDO, Amparo, Casa No. 19, Avenida Lago, Ciudad Jardin, Cali, Colombia; c/o CREDIREBAJA S.A., Cali, Colombia; c/o INTERAMERICANA DE CONSTRUCCIONES S.A., Cali, Colombia; c/o INVERSIONES ARA LTDA., Cali, Colombia; c/o LABORATORIOS KRESSFOR DE COLOMBIA S.A., Bogota, Colombia; c/o VALORES MOBILIARIOS DE OCCIDENTE, Bogota, Colombia; DOB 9 August 1950; Passports AC568973 (Colombia), PE001850 (Colombia); Cedula No. 31218903 (Colombia) (individual) [SDNT]
 ARBOLEDA ARROYAVE, Pedro Nicholas (Nicolas), c/o CREDIREBAJA S.A., Cali, Colombia; c/o D'CACHE S.A., Cali, Colombia; c/o DEPOSITO POPULAR DE DROGAS S.A., Cali, Colombia; c/o DISTRIBUIDORA DE DROGAS CONDOR LTDA., Bogota, Colombia; DOB 23 June 1957; Cedula No. 16602372 (Colombia) (individual) [SDNT]
 BENITEZ CASTELLANOS, Cesar Tulio, Carrera 65 No. 13B-82, Cali, Colombia; c/o COMUNICACION VISUAL LTDA., Cali, Colombia; c/o D'CACHE S.A., Cali, Colombia; c/o DROGAS LA REBAJA, Cali, Colombia; c/o INVERSIONES MONDRAGON Y CIA. S.C.S., Cali, Colombia; c/o INVERSIONES Y CONSTRUCCIONES ABC S.A., Cali, Colombia; c/o RIONAP COMERCIOS Y REPRESENTACIONES S.A., Quito,

Ecuador; Cedula No. 14969366 (Colombia) (individual) [SDNT]
 CARRILLO QUINTERO, Eugenio, c/o BONOMERCAD S.A., Bogota, Colombia; c/o DECAFARMA S.A., Bogota, Colombia; c/o DISTRIBUIDORA AGROPECUARIA COLOMBIANA S.A., Cali, Colombia; c/o PATENTES MARCAS Y REGISTROS S.A., Bogota, Colombia; c/o SHARPER S.A., Bogota, Colombia; Cedula No. 73094061 (Colombia) (individual) [SDNT]
 CAVIEDES CRUZ, Leonardo, Calle 21 Norte No. 3N-84, Cali, Colombia; c/o CAVIEDES DILEO Y CIA S.C.S., Cali, Colombia; c/o INVERSIONES SANTA LTDA., Cali, Colombia; DOB 23 November 1952; Passports AB151486 (Colombia); AC444270 (Colombia), OC444290 (Colombia); Cedula No. 16593470 (Colombia) (individual) [SDNT]
 MUNOZ RODRIGUEZ, Juan Carlos, c/o BLANCO PHARMA S.A., Bogota, Colombia; c/o CREDIREBAJA S.A., Cali, Colombia; c/o DEPOSITO POPULAR DE DROGAS S.A., Cali, Colombia; c/o DISTRIBUIDORA DE DROGAS CONDOR LTDA., Bogota, Colombia; c/o DISTRIBUIDORA DE DROGAS LA REBAJA S.A., Bogota, Colombia; c/o DISTRIBUIDORA MIGIL LTDA., Cali, Colombia; c/o GRACADAL S.A., Cali, Colombia; c/o INVERSIONES Y CONSTRUCCIONES ABC S.A., Cali, Colombia; c/o LABORATORIOS BLAIMAR DE COLOMBIA S.A., Bogota, Colombia; c/o LABORATORIOS KRESSFOR DE COLOMBIA S.A., Bogota, Colombia; DOB 25 September 1964; Passport 16703148 (Colombia); Cedula No. 16703148 (Colombia) (individual) [SDNT]
 MUNOZ RODRIGUEZ, Soraya, c/o BLANCO PHARMA S.A., Bogota, Colombia; c/o DEPOSITO POPULAR DE DROGAS S.A., Cali, Colombia; c/o DISTRIBUIDORA DE DROGAS CONDOR LTDA., Bogota, Colombia; c/o DISTRIBUIDORA DE DROGAS LA REBAJA S.A., Bogota, Colombia; c/o DISTRIBUIDORA MIGIL LTDA., Cali, Colombia; c/o INVERSIONES Y CONSTRUCCIONES ABC S.A., Cali, Colombia; c/o LABORATORIOS BLAIMAR DE COLOMBIA S.A., Bogota, Colombia; c/o LABORATORIOS KRESSFOR DE COLOMBIA S.A., Bogota, Colombia; c/o RADIO UNIDAS FM S.A., Cali, Colombia; c/o SORAYA Y HAYDEE LTDA., Cali, Colombia; DOB 26 July 1967; Passport AC569012 (Colombia); Cedula No. 31976822 (Colombia) (individual) [SDNT]
 NASSER ARANA, Jorge, Calle 74 No. 53-30, Barranquilla, Colombia; c/o AGRICOLA SONGO LTDA., Barranquilla, Colombia; c/o DESARROLLOS URBANOS "DESARROLLAR" LTDA., Barranquilla, Colombia; c/o EDIFICACIONES DEL CARIBE LTDA., Barranquilla, Colombia; c/o GRAN COMPANNIA DE HOTELES LTDA., Barranquilla, Colombia; c/o HAPPY DAYS S. de H., Barranquilla, Colombia; c/o HOTELES E INMUEBLES DE COLOMBIA LTDA., Barranquilla,

- Colombia; c/o INMOBILIARIA DEL CARIBE LTDA., Barranquilla, Colombia; INMOBILIARIA HOTELERA DEL CARIBE LTDA., Barranquilla, Colombia; INVERSIONES HOTELERAS DEL LITORAL LTDA., Barranquilla, Colombia; INVERSIONES PRADO TRADE CENTER LTDA., Barranquilla, Colombia; c/o NEGOCIOS Y PROPIEDADES DEL CARIBE LTDA., Barranquilla, Colombia; c/o PROMOCIONES Y CONSTRUCCIONES DEL CARIBE LTDA., Barranquilla, Colombia; c/o PROMOCIONES Y CONSTRUCCIONES DEL CARIBE LTDA. Y CIA. S.C.A., Barranquilla, Colombia; c/o PROMOTORA HOTEL BARRANQUILLA LTDA., Barranquilla, Colombia; c/o SURAMERICANA DE HOTELES LTDA., Barranquilla, Colombia; c/o VESTIMENTA J Y J S. de H., Barranquilla, Colombia; DOB 6 November 1966; Passports T705915 (Colombia), AC143719 (Colombia); Cedula No. 72139939 (Colombia) (individual) [SDNT]
- RODRIGUEZ ABADIA, William, c/o ANDINA DE CONSTRUCCIONES S.A., Cali, Colombia; c/o ASPOIR DEL PACIFICO Y CIA. LTDA., Cali, Colombia; c/o BLANCO PHARMA S.A., Bogota, Colombia; c/o CLAUDIA PILAR RODRIGUEZ Y CIA. S.C.S., Bogota, Colombia; c/o CREDIREBAJA S.A., Cali, Colombia; c/o DEPOSITO POPULAR DE DROGAS S.A., Cali, Colombia; c/o DERECHO INTEGRAL Y CIA. LTDA., Cali, Colombia; c/o DISTRIBUIDORA DE DROGAS CONDOR LTDA., Bogota, Colombia; c/o DISTRIBUIDORA DE DROGAS LA REBAJA S.A., Bogota, Colombia; c/o DISTRIBUIDORA MIGIL LTDA., Cali, Colombia; INTERAMERICANA DE CONSTRUCCIONES S.A., Cali, Colombia; c/o INVERSIONES ARA LTDA., Cali, Colombia; c/o INVERSIONES MIGUEL RODRIGUEZ E HIJO, Cali, Colombia; c/o LABORATORIOS BLAIMAR DE COLOMBIA S.A., Bogota, Colombia; c/o LABORATORIOS KRESSFOR DE COLOMBIA S.A., Bogota, Colombia; c/o M. RODRIGUEZ O- Y CIA. S. EN C., Cali, Colombia; c/o MUNOZ Y RODRIGUEZ Y CIA. LTDA., Cali, Colombia; c/o PRODUCCIONES CARNAVAL DEL NORTE Y COMPANIA LIMITADA, Cali, Colombia; c/o RADIO UNIDAS FM S.A., Cali, Colombia; c/o REVISTA DEL AMERICA LTDA., Cali, Colombia; c/o RIONAP COMERCIO Y REPRESENTACIONES S.A., Quito, Ecuador; c/o VALORES MOBILIARIOS DE OCCIDENTE S.A., Bogota, Colombia; DOB 31 July 1965; Cedula No. 16716259 (Colombia) (individual) [SDNT]
- RODRIGUEZ ARBELAEZ, Maria Fernanda, c/o CREDIREBAJA S.A., Cali, Colombia; c/o D'CACHE S.A., Cali, Colombia; c/o DEPOSITO POPULAR DE DROGAS S.A., Cali, Colombia; c/o DISTRIBUIDORA DE DROGAS LA REBAJA S.A., Bogota, Colombia; c/o DROGAS LA REBAJA BOGOTA S.A., Bogota, Colombia; c/o INTERAMERICANA DE CONSTRUCCIONES S.A., Cali, Colombia; c/o INVERSIONES ARA LTDA., Cali, Colombia; c/o PRODUCCIONES CARNAVAL DEL NORTE Y COMPANIA LIMITADA, Cali, Colombia; c/o RIONAP COMERCIO Y REPRESENTACIONES S.A., Quito, Ecuador; c/o VALORES MOBILIARIOS DE OCCIDENTE S.A., Cali, Colombia; DOB 28 November 1973; Alt. DOB 28 August 1973; Passport AC568974 (Colombia); Cedula No. 66860965 (Colombia) (individual) [SDNT]
- RODRIGUEZ DE ROJAS, Haydee, (a.k.a. RODRIGUEZ DE MUNOZ, Haydee; a.k.a. RODRIGUEZ OREJUELA, Haydee), c/o BLANCO PHARMA S.A., Bogota, Colombia; c/o CORPORACION DEPORTIVA AMERICA, Cali, Colombia; c/o CREACIONES DEPORTIVAS WILLINGTON LTDA., Cali, Colombia; c/o DISTRIBUIDORA DE DROGAS CONDOR LTDA., Bogota, Colombia; c/o DISTRIBUIDORA MIGIL LTDA., Cali, Colombia; c/o HAYDEE DE MUNOZ Y CIA. S. EN C., Cali, Colombia; c/o RADIO UNIDAS FM S.A., Cali, Colombia; c/o SORAYA Y HAYDEE LTDA., Cali, Colombia; DOB 22 September 1940; Cedula No. 38953333 (Colombia) (individual) [SDNT]
- RODRIGUEZ MONDRAGON, Maria Alexandra, (a.k.a. RODRIGUEZ MONDRAGON, Alexandra), c/o BLANCO PHARMA S.A., Bogota, Colombia; c/o CORPORACION DEPORTIVA AMERICA, Cali, Colombia; c/o CREDIREBAJA S.A., Cali, Colombia; c/o D'CACHE S.A., Cali, Colombia; c/o DEPOSITO POPULAR DE DROGAS S.A., Cali, Colombia; c/o DISTRIBUIDORA DE DROGAS CONDOR LTDA., Bogota, Colombia; c/o DISTRIBUIDORA DE DROGAS LA REBAJA S.A., Bogota, Colombia; c/o DISTRIBUIDORA MIGIL LTDA., Cali, Colombia; c/o GRACADAL S.A., Cali, Colombia; c/o INTERAMERICANA DE CONSTRUCCIONES S.A., Cali, Colombia; c/o INVERSIONES MONDRAGON Y CIA. S.C.S., Cali, Colombia; c/o LABORATORIOS BLAIMAR DE COLOMBIA S.A., Bogota, Colombia; c/o MARIELA DE RODRIGUEZ Y CIA. S. EN C., Cali, Colombia; c/o MARIELA MONDRAGON DE R. Y CIA. S. EN C., Cali, Colombia; c/o PENTA PHARMA DE COLOMBIA S.A., Bogota, Colombia; c/o TOBOGON, Cali, Colombia; DOB 30 May 1969; alt. DOB 5 May 1969; Passport AD359106 (Colombia); Cedula No. 66810048 (Colombia) (individual) [SDNT]
- RODRIGUEZ MONDRAGON, Humberto, c/o ANDINA DE CONSTRUCCIONES S.A., Cali, Colombia; c/o BLANCO PHARMA S.A., Bogota, Colombia; c/o CLAUDIA PILAR RODRIGUEZ Y CIA. S.C.S., Bogota, Colombia; c/o CREDIREBAJA S.A., Cali, Colombia; c/o D'CACHE S.A., Cali, Colombia; c/o DEPOSITO POPULAR DE DROGAS S.A., Cali, Colombia; c/o DISTRIBUIDORA DE DROGAS CONDOR LTDA., Bogota, Colombia; c/o DISTRIBUIDORA DE DROGAS LA REBAJA S.A., Bogota, Colombia; c/o DISTRIBUIDORA MIGIL LTDA., Cali, Colombia; c/o FARMATODO S.A., Bogota, Colombia; c/o GRACADAL S.A., Cali, Colombia; c/o INDUSTRIAL DE GESTION DE NEGOCIOS E.U., Cali, Colombia; c/o INTERAMERICANA DE CONSTRUCCIONES S.A., Cali, Colombia; c/o INVERSIONES MONDRAGON Y CIA. S.C.S., Cali, Colombia; c/o LABORATORIOS BLAIMAR DE COLOMBIA S.A., Bogota, Colombia; c/o LABORATORIOS KRESSFOR DE COLOMBIA S.A., Bogota, Colombia; c/o MARIELA DE RODRIGUEZ Y CIA. S. EN C., Cali, Colombia; c/o PENTA PHARMA DE COLOMBIA S.A., Bogota, Colombia; c/o RADIO UNIDAS FM S.A., Cali, Colombia; c/o RIONAP COMERCIO Y REPRESENTACIONES S.A., Quito, Ecuador; DOB 21 June 1963; Passport AD387757 (Colombia); Cedula No. 16688683 (Colombia) (individual) [SDNT]
- RODRIGUEZ MONDRAGON, Jaime, c/o BLANCO PHARMA S.A., Bogota, Colombia; c/o CORPORACION DEPORTIVA AMERICA, Cali, Colombia; c/o CREDIREBAJA S.A., Cali, Colombia; c/o D'CACHE S.A., Cali, Colombia; c/o DEPOSITO POPULAR DE DROGAS S.A., Cali, Colombia; c/o DISTRIBUIDORA DE DROGAS CONDOR LTDA., Bogota, Colombia; c/o DISTRIBUIDORA DE DROGAS LA REBAJA S.A., Bogota, Colombia; c/o DISTRIBUIDORA MIGIL LTDA., Cali, Colombia; c/o FARMATODO S.A., Bogota, Colombia; c/o FLEXOEMPAQUES LTDA., Cali, Colombia; c/o GRACADAL S.A., Cali, Colombia; c/o INVERSIONES MONDRAGON Y CIA. S.C.S., Cali, Colombia; c/o LABORATORIOS BLAIMAR DE COLOMBIA S.A., Bogota, Colombia; c/o LABORATORIOS KRESSFOR DE COLOMBIA S.A., Bogota, Colombia; c/o MARIELA DE RODRIGUEZ Y CIA. S. EN C., Cali, Colombia; c/o PENTA PHARMA DE

COLOMBIA S.A., Bogota, Colombia;
c/o PLASTICOS CONDOR LTDA.,
Cali, Colombia; c/o RIONAP
COMERCIO Y
REPRESENTACIONES S.A., Quito,
Ecuador; DOB 30 March 1960;
Passport AE426347 (Colombia);
Cedula No. 16637592 (Colombia)
(individual) [SDNT]

RODRIGUEZ RAMIREZ, Claudia Pilar
(Patricia), c/o CLAUDIA PILAR
RODRIGUEZ Y CIA. S.C.S., Bogota,
Colombia; c/o CREDIREBAJA S.A.,
Cali, Colombia; c/o D'CACHE S.A.,
Cali, Colombia; c/o DEPOSITO
POPULAR DE DROGAS S.A., Cali,
Colombia; c/o DISTRIBUIDORA DE
DROGAS CONDOR LTDA., Bogota,
Colombia; c/o DISTRIBUIDORA DE
DROGAS LA REBAJA S.A., Bogota,
Colombia; c/o DISTRIBUIDORA
MIGIL LTDA., Cali, Colombia; c/o
FARMATODO S.A., Bogota,
Colombia; c/o GRACADAL S.A.,
Cali, Colombia; c/o
INTERAMERICANA DE
CONSTRUCCIONES S.A., Cali,
Colombia; c/o LABORATORIOS
BLAIMAR DE COLOMBIA S.A.,
Bogota, Colombia; c/o
LABORATORIOS KRESSFOR DE
COLOMBIA S.A., Bogota, Colombia;
DOB 30 June 1963; alt. DOB 30
August 1963; alt. DOB 1966;
Passports 007281 (Colombia),
P0555266 (Colombia); Cedula No.
51741013 (Colombia) (individual)
[SDNT]

SOSSA RIOS, Diego Alberto, (a.k.a.
SOSA RIOS, Diego Alberto), Calle
46 No. 13-56 of. 111, Bogota,
Colombia; c/o BONOMERCAD S.A.,
Bogota, Colombia; c/o
DECAFARMA S.A., Bogota,
Colombia; c/o DISTRIBUIDORA
AGROPECUARIA COLOMBIANA
S.A.; c/o FARMACOOOP, Bogota,
Colombia; c/o INVERSIONES
BOMBAY S.A., Bogota, Colombia;
c/o PENTAPHARMA DE
COLOMBIA S.A., Bogota, Colombia;
c/o SHARPER S.A., Bogota,
Colombia; Cedula No. 71665932
(Colombia) (individual) [SDNT]

Dated: December 6, 2000.

R. Richard Newcomb,

Director, Office of Foreign Assets Control.

Approved: December 7, 2000.

Elisabeth A. Bresee,

*Assistant Secretary (Enforcement),
Department of the Treasury.*

[FR Doc. 00-32618 Filed 12-19-00; 10:58
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BILLING CODE 4810-25-P

DEPARTMENT OF THE TREASURY

31 CFR Part 29

Federal Benefit Payments Under Certain District of Columbia Retirement Plans

AGENCY: Departmental Offices,
Department of the Treasury.

ACTION: Interim rule with request for
comments.

SUMMARY: The Department of the
Treasury, Departmental Offices, is
issuing interim regulations and
requesting comments on these
regulations to implement the provisions
of the Balanced Budget Act of 1997, as
amended (Act). The Act assigns the
Secretary of the Treasury responsibility
for payment of benefits under the
District of Columbia (District) retirement
plans for police and firefighters, and
teachers for benefits based on credit for
service accrued as of June 30, 1997, and
under the District retirement plan for
judges. The interim regulations establish
general rules for claiming Federal
Benefit Payments and for appeals of
administrative decisions affecting
Federal Benefit Payments.

DATES: Interim rules effective January
22, 2001, except for § 29.102(a)(3) which
will become effective March 31, 2001;
comments must be received on or before
February 20, 2001.

ADDRESSES: Send comments to Ronald
A. Glaser, Director, Office of Personnel
Policy, Department of the Treasury,
Metropolitan Square Building, Room
6075, 1500 Pennsylvania Avenue, NW,
Washington, DC 20220. Comments may
also be submitted by electronic mail to
dcpensions@do.treas.gov.

FOR FURTHER INFORMATION CONTACT:
Harold L. Siegelman, (202) 622-1540,
Department of the Treasury,
Metropolitan Square Building, Room
6033, 1500 Pennsylvania Avenue, NW,
Washington, DC 20220.

SUPPLEMENTARY INFORMATION: Title XI of
the Balanced Budget Act of 1997, Public
Law 105-33, 111 Stat. 251, 712-731,
756-759, enacted August 5, 1997, as
amended by the Omnibus Consolidated
and Emergency Supplemental
Appropriations Act for Fiscal Year 1999,
Public Law 105-277, 112 Stat. 2681,
2681-530 through 538, 2681-552,
transferred certain unfunded pension
liabilities from the District government
to the Federal Government. The Act
requires the Federal Government to
assume responsibility for payment of
certain benefits that accrued on or
before June 30, 1997, under the
retirement plans for District teachers
(Teachers Plan), police and firefighters

(Police and Firefighters Plan), and for
past and future benefits under the
retirement plan for judges (Judges Plan).
The Act also required the District
government to establish replacement
retirement plans that will provide
retirement benefits for service after June
30, 1997, for current and future
teachers, police, and firefighters.

1. Requirement To Establish Processes for Benefit Determinations and Appeals

(a) Claims for Federal Benefit Payments

The interim regulations implement
sections 11021(1) and (2) of the Act and
section 11-1570(c)(2)(A) of the D.C.
Code, as amended by section 11251 of
the Act. These statutes provide for,
among other things, the determination
of eligibility for and the amount and
form of Federal Benefit Payments.

(b) Appeals of Benefit Denials

The interim regulations also
implement section 11022 of the Act,
which provides for the right to appeal
denials of Federal Benefit Payments, in
whole or in part, under the Teachers
Plan and the Police and Firefighters
Plan. No parallel provision in the Act or
the D.C. Code exists with respect to
appeal rights under the Judges Plan. To
ensure uniform treatment of participants
in the three plans, and in accordance
with principles of fundamental fairness,
the interim regulations with respect to
appeal procedures shall also apply to
the Judges Plan.

The interim regulations are based on
the Office of Personnel Management
(OPM) regulations for Civil Service
Retirement with respect to similar
functions. See 5 CFR 831.109-831.110.
In general, the Treasury Department
intends these regulations to have the
same general effect as the corresponding
OPM regulations.

Minor changes from the OPM
regulations were necessary because of
differences in the programs being
administered. Under sections 8347(d)
and 8461(e) of title 5 of the United
States Code, OPM's retirement decisions
are subject to administrative review by
the Merit Systems Protection Board and
the judicial review process begins in the
United States Court of Appeals. Under
section 11022 of the Act, a claimant
whose claim for a Federal Benefit
Payment has been denied (in whole or
part) shall have a reasonable
opportunity for a full and fair review of
the decision denying such claim. The
Act also vests the United States District
Court for the District of Columbia with
exclusive jurisdiction and venue for
civil actions brought by participants or
beneficiaries pursuant to the Act.

2. Contracting for Administrative Services

The Act provides in sections 11035(a) and (b) for the selection of a Trustee to administer the Department's responsibilities for the District retirement programs under the Act, including determining eligibility for and amount of Federal Benefit Payments. Subsection (c) of section 11035 authorizes the Trustee to subcontract with the District government or any person to provide services to the Trustee in connection with the Trustee's performance of its contract with the Department. Subsection (d) of section 11035 authorizes the Secretary to perform any function of the Trustee if the Secretary determines that, in the interest of economy and efficiency, the Secretary rather than the Trustee should perform such function. Until such time as the Secretary notifies the District that the Trustee has been directed to carry out the duties and responsibilities required under the contract or determines that the Department shall carry out those functions, section 11041(a) of the Act requires the District to continue to discharge its duties with respect to making Federal Benefit Payments. Because the District is currently making Federal Benefit determinations under section 11041(a) of the Act, and it is likely that such determinations will be made in the future by the Trustee, a subcontractor of the Trustee, or another agent of the Department, the regulations use the term "Benefits Administrator" throughout this subpart to denote the entity making Federal Benefit determinations. It should be noted, however, that the Department potentially may be the "Benefits Administrator" for the purpose of this subpart.

3. Development of These Procedures.

Subpart D establishes procedures for claims processing and appeals. All claims for Federal Benefit Payments must be filed in writing with the Benefits Administrator. The Benefits Administrator will be responsible for processing claims through the reconsideration-decision stage. The Department will decide appeals of the Benefits Administrator's reconsideration decisions if it receives a timely request to do so. Judicial review of the Department's final decision is available in the United States District Court for the District of Columbia, which has exclusive jurisdiction and venue over such appeals under section 11072 of the Act.

Pursuant to section 553(b)(3)(B) of title 5, United States Code, it has been determined that good cause exists for waiving a general notice of proposed rulemaking for this rule. Overpayments of Federal Benefit Payments must be corrected expeditiously to protect and maintain the integrity of the Trust Funds from which Federal Benefit Payments are made. Delaying implementation of these regulations could forestall efforts to correct overpayments promptly. Moreover, beneficiaries whose Federal Benefit Payments have been denied or reduced need the clear procedures provided in this rule for seeking review of such decisions. Delaying implementation of these provisions would be contrary to the public interest.

E.O. 12866, Regulatory Review

Because this interim rule is not a significant regulatory action for purposes E.O. 12866, a regulatory assessment is not required.

Regulatory Flexibility Act

Because no notice of proposed rulemaking is required, the provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) do not apply. Moreover, the regulation will only affect the determination of the Federal portion of retirement benefits to certain former employees of the District of Columbia.

List of Subjects in 31 CFR Part 29

Administrative practice and procedure, Claims, Disability benefits, Firefighters, Government employees, Intergovernmental relations, Law enforcement officers, Pensions, Retirement, Teachers.

Department of the Treasury.

Lisa G. Ross,

Acting Assistant Secretary of the Treasury.

Accordingly, the Department of the Treasury is amending part 29 of Title 31 of the Code of Federal Regulations, as follows:

PART 29—FEDERAL BENEFIT PAYMENTS UNDER CERTAIN DISTRICT OF COLUMBIA RETIREMENT PROGRAMS

1. The authority citation for part 29 is revised to read as follows:

Authority: Sections 11083 and 11251(a) of Pub. L. 105–33, 111 Stat. 730 and 756, as amended by Pub. L. 105–277, 112 Stat. 2681–530 through 538; subpart D also issued under section 11022 of Pub. L. 105–33, 111 Stat. 730 and 756, as amended by Pub. L. 105–277, 112 Stat. 2681–530 through 538.

2. In § 29.102, paragraph (a) is revised as follows:

§ 29.102 Related regulations.

(a) This part contains the following subparts:

- (1) General Provisions (Subpart A);
- (2) Coordination With the District Government (Subpart B);
- (3) Split Benefits (Subpart C); and
- (4) Claims and Appeals Procedures (Subpart D).

* * * * *

3. In § 29.203, paragraph (b) is revised to read as follows:

§ 29.203 Service of Process.

* * * * *

(b) All other process regarding Federal Benefit Payments (including requests for judicial review under § 29.406) must be served upon the United States in accordance with applicable law.

* * * * *

4. Subpart D is added to read as follows:

Subpart D—Claims and Appeals Procedures

Sec.

29.401 Purpose.

29.402 Definitions.

29.403 Applications filed with the Benefits Administrator.

29.404 Initial benefit determinations and reconsideration by the Benefits Administrator.

29.405 Appeals to the Department.

29.406 Judicial review.

29.407 Competing claimants.

§ 29.401 Purpose.

(a) This subpart explains—

(1) The procedures that participants and beneficiaries in the Judges Plan, Police and Firefighters Plan, and the Teachers Plan must follow in applying for Federal Benefit Payments;

(2) The procedures for determining an individual's eligibility for a Federal Benefit Payment and the amount and form of an individual's Federal Benefit Payment as required by section 11021 of the Act and section 11–1570 of the D.C. Code;

(3) The appeal rights available under section 11022(a) of the Act to claimants whose claim for Federal Benefit Payments is denied in whole or in part; and

(4) The special rules for processing competing claimant cases.

(b) This subpart does not apply to processing collection of debts due to the United States.

§ 29.402 Definitions.

In this subpart—

Act means the Balanced Budget Act of 1997, Public Law 105–33, 111 Stat. 251, 712–731, 756–759, enacted August 5, 1997, as amended by the Omnibus Consolidated and Emergency

Supplemental Appropriations Act for Fiscal Year 1999, Public Law 105-277, 112 Stat. 2681, 2681-530 through 538, 2681-552.

Beneficiary means an individual designated by a participant, or by the terms of the Judges Plan, Police and Firefighters Plan, or Teachers Plan, who is or may become entitled to a benefit under those plans.

Benefits Administrator means:

(1) During the interim administration period under section 11041 of the Act, the District of Columbia government, or

(2) After the Secretary notifies the District that the Trustee has been directed to carry out the duties and responsibilities required under the contract or determines that the Department shall carry out those functions, the Department, the Trustee selected by the Department under section 11035 of the Act, or any other agent of the Department designated to make initial benefit determinations under the Act.

Claimant means any person seeking a benefit for themselves or another under the Judges Plan, Police and Firefighters Plan, or Teachers Plan.

Department means the Secretary of the Treasury or a designee authorized to exercise the Secretary's authority with respect to Federal Benefit Payments under the Act.

Participant means an individual who is or may become eligible to receive a benefit under the Police and Firefighters Plan or the Teachers Plan based on credit for service accrued as of June 30, 1997, or under the Judges Plan, or whose beneficiaries may be eligible to receive any such benefit.

§ 29.403 Applications filed with the Benefits Administrator.

All claimants for Federal Benefit Payments must file applications for benefits (including applications for retirement, refunds of contributions, and death benefits) with the Benefits Administrator.

§ 29.404 Initial benefit determinations and reconsideration by the Benefits Administrator.

(a) *Initial benefit determinations.* The Benefits Administrator will process applications for Federal Benefit Payments and determine the eligibility for and the amount and form of Federal Benefit Payments. All initial benefit determination decisions which may reasonably be construed as a denial (in whole or part) of a claim for Federal Benefit Payments must be in writing, must advise claimants of their right to request reconsideration under paragraph (b), of this section and must state the time limits applicable to such a request.

(b) *Claimant's right to reconsideration of benefit denials.* (1) Except as provided in paragraph (b)(2) of this section, claimants who disagree with the amount or form of a Federal Benefit Payment determination and wish to contest the determination must first request the Benefits Administrator to reconsider its determination.

(2) A decision to collect a debt is not a denial of a benefit claim under this section.

(c) *Form and timing of requests for reconsideration.* (1) A request for reconsideration must be in writing, must include the claimant's name, address, date of birth and claim number, if applicable, and must state the basis for the request.

(2) A request for reconsideration must be received by the Benefits Administrator within 30 calendar days from the date of the written notice of the initial benefit determination.

(d) *Reconsideration decisions.* A reconsideration decision by the Benefits Administrator denying (in whole or part) a claim for a Federal Benefit Payment must—

(1) Be in writing;

(2) Provide adequate notice of such denial, setting forth the specific reason for the denial in a manner calculated to be understood by the average participant; and

(3) Provide notice of the right to appeal the Benefit Administrator's decision to the Department, the address to which such an appeal must be submitted, and the time limits applicable to such an appeal.

(e) *Appeal of reconsideration decisions.* The Department will review an appeal of a reconsideration decision under § 29.405.

§ 29.405 Appeals to the Department.

(a) *Who may file.* Any claimant whose claim for a Federal Benefit Payment has been denied (in whole or part) by the Benefits Administrator in a reconsideration decision under § 29.404(d) may appeal that decision to the Department.

(b) *Form of appeal.* An appeal must be in writing, must include the claimant's name, address, date of birth and claim number, if applicable, and must state the basis for the appeal.

(c) *Time limits on Appeals.* (1) An appeal must be received by the Department within 30 calendar days from the date of the reconsideration decision under § 29.404(d).

(2) The Department may extend the time limit for filing when the claimant shows that he or she was not notified of the time limit and was not otherwise aware of it, or that he or she was

prevented by circumstances beyond his or her control from making the request within the time limit, or for other good and sufficient reason.

(d) *Final decision.* After consideration of the appeal, the Department will issue a final decision. The Department's decision must be in writing, must fully set forth the Department's findings and conclusions on the appeal, and must contain notice of the right to judicial review provided in § 29.406. Copies of the final decision must be sent to the claimant seeking appeal, to any competing claimants (see § 29.407) and to the Benefits Administrator.

§ 29.406 Judicial review.

An individual whose claim for a Federal Benefit Payment has been denied (in whole or part) in a final decision by the Department under § 29.405 may, within 180 days of the date of the final decision, file a civil action in the United States District Court for the District of Columbia. Any such civil action must be filed in accordance with the rules of that court.

§ 29.407 Competing claimants.

(a) *Competing claimants* are applicants for survivor benefits based on the service of a participant when—

(1) A benefit is payable based on the service of the participant;

(2) Two or more claimants have applied for benefits based on the service of the participant; and

(3) A decision in favor of one claimant will adversely affect another claimant(s).

(b)(1) When a competing claimant files a request for reconsideration under this section, the other competing claimants shall be notified of the request and given an opportunity to submit written substantiation of their claim.

(2) When the Benefits Administrator receives an application from a competing claimant(s) before any payments are made based upon the service of the participant, and an initial determination of benefits in favor of one claimant adversely affects another claimant, all known claimants concerned will be notified in writing of that decision and those adversely affected will be given an opportunity to request reconsideration under the procedures and time limitations set forth in § 29.404(c). The Benefits Administrator must not execute its decision until the time limit for filing a request for reconsideration has expired, or, if a reconsideration decision is made, until the time limit for filing an appeal to the Department has expired or the Department has issued a final decision on a timely appeal, whichever is later.

(3) When the Benefits Administrator does not receive an application from a competing claimant(s) until after another person has begun to receive payments based upon the service of the participant, the payments will continue until the time limit for filing a request for reconsideration has expired, or, if a reconsideration decision is made, until the time limit for filing an appeal to the Department has expired or the Department has issued a final decision on a timely appeal, whichever is later.

[FR Doc. 00-32722 Filed 12-21-00; 8:45 am]

BILLING CODE 4810-25-P

DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

37 CFR Part 1

RIN 0651-AA98

Changes to Implement the Patent Business Goals

AGENCY: United States Patent and Trademark Office, Commerce.

ACTION: Final rule; correction.

SUMMARY: The United States Patent and Trademark Office (Office) published a final rule in the **Federal Register** of September 8, 2000, revising the rules of practice in patent cases to implement the Patent Business Goals. The Office also published a correction notice in the **Federal Register** of December 18, 2000, correcting errors in the final rule. This document corrects an error in the correction notice and makes the correction retroactive to December 18, 2000.

EFFECTIVE DATE: December 18, 2000.

FOR FURTHER INFORMATION CONTACT: Hiram H. Bernstein ((703) 305-8713), Senior Legal Advisor, or Robert J. Spar, Director ((703) 308-5107), Office of Patent Legal Administration (OPLA), directly by phone, or by facsimile to (703) 305-1013, marked to the attention of Mr. Bernstein, or by mail addressed to: Box Comments—Patents, Commissioner for Patents, Washington, D.C. 20231.

SUPPLEMENTARY INFORMATION: The Office published a final rule in the **Federal Register** of September 8, 2000 (65 FR 54604), entitled "Changes to Implement Patent Business Goals," and a correction notice in the **Federal Register** of December 18, 2000 (65 FR 78958) correcting errors in the final rule. The correction notice inadvertently indicated that the processing fee for

correcting inventorship in a patent under 37 CFR 1.324 is \$55.00. The processing fee for correcting inventorship in a patent under § 1.324 is actually \$130.00.

In rule FR Doc. 00-31958, published on December 18, 2000 (65 FR 78958), and in 37 CFR Part 1 make the following corrections:

§ 1.20 [Corrected]

1. On page 78960, in the first column, § 1.20, paragraph (b), line 3, correct "\$55.00" to read "\$130.00".

Dated: December 19, 2000.

Albin F. Drost,

Acting General Counsel.

[FR Doc. 00-32773 Filed 12-21-00; 8:45 am]

BILLING CODE 3510-16-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 9 and 63

[AD-FRL-6917-1]

RIN 2060-AH74

National Emission Standards for Hazardous Air Pollutants from the Pulp and Paper Industry

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule; amendments.

SUMMARY: On January 25, 2000 (65 FR 3907), we proposed amendments to the pulp and paper national emission standards for hazardous air pollutants (NESHAP) (63 FR 18504, April 15, 1998). The 1998 Pulp and Paper NESHAP is the air component of the integrated air and water rules for the pulp and paper industry (known as the Pulp and Paper Cluster Rules). The NESHAP limit and control hazardous air pollutants (HAP) that are known to cause or suspected to cause cancer or other serious health or environmental effects. These final amendments include changes to the pulping process vent standards, the biological treatment system standards, monitoring requirements, and test methods and procedures to address technical issues identified after promulgation of the 1998 Pulp and Paper NESHAP. Also, drafting errors in the final rule that were identified since proposal of these amendments are being corrected by this action. These amendments do not change the level of control or compromise the environmental protection achieved by the 1998 Pulp and Paper NESHAP. This action also clarifies that downtime due to routine

maintenance of pulping process vent control devices is included in the excess emissions allowances. Lastly, in compliance with the Paperwork Reduction Act (PRA), we are amending as a final rule the Office of Management and Budget (OMB) approval table to list the OMB control number issued under the PRA for information collection requirements for the 1998 Pulp and Paper NESHAP.

EFFECTIVE DATE: February 20, 2001.

ADDRESSES: Docket No. A-92-40 contains supporting information for this action and the prior promulgated and proposed amendments to the 1998 Pulp and Paper NESHAP. The docket is located at the U.S. EPA, Air and Radiation Docket and Information Center (6102), 401 M Street SW, Washington, DC 20460, in Room M-1500, Waterside Mall (ground floor), and is available for inspection and copying between 8 a.m. and 5:30 p.m., Monday through Friday except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Mr. Stephen Shedd, Emission Standards Division (MD-13), U.S. EPA, Research Triangle Park, NC 27711; telephone (919) 541-5397, e-mail shedd.steve@epa.gov. For questions on compliance and applicability determinations, contact Mr. Seth Heminway, Office of Enforcement and Compliance Assessment (2223A), U.S. EPA, 1200 Pennsylvania Avenue NW, Washington, DC 20460; telephone (202) 564-7017, e-mail heminway.seth@epa.gov.

SUPPLEMENTARY INFORMATION: *Docket.* The docket is an organized and complete file of all the information considered by the EPA in the development of this rulemaking. The docket is a dynamic file because material is added throughout the rulemaking process. The docketing system is intended to allow members of the public and industries involved to readily identify and locate documents so that they can effectively participate in the rulemaking process. Along with the proposed and promulgated standards and their preambles, the contents of the docket will serve as the record in the case of judicial review. (See section 307(d)(7)(A) of the Clean Air Act (CAA).) The regulatory text and other materials related to this rulemaking are available for review in the docket, or copies may be mailed on request from the Air Docket by calling (202) 260-7548. A reasonable fee may be charged for copying docket materials. *World Wide Web (WWW).* In addition to being available in the docket, an electronic copy of today's amendments

will be available on the WWW through the Technology Transfer Network (TTN). Following signature, we will post a copy of these amendments on the TTN's policy and guidance page for newly proposed or promulgated rules <http://www.epa.gov/ttn/oarpg>. The TTN provides information and technology exchange in various areas of air pollution control. Also, a separate page on the TTN provides all the proposal and promulgation notices, support documents, and implementation

information for the 1998 Pulp and Paper NESHAP <http://www.epa.gov/ttn/uatw/pulp/pulppg.html>. If you need more information regarding the TTN, call the TTN HELP line at (919) 541-5384.

Judicial Review. The EPA proposed these amendments to the 1998 Pulp and Paper NESHAP on January 25, 2000 (65 FR 3907). This final rule adopting the amendments constitutes final administrative action concerning that proposal. Under section 307(b)(1) of the CAA, judicial review of final rules is

available only by filing a petition for review in the U.S. Court of Appeals for the District of Columbia Circuit by February 20, 2001. Under section 307(b)(2) of the CAA, the requirements established by today's final rule may not be challenged later in civil or criminal proceeding brought by the EPA to enforce these requirements.

Regulated Entities. Entities potentially regulated by this action include:

Category	SIC	NAICS	Examples of regulated entities
Industry	26	3221	Pulp mills and integrated mills (mills that manufacture pulp and paper/paperboard) that chemically pulp wood fiber.

This list is not intended to be exhaustive. It provides a guide regarding the types of entities that we expect to regulate by this action. To determine whether this action would regulate your facility, you must carefully examine the applicability criteria in § 63.440 of the final rule. If you have questions regarding the applicability of this action to a particular situation or questions about compliance approaches, permitting, enforcement, and rule determinations, please contact the local or State air pollution control agency who has permitting authority for your facility. If you are unsure of who has the permitting authority or need additional assistance, you should contact the appropriate EPA regional office below.

Region I: U.S. EPA New England
Director, Air Compliance Program,
1 Congress Street, Suite 1100 (SEA),
Boston, MA 02114-2023, Phone:
(617) 918-1650, Fax: (617) 918-
1505

**Region II: U.S. EPA—Region 2, Air
Compliance Branch, 290 Broadway,
New York, NY 10007, Phone: (212)
637-4080, Fax: (212) 637-3998**

**Region III: U.S. EPA—Region 3, Chief,
Air Enforcement Branch (3AP12),
1650 Arch Street, Philadelphia, PA
19103-2029, Phone: (215) 814-
3438, Fax: (215) 814-2134, Region 3
Office Website: [http://
www.epa.gov/reg3artd/hazpollut/
hazairpol.htm](http://www.epa.gov/reg3artd/hazpollut/hazairpol.htm)**

**Region IV: U.S. EPA—Region 4, Air and
Radiation Technology Branch,
Atlanta Federal Center, 61 Forsyth
Street, Atlanta, Georgia 30303-
3104, Phone: (404) 562-9105, Fax:
(404) 562-9095**

**Region V: U.S. EPA—Region 5, Air
Enforcement and Compliance
Assurance Branch (AE-17)), 77
West Jackson Boulevard, Chicago,
IL 60604-3590, Phone: (312) 353-
2088, Fax: (312) 353-8289**

**Region VI: U.S. EPA—Region 6, Chief,
Toxics Enforcement Section (6EN-
AT), 1445 Ross Avenue, Dallas, TX
75202-2733, Phone: (214) 665-
7224, Fax: (214) 665-7446, Region 6
Office Website: [www.epa.gov/
region6](http://www.epa.gov/region6)**

**Region VII: U.S. EPA—Region 7, 901 N.
5th Street, Kansas City, KS 66101,
Phone: (913) 551-7020, Fax: (913)
551-7844, Office Website: [http://
www.epa.gov/region07/programs/
artd/air/toxics/airtox1.htm](http://www.epa.gov/region07/programs/artd/air/toxics/airtox1.htm).**

**Region VIII: U.S. EPA—Region 8, Air
Enforcement Program (8ENF-T),
999 18th Street, Suite 500, Denver,
CO 80202, Phone: (303) 312-6312,
Fax: (303) 312-6409**

**Region IX: U.S. EPA—Region 9, Air
Division, 75 Hawthorne Street, San
Francisco, CA 94105, Phone: (415)
744-1219, Fax: (415) 744-1076**

**Region X: U.S. EPA—Region 10, Office
of Air Quality (OAQ-107), 1200
Sixth Avenue, Seattle, WA 98101,
Phone: (206) 553-4273, Fax: (206)
553-0110**

Outline. The information presented in
this preamble is organized as follows:

- I. Background
- II. Summary of the Final Amendments
- III. Summary of Public Comments,
Responses, and Changes to the Standards
- IV. Information Collection Request (ICR)
- V. Administrative Requirements
 - A. Executive Order 12866, Regulatory
Planning and Review
 - B. Executive Order 13132, Federalism
 - C. Executive Order 13084, Consultations
and Coordination with Indian Tribal
Governments
 - D. Executive Order 13045, Protection of
Children from Environmental Health
Risks and Safety Risks
 - E. Unfunded Mandates Reform Act of 1995
 - F. Regulatory Flexibility Act (RFA) as
amended by the Small Business
Regulatory Enforcement Fairness Act of
1996 (SBREFA), 5 U.S.C. 601 *et seq.*
 - G. Paperwork Reduction Act

- H. National Technology Transfer and
Advancement Act
- I. Congressional Review Act

I. Background

The EPA promulgated the 1998 Pulp and Paper NESHAP on April 15, 1998 (63 FR 18504), with subsequent amendments for corrections, clarifications, and to provide technical amendments.

On January 25, 2000 (65 FR 3907), we proposed amendments to the 1998 Pulp and Paper NESHAP to revise the compliance demonstration procedures for combustion devices used to control pulping vent gases and for biological treatment systems used to treat pulping condensates, and to correct minor drafting errors. The proposed amendment regarding the pulping vent combustion devices removed the requirement, in some cases, to conduct an initial performance test or to continuously monitor the temperature of the control device. Briefly, the proposed amendments for biological treatment systems: Added an alternative emission standard (minimum HAP or methanol mass removal), specified a finite list of HAP (instead of total HAP) for use in demonstrating compliance, allowed for determination of site-specific monitoring parameters, and added testing and monitoring procedures for biological treatment systems that do not meet the criteria for a "thoroughly mixed" system.

In response to the January 25, 2000 proposed amendments, we received four public comment letters from industry representatives. In developing today's final rule amendments, we considered public comment where appropriate, and we are revising the compliance demonstration procedures for combustion devices used to control pulping vent gases; revising the standards, monitoring requirements,

and test methods and procedures for biological treatment systems; and correcting minor drafting errors. We are also specifying that downtime due to routine maintenance of pulping process vent control devices is included in the excess emissions allowances. Although maintenance downtime was not part of the January 25, 2000 proposed amendments, we are using this notice to clarify our intent.

II. Summary of the Final Amendments

In today's final rule, we are promulgating the following amendments to the 1998 Pulp and Paper NESHAP and clarifying the downtime provision for pulping vent control devices. We are amending:

- The standards for the pulping system at kraft, soda, and semi-chemical processes (§ 63.443(d)(4)) to remove the requirement, in some cases, to conduct an initial performance test or to continuously monitor the temperature of the pulping vent control device.
- The standards for kraft pulping process condensates to add mass emissions standards for biological treatment provisions (§ 63.446(e)(2)) and to refer to the procedure for measuring total HAP in § 63.457(g).
- The standards for kraft pulping process condensates (§ 63.446(i)) to add a reference to the minimum mass condensate collection option (§ 63.446(c)(3)) and to correct a minor drafting error.
- The open biological treatment system monitoring requirements (§ 63.453(j)) to allow for site-specific monitoring parameters and to clarify the quarterly performance test procedures.
- The monitoring requirements section (§ 63.453(n)) to include the reference to the site-specific biological treatment system monitoring parameters and to correct a minor drafting error.
- The open biological treatment system monitoring requirements (§ 63.453(p)) to revise the procedures for conducting the optional performance tests and clarify the timing of corrective actions taken during monitoring parameter excursions.
- § 63.454 to address recordkeeping requirements for documenting unsafe sampling conditions and the results of optional performance tests conducted in response to monitoring parameter excursions, and add corresponding reference.
- The reporting requirements section (§ 63.455(e)) to add performance testing notification requirements to be used if open biological treatment system performance test results are used to revise approved monitoring values or ranges.

- The test methods and procedures section (§ 63.457(c)(1)) to correct the reference to the liquid sampling procedures.

- The test methods and procedures section (§ 63.457(c)(4)) to add the word "open" before "biological treatment system."

- The test methods and procedures section (§ 63.457(c)(5) and (6)) to specify the procedures for determining the minimum measurement level of HAP for a given test method.

- The test methods and procedures section (§ 63.457(g)) to specify the measurement of only four HAP for biological treatment systems.

- The test methods and procedures for open biological treatment systems (§ 63.457(l)) to remove the total HAP percent reduction procedure, to add the methanol percent reduction and mass removal procedures, to add an equation for determining the ratio of nonmethanol HAP to methanol, to add clarity to the purpose of the requirements, and to correct minor drafting errors.

- The test methods and procedures for open biological treatment systems (§ 63.457(m)) to correct references.

- The test methods and procedures for open biological treatment systems (§ 63.457(n)) to add the word "open" to the paragraph title and to correct minor drafting errors.

- The delegation of authority section (§ 63.458(b)(5)) to add a reference to the procedure for determining the minimum measurement level of HAP.

- To add monitoring procedures (appendix E) for biological treatment systems when more detailed sampling is unsafe.

- The table in part 9 that includes the currently approved information request control numbers to add the 1998 Pulp and Paper NESHAP information collection requirements.

III. Summary of Public Comments, Responses, and Changes to the Standards

Generally, the comments were supportive of the proposed amendments, and we have not summarized those positive comments. We received no adverse comments regarding the proposed amendment for pulping vent combustion devices; therefore, the amendment is being promulgated as proposed. Below is an overview of the major issues raised by commenters and our responses. A complete summary of major comments and responses is available in the docket and on the WWW. The **ADDRESSES** and **SUPPLEMENTARY INFORMATION** sections of

this preamble contain detailed information on the docket and WWW.

The major public comments we received suggested changes and clarifications to the proposed amendments for the standards, monitoring requirements, and test methods for biological treatment systems.

Individual HAP procedure. We proposed a procedure (the "individual HAP procedure") that can be used to demonstrate compliance of biological treatment systems on an individual HAP basis (either percent reduction or mass removal). The procedure was proposed as an alternative to demonstrating compliance by measuring total HAP. To use the procedure, you must measure the mass of the individual HAP entering and exiting the biological treatment system.

The comments stated that the proposed procedure is not viable because the outlet concentrations of the nonmethanol HAP will be below the detection limit of the test methods specified in the 1998 Pulp and Paper NESHAP. We agree with the commenter that the proposed individual HAP procedure is not viable due to lack of adequate test methods. Therefore, we are withdrawing the proposed individual HAP procedure and its associated test methods (§ 63.446(e)(2)(i) and § 63.457(l)(1) and (2) of the proposed amendments).

Minimum measurement level procedure. We proposed amendments to the test methods and procedures section (§ 63.457(c)) that added two alternative procedures for determining the minimum measurement level (MML) of specific HAP in pulping process condensate streams. The comments received stated that several clarifications and corrections to the proposed procedures were needed. We agree with the suggested clarifications and corrections, and we have revised the 1998 Pulp and Paper NESHAP accordingly.

Methanol procedure for biological treatment systems. We proposed a procedure (the "methanol procedure") that can be used as an alternative to demonstrating compliance of biological treatment systems on an individual HAP basis. As part of the methanol procedure, you are required to measure the ratio of nonmethanol HAP (acetaldehyde, methyl ethyl ketone, and propionaldehyde) mass to methanol mass. The value of this ratio is designated in the proposed amendments as "r." The 1998 Pulp and Paper NESHAP require total HAP measurements on a quarterly basis. We requested comments and data to

determine if quarterly testing for total HAP is still warranted, or if testing for total HAP annually is adequate.

The comments received stated that an annual measurement of "r" is sufficient since the value of "r" is very low and the corresponding impact on the mass removal determinations will be small. We agree with the commenter that an annual measurement of "r" is sufficient. Therefore, we are revising the biological treatment system monitoring requirements (§ 63.453(j)(3)(ii)) to specify that the value of "r" must be determined only during the first-quarter test of each year.

Quarterly performance tests versus initial performance tests. We proposed adding a mass removal option for biological treatment systems in addition to the percent reduction standard already contained in the 1998 Pulp and Paper NESHAP. We also proposed to amend the quarterly testing and compliance monitoring requirements to make conforming revisions by replacing the term "percent reduction tests" with "performance test" or "compliance test."

The comments received stated that the EPA should clarify that the requirements for the quarterly tests are less extensive than for the initial performance test since the quarterly tests are part of the monitoring requirements. We disagree with the comments, and we are making text changes to the quarterly testing requirements and the reporting requirements to use consistent language.

Condensate variability. We received several comments stating that the performance test and continuous monitoring procedures for the condensate collection and treatment requirements should account for inherent hour-to-hour and day-to-day variability in the amount of methanol generated in the regulated condensates. Based on the data being collected for industry condensate characterization studies, the comments stated that there is significant variability over all time scales, and the causes of methanol variability are beyond the control of the mill operator. Consequently, there is a chance that the amount of methanol collected and sent to treatment on a short-term basis can be less than that required by the standards and can lead to noncompliance, even though the pulping processes and controls are operating normally.

We agree that condensate variability is a concern in both the initial and continuous compliance demonstrations. Variability is particularly a concern for the mass removal option where compliance is based on an amount of

mass collected and the performance of the control device or system.

Some comments recommended that because of the variability of methanol in condensate streams, the rule should be revised to clarify that long-term averages are necessary for demonstrating initial and continuous compliance with the condensate collection standards. While we agree that variability should be considered in establishing appropriate averaging periods, the 1998 Pulp and Paper NESHAP already provide you with flexibility in establishing the appropriate averaging periods for demonstrating initial compliance and conducting continuous compliance monitoring. Consequently, we are not changing the 1998 Pulp and Paper NESHAP text to address this issue.

We proposed mass removal standards, expressed as either individual HAP or methanol, for biological treatment systems as an alternative to the percent reduction standards. Compliance with a mass removal standard requires that the inlet HAP (methanol) mass and the performance of the treatment device be measured over the same time period. The comments recommended that the rule be revised to consider variability of inlet mass concentrations during performance tests of condensate treatment devices (i.e., steam strippers and biological treatment systems). To address short-term variability in condensates on the day the performance test is conducted, these comments recommended that the mass in condensates be based on long-term averages established prior to the date of the test.

We disagree with the comments that the mass in condensates be based on data established prior to the date of the treatment system performance test. The performance test for the treatment standard must be based on actual test data of the inlet HAP (or methanol) mass and the treatment device performance on the same time basis. However, we agree with the comments that the proposed rule amendments did not adequately account for variability during optional tests to confirm the performance of biological treatment systems during parameter excursions. Today's final rule amendments, therefore, provide some additional flexibility in conducting these tests.

Procedures for responding to parameter excursions in biological treatment systems. We proposed a modeling procedure (appendix E of 40 CFR part 63) to use during unsafe sampling conditions. The procedure would be used whenever a parameter excursion occurs during an event when it is too dangerous, hazardous, or

otherwise unsafe for personnel to collect samples from an open nonthoroughly mixed biological treatment system. The procedure would be used to satisfy the daily monitoring requirements until such time as a full performance test can be conducted under safe conditions.

The comments received stated that a conflict exists between the timing of the modeling procedure and the subsequent performance test, and on initiating steps to end the parameter excursion. We are revising the monitoring requirements of the rule to clarify the timing of the modeling procedure, the performance test, and implementation of corrective actions; however, the intent of the 1998 Pulp and Paper NESHAP remains unchanged since we believe that there is no conflict in this rule requirement.

Monitoring procedures for biological treatment systems during unsafe conditions. We proposed a modeling procedure (appendix E of 40 CFR part 63) for monitoring open biological treatment systems that can be used when unsafe conditions exist in the system that would prevent personnel from conducting the sampling necessary to conduct a full performance test. The comments suggested several clarifications and corrections to the proposed modeling procedure. We agree that clarifications are needed in some of the cases identified by the commenter, and these clarifications have been added.

Performance test notifications. We proposed that the notification period for certain compliance monitoring testing be reduced from 60 days, as required by the 1998 Pulp and Paper NESHAP general provisions (§ 63.7(b)), to 15 days. This shortened notification period would be used if a mill intends to revise the allowable monitoring parameter ranges or values using data recorded during any valid subsequent performance tests required in the monitoring requirements section of the 1998 Pulp and Paper NESHAP. We received comments stating that the 15-day period was too long, and that same day notification should be allowed. We disagree with the comments, and we believe the length of the notification period (15 days) is appropriate. Consequently, the 15-day notification change is being made to the 1998 Pulp and Paper NESHAP as proposed.

Drafting errors and clarifications. We proposed several corrections to minor drafting errors identified following promulgation of the 1998 Pulp and Paper NESHAP. No comments were received regarding those proposed corrections. Therefore, the amendments for the corrections and minor drafting errors are being published as proposed.

However, below are some additional corrections found since these amendments were proposed on January 25, 2000.

In the April 12, 1999 final rule interpretation and technical amendments, we inserted a new test procedure into the middle of a list of other procedures. One of those other procedures is cross referenced in another section of the rule, and we did not change the cross reference text. In today's final rule amendments, we are correcting that error by changing the cross referenced procedure text in § 63.458(b)(4), from § 63.457(c)(3)(ii) to its new location in § 63.457(c)(3)(iii). Additionally, commenters identified a drafting error in the original rule text published on April 15, 1998. We are correcting the error by changing the cross referenced text in the standards for condensate closed collection systems (§ 63.446(d)(1)), from § 63.962(b)(3)(ii)(B)(5)(iii) to its correct location in § 63.962(b)(5)(iii).

In the January 25, 2000 proposed amendments notice, we proposed several amendments to the standards (§ 63.446(e)(2)), monitoring requirements (§ 63.453(j)), and test methods and procedures (§ 63.457(l)) used for biological treatment system. These proposed amendments allow you to comply with a percent reduction or mass removal standard using individual HAP or using methanol under certain conditions. In these proposed amendments, the following drafting errors and corrections were identified by commenters:

- The quarterly testing requirements in § 63.453(j)(3)(i) contain incorrect language from the 1998 Pulp and Paper NESHAP and references to the condensate standards,
- An incorrect variable was used in the proposed amendments (§ 63.457(l)) to the test methods and procedures section, and
- The definition of "r" (the ratio of nonmethanol HAP to methanol) and the equation to determine "r" was not included in the proposed amendments (§ 63.457(l)(3) and

(4) to the test methods and procedures section. We agree with each of the drafting errors identified by the commenters, and we are revising the rule accordingly.

Control device downtime due to scheduled maintenance. In today's final rule amendments, we are clarifying that downtime associated with routine maintenance of control devices used to reduce emissions of HAP from pulping process vents is included in the excess emissions allowances. Following promulgation of the 1998 Pulp and

Paper NESHAP, we received comments stating that routine maintenance of control devices should be included in the excess emission allowances, since this category of outages is not covered under the startup, shutdown, and malfunction provisions.

In the 1998 Pulp and Paper NESHAP, the excess emission allowances include periods when the control device is inoperable and when the operating parameter values established during the initial performance test cannot be maintained at the appropriate level. However, in the promulgation preamble (63 FR 18529–18530), we specifically stated that excess emission allowances did not include scheduled maintenance activities. When the 1998 Pulp and Paper NESHAP was promulgated, the EPA was considering revisions to the NESHAP general provisions that would address downtime associated with scheduled maintenance. Those revisions have not been made. Therefore, in today's final rule amendments, we are clarifying that excess emission allowances for pulping vent control devices (§ 63.443(e)) can include downtime due to scheduled maintenance activities.

IV. Information Collection Request (ICR)

This final rule amends the table of currently approved ICR control numbers issued by OMB. This final rule updates the table to list those 1998 Pulp and Paper NESHAP information requirements promulgated in 1998. We will continue to present OMB control numbers in a consolidated table format to be codified in 40 CFR part 9 of the Agency's regulations and in each CFR volume containing EPA regulations. The table lists the section numbers with reporting and recordkeeping requirements and the current OMB control numbers. This listing of the OMB control numbers and their subsequent codification in the CFR satisfy the requirements of the Paperwork Reduction Act and OMB's implementing regulations at 5 CFR part 1320. The ICR itself was subject to public notice and comment prior to OMB's approval of the ICR. Further, because amendment of the table in part 9 is technical in nature, we believe that another notice and comment period for this amendment is unnecessary. For these reasons, we believe that there is good cause under the Administrative Procedure Act (5 U.S.C. 553(b) to amend this table without prior notice and comment.

V. Administrative Requirements

A. Executive Order 12866, Regulatory Planning and Review

Under Executive Order 12866 (58 FR 51375, October 4, 1993), the EPA must determine whether a regulatory action is "significant" and, therefore, subject to review by the Office of Management and Budget (OMB) and the requirements of the Executive Order. The Executive Order defines "significant regulatory action" as one that is likely to lead to a rule that may:

- (1) Have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, completion, jobs, the environment, public health or safety, or State, local, or tribal governments or communities;
- (2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;
- (3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs, or the rights and obligations of recipients thereof; or
- (4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

The 1998 Pulp and Paper NESHAP was considered a "significant regulatory action" under Executive Order 12866. Accordingly, EPA prepared a regulatory impact analysis. These final rule amendments make technical revisions and correct inadvertent drafting errors. The OMB evaluated this action and determined it to be nonsignificant; thus, it did not require OMB review.

B. Executive Order 13132, Federalism

Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999), requires the EPA to develop an accountable process to ensure "meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications." "Policies that have federalism implications" is defined in the Executive Order to include regulations that have "substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government."

Under Section 6 of Executive Order 13132, the EPA may not issue a regulation that has federalism implications, that imposes substantial direct compliance costs, and that is not required by statute, unless the Federal government provides the funds necessary to pay the direct compliance

costs incurred by State and local governments, or the EPA consults with State and local officials early in the process of developing the proposed regulation. The EPA also may not issue a regulation that has federalism implications and that preempts State law unless the EPA consults with State and local officials early in the process of developing the proposed regulation.

If EPA complies by consulting, Executive Order 13132 requires EPA to provide to the OMB, in a separately identified section of the preamble to the rule, a federalism summary impact statement (FSIS). The FSIS must include a description of the extent of EPA's prior consultation with State and local officials, a summary of the nature of their concerns and the EPA's position supporting the need to issue the regulation, and a statement of the extent to which the concerns of State and local officials have been met. Also, when EPA transmits a draft rule with federalism implications to OMB for review pursuant to Executive Order 12866, EPA must include a certification from the agency's Federalism Official stating that EPA has met the requirements of Executive Order 13132 in a meaningful and timely manner.

These final amendments to the 1998 Pulp and Paper NESHAP will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132. While the 1998 Pulp and Paper NESHAP do not create mandates upon State, local, or tribal governments, EPA involved State and local air pollution control agencies in its development. Today's action does not create a mandate upon State, local, or tribal governments. Thus, the requirements of section 6 of the Executive Order do not apply to this rule.

C. Executive Order 13084, Consultations and Coordination with Indian Tribal Governments

Under Executive Order 13084, the EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments, or if EPA consults with those governments. If EPA complies by consulting, Executive Order 13084

requires EPA to provide to OMB, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected officials and other representatives of Indian tribal governments "to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities."

Today's final rule amendments do not significantly or uniquely affect the communities of Indian tribal governments. The 1998 Pulp and Paper NESHAP do not create mandates upon tribal governments. These amendments do not create a mandate on tribal governments. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply.

D. Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks

Executive Order 13045 (62 FR 19885, April 23, 1997) applies to any rule that: (1) is determined to be "economically significant" as defined under Executive Order 12866, and (2) concerns an environmental health or safety risk that the EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the EPA must evaluate the environmental health or safety effects of the rule on children and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the EPA.

The EPA interprets Executive Order 13045 as applying only to those regulatory actions that are based on health or safety risks, such that the analysis required under section 5-501 of the Executive Order has the potential to influence the regulation. The 1998 Pulp and Paper NESHAP fall into that category only in part: the minimum rule stringency is set according to a congressionally mandated, technology-based lower limit called the "floor," while a decision to increase the stringency beyond this floor can be partly based on risk considerations.

No children's risk analysis was performed for the 1998 Pulp and Paper NESHAP rulemaking because no alternative technologies exist that would provide greater stringency at a reasonable cost, and, therefore, the results of any such analysis would have

no impact on the stringency decision. Today's final rule amendments are not subject to Executive Order 13045 because they do not involve decisions on environmental health risks or safety risks that may disproportionately affect children.

E. Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104-4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments and the private sector. Under section 202 of the UMRA, the EPA generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with "Federal mandates" that may result in expenditures to State, local, and tribal governments, in the aggregate, or to the private sector, of \$100 million or more in any 1 year.

Before promulgating an EPA rule for which a written statement is needed, section 205 of the UMRA generally requires the EPA to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, most cost-effective, or least burdensome alternative that achieves the objectives of the rule. The provisions of section 205 do not apply when they are inconsistent with applicable law. Moreover, section 205 allows the EPA to adopt an alternative other than the least costly, most cost-effective, or least burdensome alternative if the Administrator publishes with the final rule an explanation of why that alternative was not adopted.

Before the EPA establishes any regulatory requirements that may significantly or uniquely affect small governments, including tribal governments, it must have developed under section 203 of the UMRA a small government agency plan. The plan must provide for notifying potentially affected small governments, enabling officials of affected small governments to have meaningful and timely input in the development of EPA regulatory proposals with significant Federal intergovernmental mandates, and informing, educating, and advising small governments on compliance with the regulatory requirements.

The EPA has determined that today's final rule amendments do not contain a Federal mandate that may result in expenditures of \$100 million or more to either State, local, or tribal governments, in the aggregate, or to the private sector in any 1 year. These amendments provide additional flexibility to the

1998 Pulp and Paper NESHAP and reduce compliance costs. Therefore, these amendments are not subject to the requirements of sections 202 and 205 of the UMRA.

F. Regulatory Flexibility Act (RFA) as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA) 5 U.S.C. 601 et seq.

The RFA generally requires an agency to conduct a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act or any other statute unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small organizations, and small governmental jurisdictions.

The EPA determined that it is not necessary to prepare a regulatory flexibility analysis in connection with today's final rule amendments. These amendments will not result in increased impacts to small entities, but will provide additional flexibility to the 1998 Pulp and Paper NESHAP by adding equivalent treatment alternatives.

G. Paperwork Reduction Act

The EPA submitted the information requirements of the 1998 Pulp and Paper NESHAP for approval to the OMB on April 27, 1998 under the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* The EPA prepared an ICR document (ICR No. 1657.03), and a copy may be obtained from Sandy Farmer at U.S. EPA, Office of Environmental Information, Collection Strategies Division (2822), 1200 Pennsylvania Avenue, NW., Washington, DC 20460 or by calling (202) 260-2740. You may also request a copy by e-mail at: farmer.sandy@epa.gov or from the

Office of Policy website at: <http://www.epa.gov/icr>. The ICR has been approved by OMB (OMB No. 2060-0387.)

These amendments to the 1998 Pulp and Paper NESHAP will have no impact on the information collection burden estimates made previously. Consequently, EPA has not revised the ICR.

H. National Technology Transfer and Advancement Act

Under section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, all Federal agencies are required to use voluntary consensus standards (VCS) in their regulatory procurement activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (*e.g.*, materials specifications, test methods, sampling procedures, business practices) developed or adopted by one or more voluntary consensus bodies. The NTTAA requires Federal agencies to provide Congress, through annual reports to OMB, with explanations when an agency decides not to use available and applicable VCS.

Today's final rule amendments do not establish new or modify existing technical standards. Therefore, consideration of VCS is not relevant to this action.

J. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the SBREFA, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. The EPA will submit a report containing this final rule and other required information to the U.S.

Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2). These amendments will be effective February 20, 2001.

List of Subjects in 40 CFR Part 63

Environmental protection, Administrative practice and procedure, Air pollution control, Hazardous substances, Intergovernmental relations, Reporting and recordkeeping requirements.

Dated: December 7, 2000.

Carol M. Browner,
Administrator.

For the reasons stated in the preamble, title 40, chapter I, parts 9 and 63 of the Code of Federal Regulations are amended as follows:

PART 9—[AMENDED]

1. The authority citation for part 9 continues to read as follows:

Authority: 7 U.S.C. 135 *et seq.*, 136–136y; 15 U.S.C. 2001, 2003, 2005, 2006, 2601–2671; 21 U.S.C. 331j, 346a, 348; 31 U.S.C. 9701; 33 U.S.C. 1251 *et seq.*, 1311, 1313d, 1314, 1318, 1321, 1326, 1330, 1342, 1344, 1345 (d) and (e), 1361; E.O. 11735, 38 FR 21243, 3 CFR, 1971–1975 Comp. p. 973; 42 U.S.C. 241, 242b, 243, 246, 300f, 300g, 300g–1, 300g–2, 300g–3, 300g–4, 300g–5, 300g–6, 300j–1, 300j–2, 300j–3, 300j–4, 300j–9, 1857 *et seq.*, 6901–6992k, 7401–7671q, 7542, 9601–9657, 11023, 11048.

2. Section 9.1 is amended by adding a new entry to the table in numerical order to read as follows:

§ 9.1 OMB approvals under the Paperwork Reduction Act.

* * * * *

40 CFR citation	OMB control no.
* * * * *	
National Emission Standards for Hazardous Air Pollutants for Source Categories	
* * * * *	
63.450, 63.453–63.455, and 63.457	2060–0387
* * * * *	

³The ICRs referenced in this section of the table encompass the applicable general provisions contained in 40 CFR part 63, subpart A, which are not independent information collection requirements.

* * * * *

PART 63—[AMENDED]

Authority: 42 U.S.C. 7401 *et seq.*

3. The authority citation for part 63 continues to read as follows:

Subpart S—National Emission Standards for Hazardous Air Pollutants from the Pulp and Paper Industry

4. Amend § 63.443 by revising paragraph (d)(4) to read as follows:

§ 63.443 Standards for the pulping system at kraft, soda, and semi-chemical processes.

* * * * *

(d) * * *

(4) Reduce total HAP emissions using one of the following:

(i) A boiler, lime kiln, or recovery furnace by introducing the HAP emission stream with the primary fuel or into the flame zone; or

(ii) A boiler or recovery furnace with a heat input capacity greater than or equal to 44 megawatts (150 million British thermal units per hour) by introducing the HAP emission stream with the combustion air.

* * * * *

5. Amend § 63.446 by revising paragraphs (d)(1), (e)(2) and (i) to read as follows:

§ 63.446 Standards for kraft pulping process condensates.

* * * * *

(d) * * *

(1) Each closed collection system shall meet the individual drain system requirements specified in §§ 63.960, 63.961, and 63.962 of subpart RR of this part, except for closed vent systems and control devices shall be designed and operated in accordance with § 63.443(d) and 63.450, instead of in accordance with § 63.693 as specified in § 63.962 (a)(3)(ii), (b)(3)(ii)(A), and (b)(5)(iii); and

* * * * *

(e) * * *

(2) Discharge the pulping process condensate below the liquid surface of a biological treatment system and treat the pulping process condensates to meet the requirements specified in paragraph (e)(3), (4), or (5) of this section, and total HAP shall be measured as specified in § 63.457(g); or

* * * * *

(i) For the purposes of meeting the requirements in paragraph (c)(2) or (3) or paragraph (e)(4) or (5) of this section at mills producing both bleached and unbleached pulp products, owners and operators may meet a prorated mass standard that is calculated by prorating the applicable mass standards (kilograms of total HAP per megagram of ODP) for bleached and unbleached mills specified in paragraph (c)(2) or (3) or paragraph (e)(4) or (5) of this section by the ratio of annual megagrams of bleached and unbleached ODP.

6. Amend § 63.453 by revising paragraphs (j), (n), and (p) to read as follows:

§ 63.453 Monitoring requirements.

* * * * *

(j) Each owner or operator using an open biological treatment system to comply with § 63.446(e)(2) shall perform the daily monitoring procedures specified in either paragraph (j)(1) or (2) of this section and shall conduct a performance test each quarter using the procedures specified in paragraph (j)(3) of this section.

(1) Comply with the monitoring and sampling requirements specified in paragraphs (j)(1)(i) and (ii) of this section.

(i) On a daily basis, monitor the following parameters for each open biological treatment unit:

(A) Composite daily sample of outlet soluble BOD₅ concentration to monitor for maximum daily and maximum monthly average;

(B) Mixed liquor volatile suspended solids;

(C) Horsepower of aerator unit(s);

(D) Inlet liquid flow; and

(E) Liquid temperature.

(ii) If the Inlet and Outlet

Concentration Measurement Procedure (Procedure 3) in appendix C of this part is used to determine the fraction of HAP compounds degraded in the biological treatment system as specified in § 63.457(l), conduct the sampling and archival requirements specified in paragraphs (j)(1)(ii)(A) and (B) of this section.

(A) Obtain daily inlet and outlet liquid grab samples from each biological treatment unit to have HAP data available to perform quarterly performance tests specified in paragraph (j)(3) of this section and the compliance tests specified in paragraph (p) of this section.

(B) Store the samples as specified in § 63.457(n) until after the results of the soluble BOD₅ test required in paragraph (j)(1)(i)(A) of this section are obtained. The storage requirement is needed since the soluble BOD₅ test requires 5 days or more to obtain results. If the results of the soluble BOD₅ test are outside of the range established during the initial performance test, then the archive sample shall be used to perform the mass removal or percent reduction determinations.

(2) As an alternative to the monitoring requirements of paragraph (j)(1) of this section, conduct daily monitoring of the site-specific parameters established according to the procedures specified in paragraph (n) of this section.

(3) Conduct a performance test as specified in § 63.457(l) within 45 days

after the beginning of each quarter and meet the applicable emission limit in § 63.446(e)(2).

(i) The performance test conducted in the first quarter (annually) shall be performed for total HAP as specified in § 63.457(g) and meet the percent reduction or mass removal emission limit specified in § 63.446(e)(2).

(ii) The remaining quarterly performance tests shall be performed as specified in paragraph (j)(3)(i) of this section except owners or operators may use the applicable methanol procedure in § 63.457(l)(1) or (2) and the value of r determined during the first quarter test instead of measuring the additional HAP to determine a new value of r.

* * * * *

(n) To establish or reestablish the value for each operating parameter required to be monitored under paragraphs (b) through (j), (l), and (m) of this section or to establish appropriate parameters for paragraphs (f), (i), (j)(2), and (m) of this section, each owner or operator shall use the following procedures:

* * * * *

(p) The procedures of this paragraph apply to each owner or operator of an open biological treatment system complying with paragraph (j) of this section whenever a monitoring parameter excursion occurs, and the owner or operator chooses to conduct a performance test to demonstrate compliance with the applicable emission limit. A monitoring parameter excursion occurs whenever the monitoring parameters specified in paragraphs (j)(1)(i)(A) through (C) of this section or any of the monitoring parameters specified in paragraph (j)(2) of this section are below minimum operating parameter values or above maximum operating parameter values established in paragraph (n) of this section.

(1) As soon as practical after the beginning of the monitoring parameter excursion, the following requirements shall be met:

(i) Before the steps in paragraph (p)(1)(ii) or (iii) of this section are performed, all sampling and measurements necessary to meet the requirements in paragraph (p)(2) of this section shall be conducted.

(ii) Steps shall be taken to repair or adjust the operation of the process to end the parameter excursion period.

(iii) Steps shall be taken to minimize total HAP emissions to the atmosphere during the parameter excursion period.

(2) A parameter excursion is not a violation of the applicable emission standard if the results of the

performance test conducted using the procedures in this paragraph demonstrate compliance with the applicable emission limit in § 63.446(e)(2).

(i) Conduct a performance test as specified in § 63.457 using the monitoring data specified in paragraph (j)(1) or (2) of this section that coincides with the time of the parameter excursion. No maintenance or changes shall be made to the open biological treatment system after the beginning of a parameter excursion that would influence the results of the performance test.

(ii) If the results of the performance test specified in paragraph (p)(2)(i) of this section demonstrate compliance with the applicable emission limit in § 63.446(e)(2), then the parameter excursion is not a violation of the applicable emission limit.

(iii) If the results of the performance test specified in paragraph (p)(2)(i) of this section do not demonstrate compliance with the applicable emission limit in § 63.446(e)(2) because the total HAP mass entering the open biological treatment system is below the level needed to demonstrate compliance with the applicable emission limit in § 63.446(e)(2), then the owner or operator shall perform the following comparisons:

(A) If the value of f_{bio} (MeOH) determined during the performance test specified in paragraph (p)(2)(i) of this section is within the range of values established during the initial and subsequent performance tests approved by the Administrator, then the parameter excursion is not a violation of the applicable standard.

(B) If the value of f_{bio} (MeOH) determined during the performance test specified in paragraph (p)(2)(i) of this section is not within the range of values established during the initial and subsequent performance tests approved by the Administrator, then the parameter excursion is a violation of the applicable standard.

(iv) The results of the performance test specified in paragraph (p)(2)(i) of this section shall be recorded as specified in § 63.454(f).

(3) If an owner or operator determines that performing the required procedures under paragraph (p)(2) of this section for a nonthoroughly mixed open biological system would expose a worker to dangerous, hazardous, or otherwise unsafe conditions, all of the following procedures shall be performed:

(i) Calculate the mass removal or percent reduction value using the procedures specified in § 63.457(l) except the value for f_{bio} (MeOH) shall be

determined using the procedures in appendix E to this part.

(ii) Repeat the procedures in paragraph (p)(3)(i) of this section for every day until the unsafe conditions have passed.

(iii) A parameter excursion is a violation of the standard if the percent reduction or mass removal determined in paragraph (p)(3)(i) of this section is less than the percent reduction or mass removal standards specified in § 63.446(e)(2), as appropriate, unless the value of f_{bio} (MeOH) determined using the procedures in appendix E of this section, as specified in paragraph (p)(3)(i), is within the range of f_{bio} (MeOH) values established during the initial and subsequent performance tests previously approved by the Administrator.

(iv) The determination that there is a condition that exposes a worker to dangerous, hazardous, or otherwise unsafe conditions shall be documented according to requirements in § 63.454(e) and reporting in § 63.455(f).

(v) The requirements of paragraphs (p)(1) and (2) of this section shall be performed and met as soon as practical but no later than 24 hours after the conditions have passed that exposed a worker to dangerous, hazardous, or otherwise unsafe conditions.

7. Amend § 63.454 by revising paragraph (a) and adding paragraphs (e) and (f) to read as follows:

§ 63.454 Recordkeeping requirements.

(a) The owner or operator of each affected source subject to the requirements of this subpart shall comply with the recordkeeping requirements of § 63.10, as shown in table 1 of this subpart, and the requirements specified in paragraphs (b) through (f) of this section for the monitoring parameters specified in § 63.453.

(e) The owner or operator of an open nonthoroughly mixed biological treatment system complying with § 63.453(p)(3) instead of § 63.453(p)(2) shall prepare a written record identifying the specific conditions that would expose a worker to dangerous, hazardous, or otherwise unsafe conditions. The record must include a written explanation of the specific reason(s) why a worker would not be able to perform the sampling and test procedures specified in § 63.457(l).

(f) The owner or operator of an open biological treatment system complying with § 63.453(p) shall prepare a written record specifying the results of the performance test specified in § 63.453(p)(2).

8. Amend § 63.455 by adding paragraphs (e) and (f) to read as follows:

§ 63.455 Reporting requirements.

* * * * *

(e) If the owner or operator uses the results of the performance test required in § 63.453(p)(2) to revise the approved values or ranges of the monitoring parameters specified in § 63.453(j)(1) or (2), the owner or operator shall submit an initial notification of the subsequent performance test to the Administrator as soon as practicable, but no later than 15 days, before the performance test required in § 63.453(p)(2) is scheduled to be conducted. The owner or operator shall notify the Administrator as soon as practicable, but no later than 24 hours, before the performance test is scheduled to be conducted to confirm the exact date and time of the performance test.

(f) To comply with the open biological treatment system monitoring provisions of § 63.453(p)(3), the owner or operator shall notify the Administrator as soon as practicable of the onset of the dangerous, hazardous, or otherwise unsafe conditions that did not allow a compliance determination to be conducted using the sampling and test procedures in § 63.457(l). The notification shall occur no later than 24 hours after the onset of the dangerous, hazardous, or otherwise unsafe conditions and shall include the specific reason(s) that the sampling and test procedures in § 63.457(l) could not be performed.

9. Section 63.457 is amended by:

- a. Revising paragraph (c)(1) introductory text;
- b. Revising paragraph (c)(4) introductory text;
- c. Adding paragraph (c)(5);
- d. Adding paragraph (c)(6);
- e. Revising paragraph (g);
- f. Revising paragraph (l) introductory text;
- g. Revising paragraph (m)(1) introductory text;
- h. Revising paragraph (m)(1)(iii);
- i. Revising paragraph (m)(2) introductory text
- j. Revising paragraph (m)(2)(ii) introductory text;
- k. Revising paragraph (n).

The revisions and additions to read as follows:

§ 63.457 Test methods and procedures.

* * * * *

(c) * * *

(1) Samples shall be collected using the sampling procedures of the test method listed in paragraph (c)(3) of this section selected to determine liquid stream HAP concentrations;

* * * * *

(4) To determine soluble BOD₅ in the effluent stream from an open biological treatment unit used to comply with §§ 63.446(e)(2) and 63.453(j), the owner or operator shall use Method 405.1 of part 136 of this chapter with the following modifications:

* * * * *

(5) If the test method used to determine HAP concentration indicates that a specific HAP is not detectable, the value determined as the minimum measurement level (MML) of the selected test method for the specific HAP shall be used in the compliance demonstration calculations. To determine the MML for a specific HAP using one of the test methods specified in paragraph (c)(3) of this section, one of the procedures specified in paragraphs (c)(5)(i) and (ii) of this section shall be performed. The MML for a particular HAP must be determined only if the HAP is not detected in the normal working range of the method.

(i) To determine the MML for a specific HAP, the following procedures shall be performed each time the method is set up. Set up is defined as the first time the analytical apparatus is placed in operation, after any shut down of 6 months or more, or any time a major component of the analytical apparatus is replaced.

(A) Select a concentration value for the specific HAP in question to represent the MML. The value of the MML selected shall not be below the calibration standard of the selected test method.

(B) Measure the concentration of the specific HAP in a minimum of three replicate samples using the selected test method. All replicate samples shall be run through the entire analytical procedure. The samples must contain the specific HAP at the selected MML concentration and should be representative of the liquid streams to be analyzed in the compliance demonstration. Spiking of the liquid samples with a known concentration of the target HAP may be necessary to ensure that the HAP concentration in the three replicate samples is at the selected MML. The concentration of the HAP in the spiked sample must be within 50 percent of the proposed MML for the demonstration to be valid. As an alternative to spiking, a field sample above the MML may be diluted to produce a HAP concentration at the MML. To be a valid demonstration, the diluted sample must have a HAP concentration within 20 percent of the proposed MML, and the field sample

must not be diluted by more than a factor of five.

(C) Calculate the relative standard deviation (RSD) and the upper confidence limit at the 95 percent confidence level using the measured HAP concentrations determined in paragraph (c)(5)(i)(B) of this section. If the upper confidence limit of the RSD is less than 30 percent, then the selected MML is acceptable. If the upper confidence limit of the RSD is greater than or equal to 30 percent, then the selected MML is too low, and the procedures specified in paragraphs (c)(5)(i)(A) through (C) of this section must be repeated.

(ii) Provide for the Administrator's approval the selected value of the MML for a specific HAP and the rationale for selecting the MML including all data and calculations used to determine the MML. The approved MML must be used in all applicable compliance demonstration calculations.

(6) When using the MML determined using the procedures in paragraph (c)(5)(ii) of this section or when using the MML determined using the procedures in paragraph (c)(5)(i), except during set up, the analytical laboratory conducting the analysis must perform and meet the following quality assurance procedures each time a set of samples is analyzed to determine compliance.

(i) Using the selected test method, analyze in triplicate the concentration of the specific HAP in a representative sample. The sample must contain the specific HAP at a concentration that is within a factor of two of the MML. If there are no samples in the set being analyzed that contain the specific HAP at an appropriate concentration, then a sample below the MML may be spiked to produce the appropriate concentration, or a sample at a higher level may be diluted. After spiking, the sample must contain the specific HAP within 50 percent of the MML. If dilution is used instead, the diluted sample must contain the specific HAP within 20 percent of the MML and must not be diluted by more than a factor of five.

(ii) Calculate the RSD using the measured HAP concentrations determined in paragraph (c)(6)(i) of this section. If the RSD is less than 20 percent, then the laboratory is performing acceptably.

* * * * *

(g) *Condensate HAP concentration measurement.* For purposes of complying with the kraft pulping condensate requirements in § 63.446, the owner or operator shall measure the

total HAP concentration as methanol. For biological treatment systems complying with § 63.446(e)(2), the owner or operator shall measure total HAP as acetaldehyde, methanol, methyl ethyl ketone, and propionaldehyde and follow the procedures in § 63.457(l)(1) or (2).

* * * * *

(l) *Biological treatment system percent reduction and mass removal calculations.* To demonstrate compliance with the condensate treatment standards specified in § 63.446(e)(2) and the monitoring requirements specified in § 63.453(j)(3) using a biological treatment system, the owner or operator shall use one of the procedures specified in paragraphs (l)(1) and (2) of this section. Owners or operators using a nonthoroughly mixed open biological treatment system shall also comply with paragraph (l)(3) of this section.

(1) *Percent reduction methanol procedure.* For the purposes of complying with the condensate treatment requirements specified in § 63.446(e)(2)(i), the methanol percent reduction shall be calculated using the following equations:

$$R = \frac{f_{\text{bio}}(\text{MeOH})}{(1 + 1.087(r))} * 100$$

$$r = \frac{F_{(\text{nonmethanol})}}{F_{(\text{methanol})}}$$

Where:

R=percent destruction.

$f_{\text{bio}}(\text{MeOH})$ =the fraction of methanol removed in the biological treatment system. The site-specific biorate constants shall be determined using the appropriate procedures specified in appendix C of this part.
r=ratio of the sum of acetaldehyde, methyl ethyl ketone, and propionaldehyde mass to methanol mass.

$F_{(\text{nonmethanol})}$ =the sum of acetaldehyde, methyl ethyl ketone, and propionaldehyde mass flow rates (kg/Mg ODP) entering the biological treatment system determined using the procedures in paragraph (j)(2) of this section.

$F_{(\text{methanol})}$ =the mass flow rate (kg/Mg ODP) of methanol entering the system determined using the procedures in paragraph (j)(2) of this section.

(2) *Mass removal methanol procedure.* For the purposes of complying with the condensate treatment requirements specified in

§ 63.446(e)(2)(ii) or (iii), the methanol mass removal shall be calculated using the following equation:

$$F = F_b * (f_{\text{bio}}(\text{MeOH}) / (1 + 1.087(r)))$$

Where:

F=methanol mass removal (kg/Mg ODP).

F_b =inlet mass flow rate of methanol (kg/Mg ODP) determined using the procedures in paragraph (j)(2) of this section.

$f_{\text{bio}}(\text{MeOH})$ =the fraction of methanol removed in the biological treatment system. The site-specific biorate constants shall be determined using the appropriate procedures specified in appendix C of this part.

r=ratio of the sum of acetaldehyde, methyl ethyl ketone, and propionaldehyde mass to methanol mass determined using the procedures in paragraph (1) of this section.

(3) The owner or operator of a nonthoroughly mixed open biological treatment system using the monitoring requirements specified in § 63.453(p)(3) shall follow the procedures specified in section III.B.1 of appendix E of this part to determine the biorate constant, K_s , and characterize the open biological treatment system during the initial and any subsequent performance tests.

* * * * *

(m) * * *

(1) To demonstrate compliance with the percent mass requirements specified in § 63.446(c)(2), the procedures specified in paragraphs (m)(1)(i) through (iii) of this section shall be performed.

* * * * *

(iii) Compliance with the segregation requirements specified in § 63.446(c)(2) is demonstrated if the condensate stream or streams from each equipment system listed in § 63.446(b)(1) through (3) being treated as specified in § 63.446(e) contain at least as much total HAP mass as the target total HAP mass determined in paragraph (m)(1)(ii) of this section.

(2) To demonstrate compliance with the percent mass requirements specified in § 63.446(c)(3), the procedures specified in paragraphs (m)(2)(i) through (ii) of this section shall be performed.

* * * * *

(ii) Compliance with the segregation requirements specified in § 63.446(c)(3) is demonstrated if the total HAP mass determined in paragraph (m)(2)(i) of this section is equal to or greater than the appropriate mass requirements specified in § 63.446(c)(3).

(n) *Open biological treatment system monitoring sampling storage.* The inlet and outlet grab samples required to be collected in § 63.453(j)(1)(ii) shall be

stored at 4°C (40°F) to minimize the biodegradation of the organic compounds in the samples.

* * * * *

10. Amend § 63.458 by revising paragraph (b)(4) and adding paragraph (b)(5) to read as follows:

§ 63.458 Delegation of authority.

* * * * *

(b) * * *

(4) Section 63.457(c)(3)(iii)—Use of an alternative test method for total HAP or methanol in wastewater.

(5) Section 63.457(c)(5)(ii)—Determination of the minimum measurement level in liquid streams for a specific HAP using the selected test method.

11. Add appendix E to this part to read as follows:

Appendix E to Part 63—Monitoring Procedure for Nonthoroughly Mixed Open Biological Treatment Systems at Kraft Pulp Mills Under Unsafe Sampling Conditions

I. Purpose

This procedure is required to be performed in subpart S of this part, entitled National Emission Standards for Hazardous Air Pollutants from the Pulp and Paper Industry. Subpart S requires this procedure in § 63.453(p)(3) to be followed during unsafe sampling conditions when it is not practicable to obtain representative samples of hazardous air pollutants (HAP) concentrations from an open biological treatment unit. It is assumed that inlet and outlet HAP concentrations from the open biological treatment unit may be obtained during the unsafe sampling conditions. The purpose of this procedure is to estimate the concentration of HAP within the open biological treatment unit based on information obtained at inlet and outlet sampling locations in units that are not thoroughly mixed and, therefore, have different concentrations of HAP at different locations within the unit.

II. Definitions

Biological treatment unit = wastewater treatment unit designed and operated to promote the growth of bacteria to destroy organic materials in wastewater.

f_{bio} = The fraction of organic compounds in the wastewater biodegraded in a biological treatment unit.

Fe = The fraction of applicable organic compounds emitted from the wastewater to the atmosphere.

K1 = First-order biodegradation rate constant, L/g mixed liquor volatile suspended solids (MLVSS)-hr

KL = Liquid-phase mass transfer coefficient, m/s

Ks = Monod biorate constant at half the maximum rate, g/m³

III. Test Procedure for Determination of f_{bio} for Nonthoroughly Mixed Open Biological Treatment Units Under Unsafe Sampling Conditions

This test procedure is used under unsafe sampling conditions that do not permit practicable sampling of open biological treatment units within the unit itself, but rather relies on sampling at the inlet and outlet locations of the unit. This procedure may be used only under unsafe sampling conditions to estimate f_{bio} . Once the unsafe conditions have passed, then the formal compliance demonstration procedures of f_{bio} based upon measurements within the open biological treatment unit must be completed.

A. Overview of Estimation Procedure

The steps in the estimation procedure include data collection, the estimation of concentrations within the unit, and the use of Form 1 to estimate f_{bio} . The data collection procedure consists of two separate components. The first data collection component demonstrates that the open biological treatment unit can be represented by Monod kinetics and characterizes the effectiveness of the open biological treatment unit as part of the initial performance test, and the second data collection component is used when there are unsafe sampling conditions. These two data collection components are used together in a data calculation procedure based on a Monod kinetic model to estimate the concentrations in each zone of the open biological treatment unit. After the first two components of data collection are completed, the calculation procedures are used to back estimate the zone concentrations, starting with the last zone in the series and ending with the first zone.

B. Data Collection Requirements

This method is based upon modeling the nonthoroughly mixed open biological treatment unit as a series of well-mixed zones with internal recycling between the units and assuming that two Monod biological kinetic parameters can be used to characterize the biological removal rates in each unit. The data collection procedure consists of two separate components. The first data collection component is part of the initial performance test, and the second data collection component is used during unsafe sampling conditions.

1. Initial Performance Test

The objective of the first data collection component is to demonstrate that the open biological treatment unit can be represented by Monod kinetics and to characterize the performance of the open biological treatment unit. An appropriate value of the biorate constant, K_s , is determined using actual sampling data from the open biological treatment unit. This is done during the initial performance test when the open biological treatment unit is operating under normal conditions. This specific K_s value obtained during the initial performance test is used in the calculation procedure to characterize the open biological treatment unit during unsafe sampling conditions. The following open biological treatment unit characterization

information is obtained from the first component of the data collection procedure:

- (1) The value of the biorate constant, K_s ;
- (2) The number and characteristics of each zone in the open biological treatment unit (depth, area, characterization parameters for surface aeration, submerged aeration rates, biomass concentration, concentrations of organic compounds, dissolved oxygen (DO), dissolved solids, temperature, and other relevant variables); and
- (3) The recycle ratio of internal recirculation between the zones. The number of zones and the above characterization of the zones are also used to determine the performance of the unit under the unsafe sampling conditions of concern.

2. Data Collected Under Unsafe Sampling Conditions

In the second data collection component obtained under unsafe sampling conditions, the measured inlet and outlet HAP concentrations and the biomass concentration are obtained for the open biological treatment unit. After the site specific data collection is completed on the day a parameter excursion occurs, the inlet and outlet concentrations are used with the prior open biological treatment unit characterization to estimate the concentrations of HAP in each zone. The following information on the open biological treatment unit must be available in the second data collection component:

- (1) Basic unit variables such as inlet and recycle wastewater flow rates, type of agitation, and operating conditions;
- (2) The value of the inlet and outlet HAP concentrations; and
- (3) The biomass concentration in the open biological treatment unit.

C. One Time Determination of a Single Value of K_s (Initial Performance Test)

A single value of K_s is calculated using Form 3 for each data set that is collected during the initial performance test. A single composite value of K_s , deemed to be representative of the biological unit, is subsequently selected so that the f_{bio} values calculated by the procedures in this appendix (using this single value of K_s) for the data sets collected during the initial performance test are within 10 percent of the f_{bio} value determined by using Form 1 with these same data sets. The value of K_s meeting these criteria is obtained by the following steps:

- (1) Determine the median of the K_s values calculated for each data set;
- (2) Estimate f_{bio} for each data set using the selected K_s value (Form 1 and Form 2);
- (3) Calculate f_{bio} for each data set using Form 1; and
- (4) Compare the f_{bio} values obtained in steps (2) and (3); if the f_{bio} value calculated using step (2) differs from that calculated using step (3) by more than 10 percent, adjust K_s (decrease K_s if the f_{bio} value is lower than that calculated by Form 1 and vice versa) and repeat this procedure starting at step (2). If a negative value is obtained for the values of K_s , then this negative kinetic constant may not be used with the Monod model. If a negative value of K_s is obtained, this test procedure cannot be used for evaluating the

performance of the open biological treatment unit.

D. Confirmation of Monod Kinetics (Initial Performance Test)

(1) Confirmation that the unit can be represented by Monod kinetics is made by identifying the following two items:

- (i) The zone methanol concentrations measured during the initial performance test; and
- (ii) The zone methanol concentrations estimated by the Multiple Zone Concentrations Calculations Procedure based on inlet and outlet concentrations (Column A of Form 2). For each zone, the concentration in item 1 is compared to the concentration in item 2.

(2) For each zone, the estimated value of item 2 must be:

- (i) Within 25 percent of item 1 when item 1 exceeds 8 mg/L; or
- (ii) Within 2 mg/L of item 1 when item 1 is 8 mg/L or less.

(3) Successful demonstration that the calculated zone concentrations meet these criteria must be achieved for 80 percent of the performance test data sets.

(4) If negative values are obtained for the values of K_1 and K_s , then these negative kinetic constants may not be used with the Monod model, even if the criteria are met. If negative values are obtained, this test procedure cannot be used for evaluating the performance of the open biological treatment unit.

E. Determination of KL for Each Zone (Unsafe Sampling Conditions)

(1) A site-specific liquid-phase mass transfer coefficient (KL) must be obtained for each zone during the unsafe sampling conditions. Do not use a default value for KL. The KL value for each zone must be based on the site-specific parameters of the specific unit. The first step in using this procedure is to calculate KL for each zone in the unit using Form 4. Form 4 outlines the procedure to follow for using mass transfer equations to determine KL. Form 4 identifies the appropriate form to use for providing the detailed calculations to support the estimate of the value of KL. Forms 5 and 6 are used to provide individual compound estimates of KL for quiescent and aerated impoundments, respectively. A computer model may be used to perform the calculations. If the WATER8 model or the most recent update to this model is used, then report the computer model input parameters that you used as an attachment to Form 4. In addition, the Bay Area Sewage Toxics Emission (BASTE) model, version 3.0, or equivalent upgrade and the TOXCHEM (Environment Canada's Wastewater Technology Centre and Environnema, Ltd.) model, version 1.10, or equivalent upgrade may also be used to determine KL for the open biological treatment unit with the following stipulations:

- (i) The programs must be altered to output a KL value that is based on the site-specific parameters of the unit modeled; and
- (ii) The Henry's law value listed in Form 4 must be substituted for the existing Henry's law values in the models.

(2) The Henry's law value listed in Form 4 may be obtained from the following sources:

- (i) Values listed by EPA with temperature adjustment if needed;
- (ii) Measured values for the system of concern with temperature adjustment; or
- (iii) Literature values of Henry's law values for methanol, adjusted for temperature if needed.

(3) Input values used in the model and corresponding output values shall become part of the documentation of the f_{bio} determination. The owner or operator should be aware that these models may not provide equivalent KL values for some types of units. To obtain an equivalent KL value in this situation, the owner or operator shall either use the appropriate procedure on Form 4 or adjust the KL value from the model to the equivalent KL value as described on Form 4.

(4) Report the input parameters that you used in the computer model on Forms 5, 6, and 7 as an attachment to Form 4. If you have submerged air flow in your unit, you must add the value of KL estimated on Form 7 to the value of KL obtained with Forms 5 and 6 before using the value of KL with Form 2.

F. Estimation of Zone Concentrations (Unsafe Sampling Conditions)

Form 2 is used to estimate the zone concentrations of HAP based on the inlet and outlet data. The value of K_s entered on the form is that single composite value of K_s discussed in section III.C of this appendix. This value of K_s is calculated during the Initial Performance Test (and subsequently updated, if necessary). A unique value of the biorate K_1 is entered on line 5 of Form 2, and the inlet concentration is estimated in Column A of Form 2. The inlet concentration is located in the row of Form 2 corresponding to zone 0. If there are three zones in the system, $n-3$ equals 0 for the inlet concentration row. These estimated zone concentrations are then used in Form 1 to estimate f_{bio} for the treatment unit.

G. Quality Control/Quality Assurance (QA/QC)

A QA/QC plan outlining the procedures used to determine the measured inlet and outlet concentrations during unsafe conditions and how the zone characterization data were obtained during the initial performance test shall be prepared and submitted with the initial performance test report. The plan should include, but may not be limited to:

- (1) A description of each of the sampling methods that were used (method, procedures, time, method to avoid losses during sampling and holding, and sampling procedures) including simplified schematic drawings;
- (2) A description of how that biomass was sampled from the biotreatment unit, including methods, locations, and times;
- (3) A description of what conditions (DO, temperature, etc.) are important, what the target values are in the zones, how the factors were controlled, and how they were monitored. These conditions are primarily used to establish that the conditions of the initial performance test correspond to the conditions of the day in question;
- (4) A description of how each analytical measurement was conducted, including

preparation of solutions, dilution procedures, sampling procedures, monitoring of conditions, etc;

(5) A description of the analytical instrumentation used, how the instruments were calibrated, and a summary of the accuracy and precision for each instrument;

(6) A description of the test methods used to determine HAP concentrations and other measurements. Section 63.457(c)(3) specifies the test methods that must be used to determine HAP concentrations. During unsafe sampling conditions, you do not have to sample over an extended period of time or obtain more than one sample at each sample point.

(7) A description of how data are captured, recorded, and stored; and

(8) A description of the equations used and their solutions for sampling and analysis, including a reference to any software used for calculations and/or curve-fitting.

IV. Calculation of Individual f_{bio} (Unsafe Sampling Conditions)

Use Form 1 with your zone concentration information to estimate the value of f_{bio} under unsafe sampling conditions. Form 1 uses measured concentrations of HAP in the unit inlet and outlet, and Form 1 also uses the estimated concentrations in each zone of the unit obtained from Form 2. This procedure may be used on an open biological treatment unit that has defined zones within the unit. Use Form 1 to determine f_{bio} for each open biological treatment unit as it

exists under subpart S of part 63. The first step in using Form 1 is to calculate KL for each zone in the unit using Form 4. Form 7 must also be used if submerged aeration is used. After KL is determined using field data, obtain the concentrations of the HAP in each zone. In this alternative procedure for unsafe sampling conditions, the actual measured concentrations of the HAP in each zone are replaced with the zone concentrations that are estimated with Form 2. After KL and the zone concentrations are determined, Form 1 is used to estimate the overall unit f_{Fe} and f_{bio} for methanol.

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Form 1

DATA FORM FOR THE ESTIMATION OF MULTIPLE ZONE BIODEGRADATION FROM UNIT CONCENTRATIONS

NAME OF THE FACILITY for site specific biorate determination		
COMPOUND for site specific biorate determination	Methanol	
Number of zones in the biological treatment unit	1	
VOLUME of full-scale system (cubic meters)	2	
Average DEPTH of the full-scale system (meters)	3	
FLOW RATE of wastewater treated in the unit (m ³ /s)	4	
Recycle flow of wastewater added to the unit, if any (m ³ /s)	5	
Concentration in the wastewater treated in the unit (mg/L)	6	
Concentration in the recycle flow, if any (mg/L)	7	
Concentration in the effluent (mg/L).	8	

TOTAL INLET FLOW (m ³ /s) line 4 plus the number on line 5	9	
TOTAL RESIDENCE TIME (s) line 2 divided by line 9.	10	
TOTAL AREA OF IMPOUNDMENT (m ²) line 2 divided by line 3	11	

Zone number	Concentration for zone, C _i (mg/L)	Area of the zone, A (m ²)	Estimate of KL in the zone (m/s) from Form 4	AIR STRIPPING KL A C _i (g/s)
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				
TOTALS sum for each zone.		12	13	

Removal by air stripping (g/s). Line 13.	14	
Loading in effluent (g/s). Line 8 times line 9.	15	
Total loading (g/s). (Line 5 * line 7) + (line 4 * line 6).	16	
Removal by biodegradation (g/s) Line 16 minus (line 14 + line 15).	17	
Fraction biodegraded: Divide line 17 by line 16.	18	
Fraction air emissions: Divide line 14 by line 16.	19	
Fraction remaining in unit effluent: Divide line 15 by line 16.	20	

Form 2

DATA FORM FOR THE DETERMINATION OF ZONE CONCENTRATIONS FROM KS AND INLET/OUTLET DATA

COMPOUND for site specific biorates determination	Methanol	
Influent Flow (m ³ /s)	1	
Inlet Concentration (g/m ³)	2	
Outlet Concentration (g/m ³) - Use value from line 3 as C _i value in column A for final Zone (zone n) in table below	3	
Saturation Coefficient, K _s (g/m ³) From Form 3	4	
Biorate K ₁ (1/s) - Estimate	5	
Number of Zones	6	

Adjust K₁ value (line 5) until Column A, Row (n - line 6) is within +/- 5% of line 2.

Instructions for completion of table: (1) Transfer value from line 3 into row n, column A. (2) Enter data for all zones into columns B, D, E, G, H, & K. (3) Beginning with row n, perform calculations for columns F, I, J, L, M, N, & O for that zone only. (4) Calculate row n-1, column A using results from previous row (i.e., J_{n-1}, M_{n-1}, N_{n-1}). (5) Repeat steps (3) and (4) until a row of calculations has been completed for each zone. (6) row n - line 6, column A is the calculated inlet concentration.

	A	B	C	D	E	F	G	H
Zone	C _i					line 5 * A * C * D		
Number	(J _{n-1} + N _{n-1}) / O _{n-1} g/m ³	Temp C	(1.045) ^(B-25)	biomass g/m ³	Volume m ³	*E / (line 4 + A) g/s	KL m/s	Area m ²
n								
n-1								
n-2								
n-3								
n-4								

	I	J	K	L	M	N	O
Zone		Reaction		(1+BM _i + BM _{i+1})	BM _{i+1} * C _{i+1}	Flux	(1+BM _i) *
Number	A * G * H g/s	F + I g/s	Backmix BM _i	*C _i * line 1 g/s	*line1 g/s	L - M g/s	line1 g/s
n							
n-1							
n-2							
n-3							
n-4							

The backmix ratio, Bm_i, is the ratio of (the return flow from the zone back to the upstream zone) to (the total inlet flow into the unit). This approach assumes that the flow is sequential through the different zones.

Form 3

DATA FORM FOR THE DETERMINATION OF MONOD CONSTANTS FROM ZONE CONCENTRATIONS WITH BACKMIXING																				
COMPOUND for site specific biorates determination						Methanol														
Total Inlet Flow (m3/s)						1														
Inlet Concentration (g/m3) - Use value from line 2 as Ci-1 value in column D for Zone 1 in table below						2														
	A	B	C	D	E	F	G	H												
Zone Number	Ci g/m ³	Backmix (BM _i)	(1+BM _i + BM _{i+1})*Ci g/m ³	(1+BM _i)*Ci-1	BM _{i+1} * Ci+1 g/m ³	KL m/s	Area m ²	A*F*G g/s												
1																				
2																				
3																				
4																				
5																				
	I	J	K	L	M	N	O													
Zone Number	Volume m3	Temp C	(1.045)^(J-25)	biomass g/m ³	I*K*L gm	M/[line 1*(D+E-C)-H] s	1/A m ³ /g													
1																				
2																				
3																				
4																				
5																				
Plot values in column N on y axis, and values in column O on x axis, up to, and including first row where Ci is equal to MDL or to last zone. <table border="1" style="margin-left: auto; margin-right: auto; border-collapse: collapse;"> <tr> <td style="padding: 2px;">Y intercept from plot. (g-s/m3)</td> <td style="padding: 2px; text-align: center;">3</td> <td style="padding: 2px;"></td> </tr> <tr> <td style="padding: 2px;">K1 (1/s). 1/line 3</td> <td style="padding: 2px; text-align: center;">4</td> <td style="padding: 2px;"></td> </tr> <tr> <td style="padding: 2px;">Slope of line</td> <td style="padding: 2px; text-align: center;">5</td> <td style="padding: 2px;"></td> </tr> <tr> <td style="padding: 2px;">Ks (g/m3). Line 5 times line 4</td> <td style="padding: 2px; text-align: center;">6</td> <td style="padding: 2px;"></td> </tr> </table>									Y intercept from plot. (g-s/m3)	3		K1 (1/s). 1/line 3	4		Slope of line	5		Ks (g/m3). Line 5 times line 4	6	
Y intercept from plot. (g-s/m3)	3																			
K1 (1/s). 1/line 3	4																			
Slope of line	5																			
Ks (g/m3). Line 5 times line 4	6																			
<i>The backmix ratio, Bmi, is the ratio of (the return flow from the zone back to the upstream zone) to (the total inlet flow into the unit). This approach assumes that the flow is sequential through the different zones.</i>																				

Form 4

PROCEDURES FORM FOR THE ESTIMATION OF THE KL FROM UNIT SPECIFICATIONS	
NAME OF THE FACILITY for site specific biorate determination	
NAME OF UNIT for site specific biorate determination	
NAME OF COMPOUND	Methanol
HENRY'S LAW constant for the compound (mole fraction in gas per mole fraction in water at 25 degrees Celsius)	
IDENTIFY THE TYPE OF UNIT (check one box below)	
Quiescent impoundment	1
Surface agitated impoundment	2
Surface agitated impoundment with submerged air present	3
Unit with submerged aeration gas	4
PROCEDURES BASED UPON THE TYPE OF UNIT 1. Use Form 5 to determine KL for the surface of the quiescent impoundment. 2. Use Form 5 to determine KL for the surface of the quiescent part of the impoundment. Use Form 6 to determine KL for the part of the surface that is agitated, then complete Form 6 with Kq as determined from Form 5. 3. Use Form 5 to determine KL for the surface of the quiescent part of the impoundment. Use Form 6 to determine KL for the part of the surface that is agitated, then complete Form 6 with Kq as determined from Form 5. The total system KL is the sum of the KL from the completed Form 6 and the equivalent KL from Form 7. 4. Evaluate the fraction of the surface that is agitated and the extent of the aeration. Use Form 5 to determine KL for the quiescent part of the surface of the impoundment. Use Form 6 to determine KL for the part of the surface that is agitated, then complete Form 6 with Kq as determined from Form 5. The total system KL is the sum of the KL from the completed Form 6 and the equivalent KL from Form 7. See section 5.6.1 in the document Air Emission Models for Waste and Wastewater.	
Estimate of surface KL obtained from above procedures (m/s)	5
If the submerged aeration is present, the equivalent KL from Form 7	6
The total KL is the sum of line 5 and line 6.	7

Form 5

FORM FOR CALCULATING THE MASS TRANSFER COEFFICIENT FOR A QUIESCENT SURFACE IMPOUNDMENT

FACILITY NAME for site specific biorate determination

COMPOUND for site specific biorate determination

Methanol

Input values

Enter the following:

F - Impoundment fetch (m)

D - Impoundment depth (m)

U10 - Windspeed 10 m above liquid surface (m/s)

Dw - Diffusivity of compound in water (cm²/s)Dether - Diffusivity of ether in water (cm²/s) μ G - Viscosity of air, (g/cm-s)G - Density of air, (g/cm³)Da - Diffusivity of compound in air, (cm²/s)A - Area of impoundment, (m²)H - Henry's law constant, (atm-m³/g mol)R - Universal gas constant, (atm-m³/g mol. K) μ L - Viscosity of water, (g/cm-s)L - Density of liquid, (g/cm³)

T - Impoundment temperature, (C)

Calculate the following:

Calculate F/D:

Calculate the liquid phase mass transfer coefficient, k_L, using one of the following procedures, (m/s)

Where F/D < 14 and U10 > 3.25 m/s, use the following procedure from MacKay and Yeun:

Calculate the Schmidt number on the liquid side, Sc_L, as follows:

$$Sc_L = \mu_L / LD_w$$

Calculate the friction velocity, U*, as follows, (m/s):

$$U^* = 0.01 \times U_{10} (6.1 + 0.63 U_{10}^{0.5})$$

Where U* is > 0.3, calculate k_L as follows:

$$k_L = (1.0 \times 10^{-6}) + (34.1 \times 10^{-4}) U^* \times Sc_L^{-0.5}$$

Where U* is < 0.3, calculate k_L as follows:

$$k_L = (1.0 \times 10^{-6}) + (144 \times 10^{-4}) (U^*)^{2.2} \times Sc_L^{-0.5}$$

For all other values of F/D and U10, calculate k_L using the following procedure from Springer:Where U10 is < 3.25 m/s, calculate k_L as follows:

Form 5

$$k_L = 2.78 \times 10^{-6} (D_w/D_{ether})^{2/3}$$

Where U_{10} is > 3.25 and $14 < F/D < 51.2$, Calculate k_L as follows:

$$k_L = [2.605 \times 10^{-9} (F/D) + 1.277 \times 10^{-7}] U_{10}^2 (D_w/D_{ether})^{2/3}$$

Where $U_{10} > 3.25$ m/s and $F/D > 51.2$, calculate k_L as follows:

$$k_L = (2.611 \times 10^{-7}) U_{10}^2 (D_w/D_{ether})^{2/3}$$

- B. Calculate the gas phase mass transfer coefficient, k_G , using the following procedure from MacKay and Matsasugu, (m/s):

Calculate the Schmidt number on the gas side, Sc_G , as follows: $Sc_G = \mu_G / GDa$

Calculate the effective diameter of the impoundment, d_e , as follows, (m):

$$d_e = (4A/3.14)^{0.5}$$

Calculate k_G as follows, (m/s): $k_G = 4.82 \times 10^{-3} U_{10}^{0.78} Sc_G^{-0.67} d_e^{-0.11}$

- C. Calculate the partition coefficient, Keq , as follows: $Keq = H/[R(T+273)]$

- D. Calculate the overall mass transfer coefficient, Kq , as follows, (m/s):
 $1/Kq = 1/k_L + 1/(Keq \cdot k_G)$

Where the total impoundment surface is quiescent:

$$K_L = Kq$$

Where a portion of the impoundment surface is turbulent, continue with Form 6.

Form 6

DATA FORM FOR CALCULATING THE MASS TRANSFER COEFFICIENT FOR AN AERATED SURFACE IMPOUNDMENT

Facility Name:

Waste Stream Compound:

Methanol

Enter the following:

J - Oxygen transfer rating of surface aerator, (lb O₂/hr-hp)

POWR - Total power to aerators, (hp)

T - Water temperature, (°C)

Ot - Oxygen transfer correction factor

MWL - Molecular weight of liquid

At - Turbulent surface area of impoundment, (ft²)

(If unknown, use values from Table 1)

A - Total surface area of impoundment, (ft²)rhoL - Density of liquid, (lb/ft³)Dw - Diffusivity of constituent in water, (cm²/s)Do - Diffusivity of oxygen in water, (cm²/s)

d - Impeller diameter, (cm)

w - Rotational speed of impeller, (rad/s)

a - Density of air, (gm/cm³)

N - Number of aerators

gc - Gravitation constant, (lbm-ft/s²/lbf)

d* - Impeller diameter, (ft)

Da - Diffusivity of constituent in air, (cm²/s)

MWa - Molecular weight of air

R - Universal gas constant, (atm-m³/g mol. °C)H = Henry's law constant, (atm-m³/g mol)

Calculate the following:

- A. Calculate the liquid phase mass transfer coefficient, k_L, using the following Equation from Thibodeaux:

$$k_L = [8.22 \times 10^{-9} J (POWR)(1.024)^{(T-20)} Ot 10^6 MWL / (At \times \rho_L / 62.37)] (Dw/Do)^{0.5}, (m/s)$$

- B. Calculate the gas phase mass transfer coefficient, k_G, using the following procedure from Reinhardt:

Calculate the viscosity of air, μ_a, as follows, (g/cm.s):

$$\mu_a = 4.568 \times 10^{-7} T + 1.7209 \times 10^{-4}$$

Calculate the Reynold's number as follows:

$$Re = d^2 w a / \mu_a$$

Calculate power to impeller, PI, as follows, (ft.lbf/s):

$$PI = 0.85 (POWR) 550/N$$

Form 6

Calculate the power number, p , as follows:

$$p = \frac{\pi g c}{\rho \omega L d^5 \omega^3}$$

Calculate the Schmidt number, Sc_G , as follows:

$$Sc_G = \frac{\mu a}{Da}$$

Calculate the Fronde number, Fr , as follows:

$$Fr = \frac{d \omega^2}{g c}$$

Calculate k_G as follows:

$$k_G = 1.35 \times 10^{-7} Re^{1.42} p^{0.4} Sc_G^{0.5} Fr^{-0.21} Da^{MWa/d}, (m/s)$$

C. Calculate the partition coefficient, Keq , as follows:

$$Keq = \frac{H}{R(T+273)}$$

D. Calculate the overall turbulent mass transfer coefficient, K_t , as follows, (m/s):

$$\frac{1}{K_t} = \frac{1}{k_L} + \frac{1}{(Keq \cdot k_G)}$$

E. Calculate the quiescent mass transfer coefficient, K_q , for the impoundment using Form 5.F. Calculate the overall mass transfer coefficient, K_L , for the impoundment as follows:

$$K_L = \frac{(A - A_t)/A}{K_q + A_t \cdot K_t/A}$$

Form 6 Table 1

PROCEDURES FORM FOR THE ESTIMATION OF THE K_L FROM WATER^{8 a,b}

Motor horsepower	At, Turbulent area,		Effective depth	V, Agitated volume	aV, Area per volume
hp	ft ²	m ²	ft	ft ³	ft ² /ft ³
5	177	16.4	10	1,767	0.1002
7.5	201	18.7	10	2,010	0.1000
10	227	21	10.5	2,383	0.0953
15	284	26.4	11	3,119	0.0911
20	346	32.1	11.5	3,983	0.0869
25	415	38.6	12	4,986	0.0832
30	491	45.7	12	5,890	0.0834
40	661	61.4	13	8,587	0.0770
50	855	79.5	14	11,970	0.0714
60	1075	100	15	16,130	0.0666
75	1452	135	16	23,240	0.0625
100	2206	205	18	39,710	0.0556

a Data for a high speed (1,200 rpm) aerator with 60 cm propeller diameter (d).

b This table provides information potentially useful for the value of A_t .

Form 7

DATA FORM FOR THE ESTIMATION OF THE EQUIVALENT KL FROM AIR STRIPPING DUE TO SUBMERGED AERATION.

NAME OF THE FACILITY for site specific biorate determination

COMPOUND for site specific biorate determination

VENT RATE of total gas leaving the unit (G, m3/s)

TEMPERATURE of the liquid in the unit (deg. C)

ESTIMATE OF Henry's law constant (H, g/m3 in gas / g/m3 in liquid).

Corrected for the temperature on line 2.

AREA OF REACTOR (m2)

CALCULATION OF THE ESTIMATE OF EQUIVALENT KL

[H G] ESTIMATE (m3/s) Multiply the number on line 1 by the number on line 3. Enter the results here.

EQUIVALENT KL. Divide the number on line 5 by the number on line 4.

Enter the results on line 6.

	Methanol
1	
2	
3	
4	

5	
6	

[FR Doc. 00-32028 Filed 12-21-00; 8:45 am]

BILLING CODE 6560-50-C

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 50

[FRL-6919-5]

RIN 2060-AJ05

National Primary and Secondary Ambient Air Quality Standards for Particulate Matter

AGENCY: Environmental Protection
Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is taking final action to remove requirements relative to the revised PM-10 NAAQS EPA issued in 1997 that were intended to clarify the applicability of the PM-10 National Ambient Air Quality Standards (NAAQS) issued in 1987 (hereafter referred to as the pre-existing PM-10 NAAQS). These requirements were added to the CFR at that time in anticipation of the transition to the implementation of the revised PM-10 NAAQS, and set forth the criteria under which the pre-existing PM-10 NAAQS would cease to apply and the revised PM-10 NAAQS would then become the solely applicable coarse particle standards. However, a recent ruling of the U.S. Court of Appeals for the District of Columbia Circuit (D.C. Circuit) vacated the revised PM-10 NAAQS and, thus, removed the basis for these requirements. Therefore, today we are taking final action to remove the

requirements from the subsection of the CFR where they are found, thus ensuring that the pre-existing PM-10 standards will continue to apply to all areas where they currently apply. In light of the action taken by the D.C. Circuit, as well as the need from a regulatory and administrative perspective to clarify the status of the pre-existing PM-10 NAAQS, we had previously proposed to remove these requirements as part of our June 26, 2000 proposal "Rescinding the Finding that the Pre-existing PM-10 Standards are No Longer Applicable in Northern Ada County/Boise, Idaho." We have not received any comments on this portion of that proposal to date and are therefore moving forward today to take final action to remove them.

DATES: This rule will become effective January 22, 2001.

FOR FURTHER INFORMATION CONTACT: Questions about this action should be addressed to Gary Blais, Office of Air Quality Planning and Standards, Air Quality Strategies and Standards Division, Integrated Policy and Strategies Group, MD-15, Research Triangle Park, NC 27711, telephone (919) 541-3223 or e-mail to blais.gary@epa.gov.

Public inspection. You may read the final rule at the Office of Air and Radiation Docket and Information Center located at 401 M Street, SW, Washington, DC 20460. It is available for public inspection from 8:00 a.m. to 5:30 p.m., Monday through Friday, excluding legal holidays. A reasonable fee may be charged for copying.

SUPPLEMENTARY INFORMATION:

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I. Background

A. What Was the Basis for EPA's Previous Rulemaking Actions Finding That the Pre-existing PM-10 Standards No Longer Apply?

On July 18, 1997 (62 FR 38856), we issued a regulation replacing the pre-existing PM-10 NAAQS with revised PM-10 NAAQS, along with new NAAQS for fine particulate matter (PM-2.5). Together, these new standards, which became effective on September 16, 1997, were issued to provide increased protection to the public,

especially children, the elderly, and other at-risk populations.

Also, on July 18, 1997, we announced that the effective date of the revocation of the pre-existing PM-10 NAAQS would be delayed and that, therefore, the existing standards and associated designations and classifications would continue to apply for an interim period. We did this to ensure continuity in public health protection during the transition from the pre-existing to the new PM-10 NAAQS. We provided, by regulation, that the pre-existing PM-10 standards would no longer apply to an area once it had attained those standards based on 3 years of quality-assured monitoring data, and had met certain other criteria. The regulation, found at 40 CFR 50.6 (d), was clearly premised upon the existence of the newly-revised PM-10 standards, and the implementation scheme developed for those standards. See 63 FR 38652, 38701.

B. What Effect Does the Recent Court Decision Have on Today's Action?

On May 14, 1999, the U.S. Court of Appeals for the D.C. Circuit issued an opinion questioning the constitutionality of the Clean Air Act (CAA) authority to review and revise the NAAQS, as applied in EPA's revision to the ozone and particulate matter NAAQS. *American Trucking Association, et al., v. EPA, et al.*, and consolidated cases. The Court stopped short of finding the statutory grant of authority unconstitutional, instead providing EPA with another opportunity to develop a determinate principle for promulgating NAAQS under the statute. In its decision, the Court found there was adequate evidence in the rulemaking record to justify EPA's choice to regulate both coarse and fine particulate matter pollution. Nevertheless, the Court went on to find that the Agency's decision to issue separate, but overlapping, regulations governing fine particles (defined as having an aerodynamic diameter of 2.5 microns or less) and regulations governing coarse particles (defined as having an aerodynamic diameter of 10 microns or less, which, therefore, includes particles sized at 2.5 microns and below) was unreasonable. In the Court's view, implementation of both PM-10 NAAQS together would have led to "double regulation" of the PM-2.5 component of the revised PM-10 NAAQS, and potential underregulation of pollution above the 2.5 micron size. Consequently, the Court determined that EPA had acted in an arbitrary and capricious manner, and vacated the revised PM-10 NAAQS.

Since the regulation at 40 CFR 50.6(d) was premised on the existence of the revised PM-10 NAAQS, this subsection is no longer appropriate or necessary and must be removed from the regulations.

II. What Action Is EPA Taking Today?

Today, we are taking final action to remove 40 CFR 50.6(d). The effect of this regulatory action is that the pre-existing PM-10 standards, as codified at 40 CFR, § 50.6(a) and (b), will remain applicable in those areas where they currently apply.

III. What Administrative Requirements Have We Considered in Writing Today's Final Rule?

A. Executive Order 12866: Regulatory Impact Analysis

Under Executive Order 12866 (58 FR 51735, October 4, 1993), the Agency must determine whether the regulatory action is "significant" and, therefore, subject to Office of Management and Budget (OMB) review and the requirements of the Executive Order. The Order defines "significant regulatory action" as one that is likely to result in a rule that may:

(1) have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities;

(2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(4) raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

Pursuant to the terms of Executive Order 12866, it has been determined that this rule is not a "significant regulatory action" because none of the listed criteria apply to this action. Consequently this action was not submitted to the OMB for review under Executive Order 12866.

B. Regulatory Flexibility Act

Under the Regulatory Flexibility Act (RFA), 5 U.S.C. 601 et seq., EPA must prepare a regulatory flexibility analysis assessing the impact of any proposed or final rule on small entities (5 U.S.C. 603 and 604), unless EPA certifies that the rule will not have a significant impact on a substantial number of small

entities. Small entities include small businesses, small not-for-profit enterprises, and government entities with jurisdiction over populations of less than 50,000. The EPA has determined that this regulatory action will not have a significant impact on a substantial number of small entities because the action does not itself directly impose any new requirements on small entities. See *Mid-Tex Electric Cooperative, Inc. v. FERC*, 773 F.2d 327 (D.C. Cir. 1985) (agency's certification need only consider the rule's impact on entities subject to the requirements of the rule). Instead, this action merely removes a regulatory provision made inapplicable by the D.C. Circuit Court's ruling that vacated the revised PM-10 NAAQS which was the underlying basis for the requirement.

Therefore, I certify that this regulatory action will not have a significant impact on a substantial number of small entities within the meaning of those terms for RFA purposes.

C. Unfunded Mandates

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

Today's regulatory action does not include a Federal mandate that may result in estimated costs of \$100 million or more to either State, local, or tribal governments in the aggregate or to the private sector. This regulatory action removes § 50.6, paragraph (d), from the CFR. The effect of this action is that the pre-existing PM-10 standards, as codified at 40 CFR, § 50.6(a) and (b), will remain applicable in those areas where they currently apply. The consequences of this action should not result in any additional costs within the affected areas.

D. Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risks

Executive Order 13045: "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885,

April 23, 1997) applies to any rule that: (1) is determined to be "economically significant" as defined under Executive Order 12866, and (2) concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency.

The EPA interprets Executive Order 13045 as applying only to those regulatory actions that are based on health or safety risks, such that the analysis required under section 5-501 of the Order has the potential to influence the regulation. This regulatory action is not subject to Executive Order 13045 because this is not an economically significant regulatory action as defined by Executive Order 12866, and it removes a no longer applicable portion of a previously-promulgated health or safety-based Federal standard, and does not itself involve decisions that affect environmental health or safety risks.

E. Executive Order 13132: Federalism

Executive Order 13132, entitled Federalism (64 FR 43255, August 10, 1999), requires EPA to develop an accountable process to ensure "meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications." "Policies that have federalism implications" are defined in the Executive Order to include regulations that have "substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government." Under Section 6 of Executive Order 13132, EPA may not issue a regulation that has federalism implications, that imposes substantial direct compliance costs, and that is not required by statute, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by State and local governments, or EPA consults with State and local officials early in the process of developing the proposed regulation. The EPA also may not issue a regulation that has federalism implications and that preempts State law unless the Agency consults with State and local officials early in the process of developing the proposed regulation.

The EPA concludes that this regulatory action will not have

substantial federalism implications, as specified in Section 6 of Executive Order 13132 (64 FR 43255, August 10, 1999), because, as noted previously, this action would simply remove § 50.6, paragraph (d), from the CFR. The effect of this action is that the pre-existing PM-10 standards, as codified at 40 CFR, § 50.6(a) and (b), will remain applicable in those areas where they currently apply. Consequently, this action will not directly impose significant new requirements on any area, or substantially alter the relationship or the distribution of power and responsibilities between the States and the Federal government.

F. Executive Order 13084: Consultation and Coordination With Indian Tribal Governments

Under Executive Order 13084, EPA may not issue a regulation that is not required by statute that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments, or EPA consults with those governments. If EPA complies by consulting, Executive Order 13084 requires EPA to provide to OMB, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected officials and other representatives of Indian tribal governments "to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities."

Today's regulatory action does not significantly or uniquely affect the communities of Indian tribal governments. This action does not involve or impose any requirements that directly affect Indian tribes. Under EPA's tribal authority rule, tribes are not required to implement CAA programs but, instead, have the opportunity to do so. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

G. Paperwork Reduction Act

This action does not contain any information collection requirements which require OMB approval under the

Paperwork Reduction Act (44 U.S.C. 3501 et seq.).

H. Executive Order 12898: Environmental Justice

Under Executive Order 12898, each Federal agency must make achieving environmental justice part of its mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of its programs, policies, and activities on minorities and low-income populations. Today's action, removing 40 CFR 50.6(d), does not adversely affect minorities and low-income populations.

I. National Technology Transfer and Advancement Act

Section 12 of the National Technology Transfer and Advancement Act (NTTAA) of 1995 requires Federal agencies to evaluate existing technical standards when developing new regulations. To comply with NTTAA, the EPA must consider and use "voluntary consensus standards" (VCS) if available and applicable when developing programs and policies unless doing so would be inconsistent with applicable law or otherwise impractical.

The EPA believes that VCS are inapplicable to this action. Today's action does not require the public to perform activities conducive to the use of VCS.

J. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 et seq., as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. The EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2). This rule will become effective 30 days after publication in the **Federal Register**.

List of Subjects in 40 CFR Part 50

Environmental protection, Air pollution control, Particulate matter.

Dated: December 13, 2000.

Carol M. Browner,
Administrator.

For the reasons set out in the preamble, chapter I, title 40 of the Code of Federal Regulations is amended as follows:

PART 50—[AMENDED]

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

Authority: 42 U.S.C. 7401, et seq.

§ 50.6 [Amended]

2. Section 50.6 is amended by removing paragraph (d).

[FR Doc. 00–32666 Filed 12–21–00; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[CO–001–0044a; FRL–6875–5]

Approval and Promulgation of Air Quality Implementation Plans; State of Colorado; Colorado Springs Revised Carbon Monoxide Maintenance Plan, and Approval of a Related Revision

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: On May 10, 2000, the Governor of Colorado submitted a revised maintenance plan for the Colorado Springs carbon monoxide (CO) maintenance area for the CO National Ambient Air Quality Standard (NAAQS). In addition, the Governor also submitted revisions to Colorado's Regulation No. 13 "Oxygenated Fuels Program". In this action, EPA is approving the Colorado Springs CO revised maintenance plan and the revisions to Regulation No. 13.

DATES: This direct final rule is effective on February 20, 2001 without further notice, unless EPA receives adverse comments by January 22, 2001. If adverse comment is received, EPA will publish a timely withdrawal of the direct final rule in the **Federal Register** and inform the public that the rule will not take effect.

ADDRESSES: Written comments may be mailed to: Richard R. Long, Director, Air and Radiation Program, Mailcode 8P–AR, United States Environmental Protection Agency, Region VIII, 999 18th Street, Suite 300, Denver, Colorado 80202–2466.

Copies of the documents relevant to this action are available for public

inspection during normal business hours at the following offices:

United States Environmental Protection Agency, Region VIII, Air and Radiation Program, 999 18th Street, Suite 300, Denver, Colorado 80202–2466; and

United States Environmental Protection Agency, Air and Radiation Docket and Information Center, 401 M Street, SW, Washington, DC 20460.

Copies of the State documents relevant to this action are available for public inspection at:

Colorado Air Pollution Control Division, Colorado Department of Public Health and Environment, 4300 Cherry Creek Drive South, Denver, Colorado, 880246–1530.

FOR FURTHER INFORMATION CONTACT: Tim Russ, Air and Radiation Program, Mailcode 8P–AR, United States Environmental Protection Agency, Region VIII, 999 18th Street, Suite 300, Denver, Colorado 80202–2466; Telephone number: (303) 312–6479.

SUPPLEMENTARY INFORMATION:

Throughout this document wherever "we," "us," or "our" are used we mean the Environmental Protection Agency.

I. What is the Purpose of This Action?

In this action, we are approving a revised maintenance plan for the Colorado Springs CO attainment/maintenance area, that is designed to keep the area in attainment for CO through 2010, and we're also approving changes to the State's Regulation No. 13 for the removal of the requirement for the implementation of the wintertime oxygenated fuels program in the Colorado Springs area.

We approved the original CO redesignation request to attainment, a maintenance plan, and revisions to Regulation No. 13 (hereafter, Reg. 13) for the Colorado Springs area on August 25, 1999 (see 64 FR 46279) which became effective on October 25, 1999.

The Governor's May 10, 2000, submittal includes changes to the original maintenance plan that: revises the attainment year from 1993 to 1990 and provides a new 1990 attainment year inventory; revises the maintenance demonstration with a revised 2010 projected emission inventory; revises Reg. 13 to eliminate the oxygenated gasoline program in El Paso County starting with the winter season of 2000–2001; revises the transportation CO emission budgets; and revises a portion of the contingency measures plan. We have determined that these changes are approvable as further described below.

II. What is the State's Process to Submit These Materials to EPA?

Section 110(k) of the CAA addresses our actions on submissions of revisions to a SIP. The CAA requires States to observe certain procedural requirements in developing SIP revisions for submittal to us. Section 110(a)(2) of the CAA requires that each SIP revision be adopted after reasonable notice and public hearing. This must occur prior to the revision being submitted by a State to us.

The Colorado Air Quality Control Commission (AQCC) held a public hearing for the revised Colorado Springs Carbon Monoxide (CO) Maintenance Plan on February 17, 2000. The AQCC adopted the revised maintenance plan directly after the hearing. This SIP revision became State effective on April 30, 2000, and was submitted by the Governor to us on May 10, 2000.

For the Regulation No. 13 revision, the AQCC held a public hearing to consider the changes to Regulation No. 13, that involved the elimination of the oxygenated gasoline program for El Paso County, on February 17, 2000. The AQCC adopted these changes directly after the February 17, 2000, public hearing. They became State effective on April 30, 2000, and were also submitted to us on May 10, 2000.

We have evaluated the Governor's submittal for the revised maintenance plan and changes to Regulation No. 13 and have determined that the State met the requirements for reasonable notice and public hearing under section 110(a)(2) of the CAA. We reviewed these SIP materials for conformance with the completeness criteria in 40 CFR part 51, appendix V and determined that the submittals were administratively and technically complete. The Governor was advised of our completeness determination through a letter from Rebecca W. Hanmer, Acting Regional Administrator, dated August 7, 2000.

III. EPA's Evaluation of the Revised Maintenance Plan

EPA has reviewed the State's revised maintenance plan for the Colorado Springs maintenance/attainment area and believes that approval is warranted. The following are the key aspects of this revision along with our evaluation of each:

(a) The State changed the attainment year from 1993 to 1990 and provided a new 1990 emissions inventory.

This is acceptable as the Colorado Springs area was attaining the CO NAAQS in 1990 (based on data from 1990 and 1991 which are archived in our Aerometric Information and

Retrieval System—AIRS) and this conforms to our September 4, 1992, redesignation guidance memorandum, signed by John Calcagni, Director of the Air Quality Management Division, entitled “Procedures for Processing Requests to Redesignate Areas to Attainment” (hereafter the “Calcagni memorandum”). Further, the area must show continuous attainment of the CO NAAQS from 1990 to present. We have reviewed the air quality data in AIRS from 1990 to present and have determined that the Colorado Springs

area has not violated the CO standard and continues to demonstrate attainment.

(b) The State revised the projected emission inventories, out to 2010, and continues to demonstrate maintenance for the Colorado Springs area.

Revised emission projections for the years 2001, 2002, 2005, and 2010 (we note that 2015 and 2020 are also included for conformity purposes) that include all source categories (point, area, non-road, and on-road) and reflect the elimination of the oxygenated fuels program are presented in “Table 3.

Carbon Monoxide Emissions for Future Years in Colorado Springs without the Oxygenated Fuels Program” of the revised maintenance plan and are archived below. All emission calculations and assumptions are provided in the State’s Technical Support Document (TSD). As shown in the maintenance plan’s Table 3. and in our Table III–1 below, emissions for all future projected year inventories are less than the 1990 levels. Therefore, the area continues to demonstrate maintenance for the CO standard.

TABLE III–1.—SUMMARY OF CO EMISSIONS IN TONS PER DAY FOR COLORADO SPRINGS

	1990	2001	2002	2005	2010
Emissions from Point, Area, & Non-road Sources	85	98	99	100	100
On-Road Mobile Sources (without Oxyfuels in 2001 and beyond)	295	209	203	194	193
Total	380	307	302	294	293

(c) The State has modified Regulation No. 13 to eliminate the Oxygenated Fuels Program for El Paso County and the Colorado Springs area.

The State performed an analysis and determined that the oxygenated fuels program could be eliminated for the Colorado Springs area without jeopardizing maintenance of the CO NAAQS. This analysis was performed using EPA’s MOBILE5b emission factor model and the latest transportation and planning data from the Pike’s Peak Area Council of Governments (PPACG) 2020 transportation plan. The methodology and analysis were reviewed by us and we have determined they are acceptable. The results of the modeling were presented in the revised maintenance plan’s “Table 1.,” “Table 2.,” and “Table 3” and are also included in our Table III–1 above. Based on our review of the State’s analysis, we agree that the Colorado Springs area continues to demonstrate maintenance of the CO NAAQS and approve the elimination of the oxygenated fuels program for El Paso County and the Colorado Springs area.

(d) The State modified the Contingency Provisions section of the maintenance plan.

With the elimination of the oxygenated fuels program for the Colorado Springs area, the State revised the contingency measures list in section “E. Contingency Provisions” to now contain the reinstatement of the 2.7% oxygenated fuels program as a contingency measure that could be implemented should the Colorado Springs area violate the CO NAAQS. Also, the State removed the prior

nonattainment area regulatory requirement that an enhanced inspection and maintenance program be a pre-approved contingency measure.

An enhanced inspection and maintenance program now appears on the same list as the 2.7% oxygenated fuels program as possible contingency measures for consideration, adoption, and implementation should a violation of the CO NAAQS occur. We agree with the above revisions to the “Contingency Provisions” section of the maintenance plan.

IV. EPA’s Evaluation of the Transportation Conformity Requirements

One key provision of our conformity regulation requires a demonstration that emissions from the transportation plan and Transportation Improvement Program are consistent with the emissions budgets in the SIP (40 CFR 93.118 and 93.124). The emissions budget is defined as the level of mobile source emissions relied upon in the attainment or maintenance demonstration to maintain compliance with the NAAQS in the nonattainment or maintenance area. The rule’s requirements and EPA’s policy on emissions budgets are found in the preamble to the November 24, 1993, transportation conformity rule (58 FR 62193–62196) and in the sections of the rule referenced above. Section C. of the revised Colorado Springs maintenance plan describes an emissions budget for on-road mobile sources. The revised section C. now states:

For the Colorado Springs attainment/maintenance area, the emissions budget is for

the period 2001 and beyond and this budget utilizes the “margin of safety” provisions of EPA’s transportation conformity rule. The rule indicates that where projected emissions from all sources are less than the amount demonstrating attainment, which is the case for the Colorado Springs area, the SIP may explicitly quantify the safety margin and include some of all of it in the motor vehicle emissions budget for purposes of conformity. When the calculations are made, there are different margins of safety for each interim year between 2001 and 2010, which could result in the establishment of different emissions budgets for each year. Because this is not practical, an emissions budget slightly less than the lowest potential emissions budget is adopted for all future years.”

The State then performed calculations (in tons per day, abbreviated as “tpd”) for each of the interim years such as in the example below for 2001:

380 tpd (1990 total emissions)—307 tpd (2001 total emissions) = 73 tpd (2001 margin of safety); 73 tpd + 209 tpd (2001 mobile emissions) = 282 tpd (potential emission budget for 2001)

The State then did the same calculations for the other interim years and came up with potential emission budgets of; 281 tpd for 2002, 280 tpd for 2005, and 280 tpd for 2010. In order to allow for uncertainties in non-mobile source emissions, and because all interim years’ emissions between 2001 and 2010 were not determined, the State took the lowest potential emissions budget of 280 tpd and further reduced this to 270 tpd to allow for potential variations in emissions and to stay below the 1990 total attainment emission level of 380 tpd. The State then set this 270 tpd on-road mobile emissions budget for 2001 and beyond.

We agree with the State's calculations and allocation of the margin of safety, and therefore, we are approving this 270 tpd mobile sources emission budget for 2001 and beyond.

This 270 tpd budget was then adopted into section V.A.4.b. of the Colorado AQCC's Ambient Air Quality Standards regulation (5 CCR 1001-14); however, the emissions budget definition in the table on page 18.01 of the Colorado Ambient Air Quality Standards regulation (5 CCR 1001-14) conflicts with the language in section C. of the maintenance plan and is internally inconsistent. Section C. of the maintenance plan states that the 270 tpd emission budget applies to 2001 and beyond; the table on page 18.01 of 5 CCR 1001-14 indicates that the emissions budget is 280 tpd in 2010 and beyond. Our interpretation, based on the language of the maintenance plan and our conformity rule, is that the maintenance plan's 270 tpd emission budget applies starting in 2001 and for all following years, superseding the incorrect language in 5 CCR 1001-14.

V. EPA's Evaluation of the Regulation No. 13 Revisions

Colorado's Regulation No. 13 is entitled "Oxygenated Fuels Program." The purpose of revisions that were adopted by the AQCC on February 17, 2000, and submitted to us by the Governor on May 10, 2000, was to eliminate the oxygenated fuels program for El Paso County and the Colorado Springs area. EPA is allowed to approve this elimination of the oxygenated fuels program for El Paso County and the Colorado Springs area based on section 211(m)(6) of the CAA which states:

ATTAINMENT AREAS—Nothing in this subsection shall be interpreted as requiring an oxygenated gasoline program in an area which is in attainment for carbon monoxide, except that in a carbon monoxide nonattainment area which is redesignated as attainment for carbon monoxide, the requirements of this subsection shall remain in effect to the extent such program is necessary to maintain such standard thereafter in the area. The State has satisfied the above requirements of section 211(m)(6) as follows:

(a) The Colorado Springs area is in attainment for the CO NAAQS. EPA approved the Colorado Springs CO redesignation to attainment on August 25, 1999 (see 64 FR 46279, effective October 25, 1999). In addition, ambient air quality that have been archived in AIRS show that the Colorado Springs area has been in attainment for the CO NAAQS beginning with the period of 1990-1991 and the area has been in

attainment for the CO NAAQS from that time to the present.

(b) The State has provided an adequate demonstration showing that the oxygenated fuels program is not needed to maintain the CO NAAQS for the Colorado Springs attainment area. This requirement was addressed with the State's revised maintenance plan for the Colorado Springs area. As presented in section "B. Emission Inventories and Maintenance Demonstration" of the revised maintenance plan, the State used EPA's MOBILE5b emission factor model to calculate mobile source emissions, without an oxygenated fuels program, for 2001, 2002, 2005, and 2010. For each projected year, mobile source emissions were less than the 1990 attainment year levels. When mobile source emissions were added to the other source categories for 2001, 2002, 2005, and 2010, total emissions for each year were still well below the 1990 attainment year levels. Therefore, elimination of the oxygenated fuels program will not interfere with continued maintenance of the CO NAAQS. In addition to the 1990 and 2010 region-wide inventories, the State prepared a 1990 and 2010 gridded emission inventory and evaluated projected growth in CO emissions in each grid cell. This assessment also indicated that the CO NAAQS would be maintained without an oxygenated fuels program.

Based on the above, the State concluded that the revisions to Regulation No. 13, to eliminate the oxygenated fuels program, would not jeopardize the revised maintenance plan's demonstration of maintenance for the CO NAAQS. We agree with the State's analysis provided in section "B." of the revised maintenance plan and as further supported in the State's TSD. Therefore, we do not believe that the elimination of the oxygenated fuels program in El Paso County and the Colorado Springs area will impact the CO maintenance demonstration for the area.

In consideration of above, we have determined that we can approve the February 17, 2000, revisions to Regulation No. 13 as meeting the requirements of section 211(m)(6) of the CAA.

As noted previously, the revisions to Regulation No. 13 were adopted by the AQCC directly after a public hearing on February 17, 2000, became State effective on April 30, 2000, and were submitted to us by the Governor on May 10, 2000.

VI. Final Action

In this action, EPA is approving the revised Colorado Springs carbon monoxide maintenance plan and the revisions to Regulation No. 13.

EPA is publishing this action without prior proposal because the Agency views this as a noncontroversial amendment and anticipates no adverse comments. However, in the proposed rules section of this **Federal Register** publication, we are publishing a separate document that will serve as the proposal to approve the SIP revision should adverse comments be filed. This rule will be effective February 20, 2001 without further notice unless the Agency receives adverse comments by January 22, 2001.

If EPA receives such comments, then we will publish a timely withdrawal of the direct final rule informing the public that the rule will not take effect. All public comments received will then be addressed in a subsequent final rule based on the proposed rule. The EPA will not institute a second comment period on this rule. Any parties interested in commenting on this rule should do so at this time. If no such comments are received, the public is advised that this rule will be effective on February 20, 2001 and no further action will be taken on the proposed rule.

Administrative Requirements

(a) Executive Order 12866

The Office of Management and Budget (OMB) has exempted this regulatory action from Executive Order 12866, entitled "Regulatory Planning and Review."

(b) Executive Order 12875: Enhancing the Intergovernmental Partnership

Under Executive Order 12875, EPA may not issue a regulation that is not required by statute and that creates a mandate upon a state, local, or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments, or EPA consults with those governments. If EPA complies by consulting, Executive Order 12875 requires EPA to provide to the Office of Management and Budget a description of the extent of EPA's prior consultation with representatives of affected state, local, and tribal governments, the nature of their concerns, copies of any written communications from the governments, and a statement supporting the need to issue the regulation. In addition, Executive Order 12875 requires EPA to develop an effective process permitting

elected officials and other representatives of state, local, and tribal governments "to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates."

Today's rule does not create a mandate on state, local, or tribal governments. The rule does not impose any enforceable duties on state, local, or tribal governments. Accordingly, the requirements of section 1(a) of Executive Order 12875 do not apply to this rule.

(c) Executive Order 13045

Executive Order 13045, *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997), applies to any rule that: (1) is determined to be "economically significant" as defined under Executive Order 12866, and (2) concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health and safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency.

This rule is not subject to Executive Order 13045 because it does not involve decisions intended to mitigate environmental health or safety risks.

(d) Executive Order 13084: Consultation and Coordination With Indian Tribal Governments

Under Executive Order 13084, EPA may not issue a regulation that is not required by statute, that significantly affects or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments, or EPA consults with those governments. If EPA complies by consulting, Executive Order 12084 requires EPA to provide to the Office of Management and Budget, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected officials and other

governments "to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities."

Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

(e) Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) generally requires an agency to conduct a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small not-for-profit enterprises, and small governmental jurisdictions. This final rule will not have a significant impact on a substantial number of small entities because SIP approvals under section 110 and subchapter I, part D of the Clean Air Act do not create any new requirements, but simply approve requirements that the State is already imposing. Therefore, because the Federal SIP approval does not create any new requirements, I certify that this action will not have a significant economic impact on a substantial number of small entities. Moreover, due to the nature of the Federal-State relationship under the Clean Air Act, preparation of a flexibility analysis would constitute Federal inquiry into the economic reasonableness of State action. The Clean Air Act forbids EPA to base its actions concerning SIPs on such grounds. *Union Electric Co. v. U.S. EPA*, 427 U.S. 246, 255-66 (1976); 42 U.S.C. 7410(a)(2). Therefore, I certify this rule will not affect a substantial number of small entities.

(f) Unfunded Mandates

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

governments that may be significantly or uniquely impacted by the rule.

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

(g) Submission to Congress and the Comptroller General

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

(h) Petitions for Judicial Review

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by February 20, 2001. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Incorporation by reference, Intergovernmental relations, Reporting and recordkeeping requirements.

Dated: September 14, 2000.

Patricia D. Hull,

Acting Regional Administrator, Region VIII.

Chapter I, title 40, part 52 of the Code of Federal Regulations are amended as follows:

PART 52—[AMENDED]

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

Authority: 42 U.S.C. 7401 *et seq.*

Subpart G—COLORADO

2. Section 52.320 is amended by adding paragraph (c)(89) to read as follows:

§ 52.320 Identification of plan.

* * * * *

(c) * * *

(89) On May 10, 2000, the Governor of Colorado submitted revisions to Regulation No. 13 “Oxygenated Fuels Program” that eliminated the Oxygenated Fuels Program for El Paso County and the Colorado Springs CO attainment/maintenance area.

(i) Incorporation by reference.

(A) Regulation No. 13 “Oxygenated Fuels Program”, 5 CCR 1001–16, as adopted on February 17, 2000, effective April 30, 2000, as follows: Sections I.D.19, II.A, II.A.1, II.A.2, II.C.1.a, II.C.1.b., and II.C.1.c.

3. Section 52.349 is amended by adding paragraph (e) to read as follows:

§ 52.349 Control strategy: Carbon monoxide.

* * * * *

(e) Revisions to the Colorado State Implementation Plan, Carbon Monoxide Revised Maintenance Plan for Colorado Springs, as adopted by the Colorado Air Quality Control Commission on February 17, 2000, State effective April 30, 2000, and submitted by the Governor on May 10, 2000.

[FR Doc. 00–32300 Filed 12–21–00; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY**40 CFR Part 52**

[DC048–2023; FRL–6921–1]

Approval and Promulgation of Air Quality Implementation Plans; District of Columbia; Nitrogen Oxides Budget Program

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is approving a State Implementation Plan (SIP) revision submitted by the District of Columbia (the District). This revision implements the District’s portion of the Ozone Transport Commission’s (OTC) September 27, 1994 Memorandum of

Understanding (MOU) which describes a regional nitrogen oxides (NO_x) cap and trade program that will significantly reduce NO_x emissions generated within the Ozone Transport Region (OTR). The intended effect of this action is to approve of the District’s regulations entitled, NO_x Emissions Budget Program as a SIP revision in accordance with the requirements of the Clean Air Act.

EFFECTIVE DATE: This final rule is effective on January 22, 2001.

ADDRESSES: Copies of the documents relevant to this action are available for public inspection during normal business hours at the Air Protection Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103; the Air and Radiation Docket and Information Center, U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460; and the District of Columbia Department of Public Health, Air Quality Division, 51 N Street, NE., Washington, DC 20002.

FOR FURTHER INFORMATION CONTACT: Cristina Fernandez, (215) 814–2178, or via e-mail at fernandez.cristina@epa.gov.

SUPPLEMENTARY INFORMATION:**I. Background**

On August 28, 2000, the District’s Department of Health submitted a revision to its SIP for parallel processing. The revision to the SIP includes the addition of a new Chapter 10, Nitrogen Oxides Emissions Budget Program, to Title 20 of the District of Columbia Municipal Regulations (DCMR). On December 8, 2000, the District submitted fully adopted regulations as a supplement to its August 28, 2000 submittal. The revisions implement the Ozone Transport Commission’s (OTC) September 27, 1994 Memorandum of Understanding (MOU) in the District. In accordance with the MOU, the revisions implement the District portion of a regional NO_x cap and trade program that significantly reduces NO_x emissions generated within the Ozone Transport Region (OTR). On October 19, 2000 (65 FR 62671), EPA published a notice of proposed rulemaking (NPR) for the District of Columbia proposing to approve the August 28, 2000 SIP revision. That NPR provided for a public comment period ending on November 9, 2000. On November 9, 2000 (65 FR 67319), EPA published a notice extending the comment period to November 20, 2000. A detailed description of these SIP revisions and EPA’s rationale for approving them were

provided in the October 19, 2000 NPR and will not be restated here. EPA received no comments on its proposed action to approve this SIP revision.

II. Final Action

EPA is approving the SIP revision request submitted for parallel processing by the District’s Department of Health on August 28, 2000. The SIP revision and its associated regulations were formally adopted by the District of Columbia on December 8, 2000. The District formally submitted the fully adopted regulations to EPA as a supplement to its August 28, 2000 submittal. The regulations formally adopted were exactly the same as the proposed version upon which EPA proposed approval. The SIP revision consists of the District’s Chapter 10—Nitrogen Oxides Emissions Budget Program and implements the District’s portion of Phase II of the OTC’s MOU to reduce nitrogen oxides. Approval of this SIP revision is necessary for full approval of the attainment demonstration SIP for the Metropolitan Washington, DC ozone nonattainment area.

III. Administrative Requirements**A. General Requirements**

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is not a “significant regulatory action” and therefore is not subject to review by the Office of Management and Budget. This action merely approves state law as meeting federal requirements and imposes no additional requirements beyond those imposed by state law. Accordingly, the Administrator certifies that this rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). Because this rule approves pre-existing requirements under state law and does not impose any additional enforceable duty beyond that required by state law, it does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). For the same reason, this rule also does not significantly or uniquely affect the communities of tribal governments, as specified by Executive Order 13084 (63 FR 27655, May 10, 1998). This rule will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132 (64 FR 43255,

August 10, 1999), because it merely approves a state rule implementing a federal standard, and does not alter the relationship or the distribution of power and responsibilities established in the Clean Air Act. This rule also is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997), because it is not economically significant. In reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the Clean Air Act. In this context, in the absence of a prior existing requirement for the State to use voluntary consensus standards (VCS), EPA has no authority to disapprove a SIP submission for failure to use VCS. It would thus be inconsistent with applicable law for EPA, when it reviews a SIP submission, to use VCS in place of a SIP submission that otherwise satisfies the provisions of the Clean Air Act. Thus, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply. As required by section 3 of Executive Order 12988 (61 FR 4729, February 7, 1996), in issuing this rule, EPA has taken the necessary steps to eliminate drafting errors and ambiguity, minimize potential litigation, and provide a clear legal standard for affected conduct. EPA has complied with Executive Order 12630 (53 FR 8859, March 15, 1988) by examining the takings implications of the rule in accordance with the "Attorney General's Supplemental Guidelines for

the Evaluation of Risk and Avoidance of Unanticipated Takings" issued under the executive order. This rule does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

B. Submission to Congress and the Comptroller General

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

C. Petitions for Judicial Review

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by February 20, 2001. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial

review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action to approve the District of Columbia NO_x Budget Program may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

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

Dated: December 14, 2000.

Bradley M. Campbell,
Regional Administrator, Region III.

40 CFR part 52 is amended as follows:

PART 52—[AMENDED]

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

Authority: 42 U.S.C. 7401 *et seq.*

Subpart J—District of Columbia

2. In § 52.470, an entry for Chapter 10 is added in numerical order in the "EPA Approved Regulations in the District of Columbia SIP" table in paragraph (c) to read as follows:

§ 52.470 Identification of plan.

* * * * *

(c) EPA approved regulations.

EPA-APPROVED REGULATIONS IN THE DISTRICT OF COLUMBIA SIP

State Citation	Title/Subject	State Effective Date	EPA Approval Date	Comments
*	*	*	*	*
CHAPTER 10 NITROGEN OXIDES EMISSIONS BUDGET PROGRAM				
Section 1000	Applicability	12/08/00	December 22, 2000.	
			65 FR 80784.	
Section 1001	General Provisions	12/08/00		
Section 1002	Allowance Allocation	12/08/00		
Section 1003	Permits	12/08/00		
Section 1004	Allowance Transfer and Use	12/08/00		
Section 1005	Allowance Banking	12/08/00		
Section 1006	NO _x Allowance Tracking System	12/08/00		
Section 1007	Emission Monitoring	12/08/00		
Section 1008	Record Keeping	12/08/00		
Section 1009	Reporting	12/08/00		
Section 1010	End-Of-Season Reconciliation	12/08/00		
Section 1011	Compliance Certification	12/08/00		
Section 1012	Penalties	12/08/00		
Section 1013	Program Audit	12/08/00		
Section 1099	Definitions and Abbreviations	12/08/00		
*	*	*	*	*

[FR Doc. 00-32566 Filed 12-21-00; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 70

[MT-001a; FRL-6920-4]

Clean Air Act Full Approval of Operating Permit Program; State of Montana

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final Rule.

SUMMARY: The EPA is promulgating full approval of the operating permit program submitted by the State of Montana. Montana's operating permit program was submitted for the purpose of meeting the federal Clean Air Act (Act) directive that states develop, and submit to EPA, programs for issuing operating permits to all major stationary sources and to certain other sources within the states' jurisdiction.

DATES: This final rule is effective on January 22, 2001.

ADDRESSES: Copies of the documents relevant to this action are available for public inspection during normal business hours at the U.S. Environmental Protection Agency, Air and Radiation Program, Region 8, 999 18th Street, Suite 300, Denver, Colorado 80202-2466 and are also available during normal business hours at the Montana Department of Environmental Quality, 1520 East 6th Avenue, Helena, Montana 59620-0901.

FOR FURTHER INFORMATION CONTACT:

Patricia Reisbeck, 8P-AR, U.S. Environmental Protection Agency, Region 8, 999 18th Street, Denver, Colorado 80202-2466, (303) 312-6435.

SUPPLEMENTARY INFORMATION:

I. Background

As required under Title V of the Clean Air Act ("the Act") as amended (42 U.S.C. 7401 *et seq.*), EPA has promulgated rules that define the minimum elements of an approvable state operating permit program and the corresponding standards and procedures by which EPA will approve, oversee, and withdraw approval of state operating permit programs (see 57 FR 32250 (July 21, 1992)). These rules are codified at 40 Code of Federal Regulations (CFR) part 70 (part 70). Title V directs states to develop, and submit to EPA, programs for issuing operating permits to all major stationary sources and to certain other sources.

The Act directs states to develop and submit operating permit programs to EPA by November 15, 1993, and requires that EPA act to approve or disapprove each program within 1 year after receiving the submittal. The EPA's program review occurs pursuant to section 502 of the Act (42 U.S.C. 7661a) and the part 70 regulations, which together outline criteria for approval or disapproval. Where a program substantially, but not fully, meets the requirements of part 70, EPA may grant the program interim approval. If EPA has not fully approved a program by two years after the November 15, 1993 date, or before the expiration of an interim program approval, it must establish and implement a federal program. The State of Montana was granted final interim approval of its program on May 11, 1995 (see 60 FR 25143) and the program became effective on June 12, 1995. Interim approval of the Montana program expires on December 1, 2001.

On June 13, 2000, EPA published a direct final rule in the **Federal Register** promulgating full approval of the Operating Permit Program for the State of Montana. See 65 FR 37049. The EPA received adverse comments on the direct final rule, which are summarized and addressed below. As stated in the **Federal Register** notice, if adverse comments were received by July 13, 2000, the rule would be withdrawn and timely notice would be published in the **Federal Register**. Therefore, due to receiving adverse comments within the comment period, EPA withdrew the final rule (65 FR 48391, August 8, 2000), and a proposed rule also published in the **Federal Register** on June 13, 2000 served as the proposed rule for this action. EPA will not institute a second comment period on this document.

In this rulemaking, EPA is taking final action to promulgate full approval of the Montana Operating Permit Program.

II. Analysis of State Submission

The Governor of Montana submitted an administratively complete Title V operating permit program for the State of Montana on March 29, 1994. This program, including the operating permit regulations (Title 16, Chapter 8, Sub-Chapter 20, Sections 16.8.2001 through 16.8.2025, inclusive, of the Administrative Rules of Montana (ARM)), substantially met the requirements of part 70. EPA deemed the program administratively complete in a letter to the Governor dated May 12, 1994. The program submittal included a legal opinion from the Attorney General of Montana stating that the laws of the State provide adequate legal authority to carry out all aspects of the program, and

a description of how the State would implement the program. The submittal additionally contained evidence of proper adoption of the program regulations, application and permit forms, and a permit fee demonstration.

EPA's comments noting deficiencies in the Montana program were sent to the State in a letter dated October 3, 1994. The deficiencies were segregated into those that would require corrective action prior to interim program approval, and those that would require corrective action prior to full program approval. The State committed to address the program deficiencies that would require corrective action prior to interim program approval in a letter dated October 20, 1994. The State submitted these corrective actions with letters dated March 30, and April 5, 1995. EPA reviewed these corrective actions and determined them to be adequate for interim program approval.

On January 15, 1998, Montana amended its operating permit program to make the corrections identified as necessary in the May 11, 1995 **Federal Register** notice of final interim approval. These program amendments, recodified at Title 17, Chapter 8, Sub-Chapter 12, Sections 1201, 1210, and 1213, ARM, were approved and adopted by the Montana Board of Environmental Review on January 15, 1998. The revised program regulations adequately addressed the problems identified in the May 11, 1995 **Federal Register** notice as requiring corrective action prior to full program approval. The State also submitted evidence of proper adoption of the revisions to its program regulations and a revised Attorney General's opinion dated July 31, 1998. The revised program and a request for full approval were submitted to EPA in a letter from the Governor of Montana dated February 4, 1999. EPA notified Montana, in a letter to the Department of Environmental Quality (DEQ) dated April 1, 1999, of two additional changes required for final approval. The DEQ revised the administrative rules to implement the two requested changes at Title 17, Chapter 8, Sub-Chapter 12, ARM. These amendments to Sub-Chapter 12 were approved and adopted by the Board on March 17, 2000. On April 12, 2000, the Governor of Montana submitted the revised program, with proof of proper adoption, and requested full approval of its operating permit program. EPA reviewed these changes and determined that they were adequate to allow for full approval. On June 13, 2000, EPA published a direct final rule in the **Federal Register** promulgating full approval of the Operating Permit Program for the State of Montana. See

65 FR 37049. The EPA received adverse comments on the direct final rule and, on August 8, 2000, published withdrawal of the direct final rule approval in the **Federal Register**. See 65 FR 48391.

III. Response to Comments

The comments received on the June 13, 2000 direct final rule in the **Federal Register** promulgating full approval of the Montana operating permit program, and EPA's response to these comments are as follows:

Comment 1: The commenter objected to EPA's approval of the Montana Operating Permit Program because a state regulation allows the administrative permit amendment process to be used for certain permit changes that are not listed in a regulation but that the Montana Department of Environmental Quality ("Department") and EPA determine are similar to the listed revisions. A list of revisions that qualify for administrative permit amendment is found in Administrative Rules of Montana ("ARM") Section 17.8.1201(1)(a) through (d). This regulation allows a source to use the administrative permit amendment process for such non-substantive changes as change in address and correction of typographical errors. The State has now added section (e), which allows "any other change which the department and EPA have determined to be similar" to the listed revisions. The commenter objected that, by allowing the Department and EPA to add other kinds of permit revisions to the list without public notice and comment, the state regulation violates EPA's regulations at 40 CFR Part 70 ("part 70 program" or "part 70 rules").

EPA Response: The definition of "administrative permit amendment" in EPA's regulations is found in 40 CFR 70.7(d)(1). The definition provides, at § 70.7(d)(1)(vi), that an administrative permit amendment "[i]ncorporates any other type of change which the Administrator has determined as part of the approved part 70 program to be similar to those in paragraphs (d)(1)(i) through (iv) of this section" 40 CFR 70.7(d)(1)(vi). The enumerated paragraphs (i) through (iv) comprise a list of four non-substantive changes that are identical to those in the State's list in section 17.8.1201(1) (a) through (d). The comment suggests that the State cannot allow a source to use an administrative permit amendment for a change that is not on the list, unless the State first undergoes formal Title V program approval or program revision approval, with public notice and comment, to add the change to the list

as a new requirement. The comment implies that "as part of the approved part 70 program" in EPA's regulation means "as part of the part 70 program approval process."

EPA does not agree with this interpretation of our regulation. EPA believes that the correct interpretation of the phrase "as part of the approved part 70 program" refers to the fact that an unlisted change must be evaluated in the context of the approved state program to determine if it qualifies for an administrative amendment. The regulation does not require that EPA must approve a formal revision of the state program before a source can make a particular change administratively, but rather requires the State to seek EPA's approval for using the administrative permit amendment process for the change as part of a specific permitting action. EPA believes that the regulation allows the State to add to the list of non-substantive changes on a case-by-case basis, if EPA agrees that a particular permit change is of the same non-substantive nature as the enumerated list of changes that automatically qualify for administrative permit amendment. EPA's regulation thus allows exactly the kind of case-specific addition to the list contemplated in the new section of Montana's rules, ARM Section 17.8.1201(1)(e).

Montana initially proposed a regulation that would allow the state to make additions to the list without consulting EPA. EPA advised that this would not be acceptable under Title V of the Clean Air Act ("Act"), since 40 CFR 70.7(d)(1)(vi) requires that EPA must make a determination that any additional change is similar to the enumerated changes—in other words, to determine that the change is of such a trivial or non-substantive nature that the administrative permit amendment process would be appropriate. The regulation does not require that the State must submit a list of anticipated non-substantive changes to EPA for prior approval, as part of the Title V program approval process, or that the State must revise its rules and submit them for approval as a program revision whenever it encounters a non-substantive change it believes should qualify for treatment as an administrative permit amendment. The provision requires, instead, that the State must notify EPA on a case-by-case basis whenever it encounters a change it believes qualifies for the simpler administrative amendment process (rather than the more complex minor or significant permit modification process), so that EPA can decide if we agree that the change qualifies for such treatment.

If we do not agree that the administration permit amendment process is appropriate for a particular permit change, we can advise the State of our disapproval at the draft permit stage of the operating permit process, or we can object to the proposed permit during our 45-day review and thus prevent the permit's issuance. If the permit has already been issued, we can require the state to re-open the permit to delete an unacceptable administrative permit amendment and instead process the change as a minor or significant permit revision.

We appreciate the concern expressed in the comment that the list should not encompass substantive permit changes. EPA would not approve as an administrative permit amendment any non-substantive change to a Title V permit. We anticipate that the authority to add to the list of administrative permit amendments will be used only infrequently.

Comment 2. a.: The commenter objected that allowing an emission threshold of five tons per year of any pollutant other than a hazardous air pollutant in the State's definition of "insignificant emission unit" exceeds the two-ton per year threshold that EPA has set in rules for federal operating permits, 40 CFR part 71 ("part 71 program" or "part 71 rules"). The commenter also stated that the two-ton per year threshold was accepted in many other states. In the **Federal Register** notice proposing interim approval, EPA stated that Montana would need to provide a demonstration to show why a higher threshold of five tons per year would be insignificant. See 60 FR 25143–25144 (May 11, 1995).

EPA Response: Insignificant emissions units are emitting units at a source that emit "insignificant" levels of emissions. For such units, the State may allow permit applicants to omit a full description of the units in their permit applications. However, there are several caveats. The applicant must still list the insignificant activity in its application and must include complete information about such unit if it is or may be subject to any applicable requirements. The pertinent provision of the part 70 rules provides: "the Administrator may approve as part of a State program a list of insignificant activities and emissions levels which need not be included in permit applications. However, for insignificant activities which are exempted because of size or production rate, a list of such insignificant activities must be included in the application. An application may not omit information needed to determine the applicability

of, or to impose, any applicable requirement * * *.” 40 CFR 70.5(c).

This provision of the part 70 rules does not set a ceiling on the level of emissions that will be considered “insignificant.” EPA has allowed states, including Montana, to determine what the state considers to be “insignificant” for the limited purpose of omitting certain information from the permit application. The comparable section in the part 71 rules, 40 CFR 71.5(c)(11), does set such a ceiling: “Potential to emit of regulated air pollutants, excluding HAP [hazardous air pollutants] for any single emissions unit shall not exceed 2 tpy [tons per year].” 40 CFR 71.5(c)(11)(ii)(A). This numerical limit applies only to federal operating permits, however, not to state operating permits or state operating permit programs. EPA’s part 71 rules establish the requirements for the operating permits that EPA issues in Indian country or anywhere else when EPA is the permitting agency. The part 71 rules do not establish minimum requirements for state operating permit programs; state programs may differ from the federal program and may still be approved as long as they meet the applicable state program requirements, which are found in 40 CFR part 70.

The Montana operating permit program differs from the federal program in this respect, but we believe it fully satisfies the program requirements of 40 CFR part 70. The part 70 rules allow permit applicants to omit certain information about “insignificant emissions units” from their permit application. Montana’s rules make clear, however, that if an emissions unit is subject to an applicable requirement other than a generally applicable requirement that applies to all sources, the unit may not be considered an insignificant emissions unit, no matter what its size may be. In other words, a unit emitting five tons per year or less of a regulated pollutant may not be treated as an insignificant emissions unit, if it is subject to a unit-specific limit or a plant-wide applicability limit. Such a unit can only be considered “insignificant” if it is subject to a state-wide regulation, such as a generic limit on opacity, or to no applicable requirements at all. And if a unit emitting five tons per year or less does not qualify for “insignificant” status because it is subject to a source-specific limit, the applicant must provide all relevant information about the unit in the permit application, not simply information necessary to determine the applicability of the applicable requirement. In this respect, Montana’s regulation is actually more

stringent than EPA’s and provides more protection for the public’s right to know than EPA’s regulation does. In any case, we believe there is no conflict with EPA’s part 70 rules.

In response to EPA’s request that the State provide justification for using a five-ton per year cut-off, the Department stated, “Experience has demonstrated that individual emitting units that are not subject to applicable requirements other than generally applicable requirements, and whose potential emissions are less than 5 tpy, have such limited impact that they can be considered insignificant.” Based on our knowledge of Montana’s industrial sources, we agree with the State’s assessment. The Department also noted that both 40 CFR part 70 and EPA’s July 10, 1995 guidance memorandum entitled, “White Paper for Streamlined Development of Part 70 Permit Applications” (“White Paper I”), allow states discretion in selecting an appropriate insignificance level for their Title V programs; and EPA has approved levels higher than two tons per year in some other states. We are aware of at least nine states, including Ohio, Florida, and Tennessee, and ten local permitting authorities with approved Title V programs, where EPA has allowed five tons per year as the cut-off for “insignificant” status. Some other states have a varying level depending on the pollutant (five tons per year for carbon monoxide in Washington State, for example) or an altogether different formula, based on pollutant or process, for determining insignificant levels. We conclude that Montana has adequately justified its use of five tons per year as a ceiling.

Comment 2. b.: For hazardous air pollutants, the commenter objected that Montana defines insignificant emissions as less than 500 pounds per year, whereas EPA’s part 71 rules provide that the insignificance threshold for hazardous air pollutants cannot exceed 1000 pounds per year or the de minimis level established under section 112(g) of the Act, whichever is less.

EPA Response: The comment implies that the part 71 rules establish minimum requirements for state operating permit programs. They do not. State operating permit programs must satisfy the requirements of 40 CFR part 70, not 40 CFR part 71. The requirements of the two programs are not, and do not need to be, identical. In particular, the part 70 rules do not require that states adopt a particular cut-off for emissions of hazardous air pollutants from “insignificant emissions units.” Although the part 71 rules do establish a cut-off, that ceiling applies to

federal operating permits only. In fact, the Montana regulation establishes a more stringent cut-off than the federal level: 500 pounds per year in ARM section 17.8.1201(22)(a)(iii), as opposed to 1000 pounds per year in 40 CFR part 71.

The commenter recognizes that a level even lower than 500 pounds per year could be established under the part 71 rules, as a determination of a de minimis increase in emissions pursuant to section 112(g)(1)(A) of the Act: To date, however, EPA has not implemented the modification provisions of section 112(g) of the Act: EPA has not published guidance under section 112(g)(1)(B) of the Act establishing de minimis levels of emission increases for purposes of applying offsets under section 112(g)(1)(A) of the Act. Therefore, the establishment of an “insignificant” level under the part 71 program which would be lower than 1,000 pounds per year, let alone 500 pounds per year, remains a merely hypothetical possibility. EPA believes that the Montana ceiling for insignificant emissions of hazardous air pollutants is more stringent than the federal requirement and will adequately protect the public interest in disclosure of information about hazardous air pollutants.

Comment 3: The commenter stated that Montana’s rules still do not adequately assure that any monitoring data or other credible evidence can be used to determine compliance and for direct enforcement. The commenter expressed a concern that the wording of ARM 17.8.1213(2), which requires that any data “generated as a condition of the permit” may be used to demonstrate compliance with the conditions of the permit and may be used for direct enforcement, might be interpreted to limit evidence of noncompliance only to monitoring or testing data required by the permit.

EPA Response: EPA does not agree with the suggested interpretation of ARM 17.8.1213(2). We do not believe that the provision, by its terms or by implication, precludes the use of other kinds of evidence to show compliance or noncompliance with applicable requirements. We believe that the provision makes clear that, if the permit requires testing or monitoring, the results of such testing or monitoring may be used as evidence of noncompliance regardless of the effect of any other rule. EPA does agree, however, that Montana must develop a credible evidence rule to eliminate any possibility of ambiguity in its regulations and thus ensure that all evidence of noncompliance may be used

for purposes of direct enforcement, as long as that evidence is credible. Montana is in the process of developing and adopting a credible evidence rule, several versions of which were available for public comment this past summer.

Comment 4: The commenter stated that the State must certify its ability to require annual certifications from part 70 sources regarding proper implementation of their Risk Management Plans (RMP) under section 112(r) of the Act, and must provide a compliance schedule for sources that fail to submit the required plan. EPA's full approval notice does not indicate whether this requirement was in fact met, but merely indicates that "the State will include a statement listing 40 CFR 68.215(a) as an applicable requirement in all Title V operating permits." There is no indication that the State has in fact committed to do this or is legally authorized and obligated to do so.

EPA Response: EPA's full approval notice should have made clear that the Governor of Montana, in a letter dated February 4, 1999, made a commitment to require annual certifications from sources regarding their compliance with all program requirements related to accident prevention, emergency response, and risk management plans under section 112(r) of the Act, and to provide compliance schedules for any sources that fail to submit their required plan to EPA. The letter stated, "The department [of Environmental Quality] will include a statement listing 40 CFR 68.215(a) as an applicable requirement in all title V operating permits." The referenced § 68.215(a) of Title 40 of the Code of Federal Regulations requires that each source subject to both section 112(r) of the Act and Title V of the Act must have, as conditions of its operating permit, a statement listing all of 40 CFR part 68 ("Chemical Accident Prevention Provisions") as an applicable requirement, together with conditions requiring the source owner or operator to submit a compliance schedule for meeting all applicable requirements of part 68, and requiring the source to include in its annual compliance certification a statement certifying that the source is in compliance with all requirements of part 68, including the requirements for registration and submission of a risk management plan.

In particular, 40 CFR part 68 requires sources that have more than a threshold level of any regulated substance to prepare and submit an RMP. See 40 CFR 68.12(a) and 68.150. Unless the source can certify in the RMP that no member of the public would be affected by any accidental release from the source, 40 CFR part 68 further requires sources to

implement a risk management system, to conduct a hazard assessment, to implement a chemical accident prevention program, to implement an emergency response program, and to include data on the implementation of these programs in the RMP. See 40 CFR 68.12(b), (c), and (d). All those requirements are included as applicable permit conditions by effect of the State's listing 40 CFR 68.215(a) in all Montana operating permits. As the Governor committed, Montana will satisfy its obligations under section 112(r) of the Act by requiring all part 70 sources to certify compliance with applicable risk management planning requirements and by developing compliance schedules for sources that have not yet submitted risk management plans to EPA. When we referred to the State's commitment in the notice proposing full approval, we should have clarified that the commitment came from the Governor, thus assuring EPA that the State would meet its statutory obligations.

Comment 5: The commenter stated that the State's revised rule on termination, revocation, and re-issuance of state permits still improperly limits the state's authority to terminate or revoke permits.

EPA Response: Section 502(b)(5)(D) of the Act requires that the permitting authority must have adequate authority to "terminate, modify, or revoke and reissue permits for cause." The State's original version of the pertinent regulation provided that the Department could terminate, modify or revoke and reissue permits "for continuing and substantial violations." EPA advised that this provision did not give adequate authority to the Department to terminate or alter permits for other kinds of cause: for example, to correct a material mistake in the permit or to respond to an EPA objection to a permit.

Subsequently, Montana revised its rule, ARM 17.8.1210(2)(a), to say that permits could be terminated, modified, or revoked and reissued "for cause." The State then added, "Appropriate 'cause' for permit termination is noncompliance with permit terms or conditions that is continuing or substantial in nature and scope." EPA regards this added language as providing an example when a permit may be terminated in the context of an enforcement action. The specific example with respect to permit termination does not limit the State's general authority to terminate, modify, or revoke and reissue any permit for cause. In addition, we believe that the phrase "continuing or substantial in nature and scope" in the specific example is not necessarily less inclusive

than the phrase "continuing *and* substantial violations" in the earlier version. We believe that the State's revision of the regulation has satisfied EPA's concern that the Department have adequate authority to revise or terminate permits, whenever sufficient cause exists.

IV. Final Action

In this document, EPA is granting full approval of the Montana part 70 operating permits program for all areas within the State except the following: any sources of air pollution located in "Indian Country" as defined in 18 U.S.C. 1151, including the following Indian reservations in the State: Northern Cheyenne, Rocky Boys, Blackfeet, Crow, Flathead, Fort Belknap, and Fort Peck Indian Reservations, or any other sources of air pollution over which an Indian Tribe has jurisdiction. See section 301(d)(2)(B) of the Act; see also 63 FR 7254 (February 12, 1998). The term "Indian Tribe" is defined under the Act as "any Indian tribe, band, nation, or other organized group or community, including any Alaska Native village, which is federally recognized as eligible for the special programs and services provided by the United States to Indians because of their status as Indians." See section 302(r) of the Act; see also 58 FR 54364 (Oct. 21, 1993).

This rule will be effective January 22, 2001.

V. Administrative Requirements

A. Executive Order 12866

The Office of Management and Budget has exempted this regulatory action from Executive Order 12866, entitled "Regulatory Planning and Review."

B. Executive Order 13132

Federalism (64 FR 43255, August 10, 1999) revokes and replaces Executive Order 12612 (Federalism) and Executive Order 12875 (Enhancing the Intergovernmental Partnership). Executive Order 13132 requires EPA to develop an accountable process to ensure "meaningful and timely input by state and local officials in the development of regulatory policies that have federalism implications." "Policies that have federalism implications" is defined in the Executive Order to include regulations that have "substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government." Under Executive Order 13132, EPA may not issue a

regulation that has federalism implications, that imposes substantial direct compliance costs, and that is not required by statute, unless the Federal Government provides the funds necessary to pay the direct compliance costs incurred by state and local governments, or EPA consults with state and local officials early in the process of developing the proposed regulation. EPA also may not issue a regulation that has federalism implications and that preempts state law unless the Agency consults with state and local officials early in the process of developing the proposed regulation.

This final rule will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132. Thus, the requirements of section 6 of the Executive Order do not apply to this rule.

C. Executive Order 13045

Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997), applies to any rule that: (1) is determined to be "economically significant" as defined under Executive Order 12866, and (2) concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency.

This rule is not subject to Executive Order 13045 because it is not an economically significant regulatory action as defined by Executive Order 12866, and it does not establish a further health or risk-based standard because it approves state rules which implement a previously promulgated health or safety-based standard.

D. Executive Order 13084

Under Executive Order 13084, EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments, or EPA consults with

those governments. If EPA complies by consulting, Executive Order 13084 requires EPA to provide to the Office of Management and Budget, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected officials and other representatives of Indian tribal governments "to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities." Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. This action does not involve or impose any requirements that affect Indian Tribes. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

E. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) generally requires an agency to conduct a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small not-for-profit enterprises, and small governmental jurisdictions.

This final rule will not have a significant impact on a substantial number of small entities because part 70 approvals under section 502 of the Act do not create any new requirements but simply approve requirements that the State is already imposing. Therefore, because this approval does not create any new requirements, I certify that this action will not have a significant economic impact on a substantial number of small entities.

F. Unfunded Mandates

Under section 202 of the Unfunded Mandates Reform Act of 1995 ("Unfunded Mandates Act"), signed into law on March 22, 1995, EPA must prepare a budgetary impact statement to accompany any proposed or final rule that includes a Federal mandate that may result in estimated costs to state, local, or tribal governments in the aggregate; or to the private sector, of \$100 million or more. Under section 205, EPA must select the most cost-effective and least burdensome alternative that achieves the objectives

of the rule and is consistent with statutory requirements. Section 203 requires EPA to establish a plan for informing and advising any small governments that may be significantly or uniquely impacted by the rule.

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

G. Submission to Congress and the Comptroller General

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

H. Petitions for Judicial Review

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by February 20, 2001. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 70

Environmental protection, Administrative practice and procedure, Air pollution control, Intergovernmental relations, Operating permits, Reporting and recordkeeping requirements.

Dated: December 13, 2000.

Patricia D. Hull,

Acting Regional Administrator, Region VIII.

40 CFR part 70 is amended as follows:

PART 70—[AMENDED]

1. The authority citation for part 70 continues to read as follows:

Authority: 42 U.S.C. 7401, *et seq.*

2. In appendix A to part 70 the entry for Montana is amended by adding paragraph (b) to read as follows:

Appendix A to Part 70—Approval Status of State and Local Operating Permits Programs

* * * * *

Montana

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(b) The Montana Department of Environmental Quality submitted an operating permits program on March 29, 1994; effective on June 12, 1995; revised January 15, 1998, and March 17, 2000; full approval effective on January 22, 2001.

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[FR Doc. 00-32558 Filed 12-21-00; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 271

[FRL-6921-6]

Arizona: Final Authorization of State Hazardous Waste Management Program Revisions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Withdrawal of Immediate Final Rule.

SUMMARY: We are withdrawing the immediate final rule for Arizona, the Final Authorization of State Hazardous Waste Management Program Revisions published on October 27, 2000, which approved revisions to Arizona's hazardous waste rules. We stated in the immediate final rule that if we received comments that oppose authorization of the revision, we would publish a timely withdrawal in the **Federal Register**. Subsequently, we received comments that oppose the authorization. We will address the comments received during the comment period in a subsequent final action based on the proposed rule also published on October 27, 2000, at 65 FR 64403.

DATES: As of December 22, 2000, we withdraw the immediate final rule published on October 27, 2000, at 65 FR 64369.

FOR FURTHER INFORMATION CONTACT: Lisa McClain-Vanderpool, U.S. EPA, Waste Management Division, 75 Hawthorne Street (mailcode WST-3) San Francisco, CA 94105.

SUPPLEMENTARY INFORMATION: Because we received comments that oppose this authorization, we are withdrawing the immediate final rule for Arizona, the Final Authorization of State Hazardous Waste Management Program Revisions published on October 27, 2000, which approved revisions to Arizona's hazardous waste rules. We stated in the immediate final rule that if we received comments that oppose authorization of the revision, we would publish a timely notice of withdrawal in the **Federal Register**. Subsequently, we received comments that oppose the authorization. We will address the comments received during the comment period in a subsequent final action based on the proposed rule also published on October 27, 2000, at 65 FR 64403. We will not provide for additional public comment during the final action.

Laura Yoshii,

Deputy Regional Administrator, Region 9.

[FR Doc. 00-32668 Filed 12-21-00; 8:45 am]

BILLING CODE 6560-50-P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[DA 00-2779; MM Docket No. 00-15; RM-9804]

Radio Broadcasting Services; Susquehanna and Hallstead, PA

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: The Commission, at the request of Tammy M. Celenza, allots Channel 227A at Susquehanna, Pennsylvania, as the community's second local FM transmission service. See 65 FR 12155, March 8, 2000. We also dismiss the counterproposal filed by Montrose Broadcasting Corporation to allot Channel 227A at Hallstead, Pennsylvania, as the community's first local aural transmission service as being technically defective. Channel 227A can be allotted at Susquehanna in compliance with the Commission's minimum distance separation requirements with a site restriction of 6.3 kilometers (3.9 miles) east to avoid a short-spacing to the licensed sites of WBZD-FM, Channel 227B1, Muncy, Pennsylvania, and Station WKXZ(FM),

Channel 230B, Norwich, New York. The coordinates for Channel 227A at Susquehanna are 41-55-44 North Latitude and 75-31-50 West Longitude. See Supplementary Information, *infra*.

DATES: Effective January 22, 2001. A filing window, will not be opened at this time. Instead, the issue of opening a filing window for this channel will be addressed by the Commission in a subsequent order.

FOR FURTHER INFORMATION CONTACT:

Sharon P. McDonald, Mass Media Bureau, (202) 418-2180.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Report and Order, MM Docket No. 00-15, adopted November 29, 2000, and released December 8, 2000. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Reference Information Center (Room CY-A257), 445 12th Street, SW, Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractors, International Transcription Service, Inc., (202) 857-3800, 1231 20th Street, NW., Washington, DC 20036.

Since Susquehanna is located within 320 kilometers (200 miles) of the U.S.-Canadian border, Canadian concurrence for the allotment of Channel 227A at Susquehanna has been requested, but not yet received. Therefore, if a construction permit is granted prior to the receipt of formal concurrence in the allotment by the Canadian government, the construction permit will include the following condition: "Operation with the facilities specified herein is subject to modification, suspension or termination without right to a hearing, if found by the Commission to be necessary in order to conform to the USA-Canadian FM Broadcast Agreement."

List of Subjects in 47 CFR Part 73

Radio broadcasting.

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

PART 73—[AMENDED]

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

Authority: 47 U.S.C. 54, 303, 334, 336.

§ 73.202 [Amended]

2. Section 73.202(b), the Table of FM Allotments under Pennsylvania, is amended by adding Channel 227A at Susquehanna.

Federal Communications Commission.

John A. Karousos,

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

[FR Doc. 00-32676 Filed 12-21-00; 8:45 am]

BILLING CODE 6712-01-P

ENVIRONMENTAL PROTECTION AGENCY

48 CFR PART 1501 and 1502

[FRL-6920-7]

Acquisition Regulation

AGENCY: Environmental Protection Agency

ACTION: Direct final rule.

SUMMARY: The Environmental Protection Agency (EPA) is issuing this rule to amend the Agency definition of "Chief of the Contracting Office" for the purpose of granting limited ratification approval authority for acquisitions of \$2,500 or less.

DATES: This rule is effective on March 22, 2001, without further notice, unless EPA receives adverse comments by January 22, 2001. If we receive adverse comments, we will, before the rule's effective date, publish a timely withdrawal in the **Federal Register** informing the public that this rule will not take effect.

ADDRESSES: Comments may be submitted to Larry Wyborski, U.S. Environmental Protection Agency, Office of Acquisition Management (3802R), 1200 Pennsylvania Avenue, Ariel Rios Building, NW., Washington, DC 20460.

FOR FURTHER INFORMATION CONTACT:

Larry Wyborski, U.S. Environmental Protection Agency, Office of Acquisition Management (3802R), 1200 Pennsylvania Avenue, NW., Washington DC 20460, (202) 564-4369, wyborski.larry@epamail.epa.gov

SUPPLEMENTARY INFORMATION:

A. Background Information

EPAAR 1502.100 currently defines Chief of the Contracting Office (CCO) as the Office of Acquisition Management Division Directors at Headquarters, Research Triangle Park and Cincinnati. One of the two CCOs at Headquarters has overall management responsibility for the Superfund/RCRA Regional Procurement Operations Division. This CCO therefore has ratification authority for ten (10) nationwide Regional Contracting Offices. This one CCO is responsible for approval of a potentially substantial number of ratification actions. Also, EPA Service Center

Managers will be given similar authority to allow for more timely processing of small dollar ratification actions in the absence of the CCO. Therefore, EPA is broadening its definition of CCO for purposes of review of ratifications only. To avoid the need for ratification actions to the maximum extent practicable, EPA has an active training program both for contracting officials and program officials who use the purchase card. In addition, EPA reports ratification actions to the Chief Financial Officer. CCOs given ratification authority by this rule will also be required to provide notice of ratification actions to the CCO that would otherwise have reviewed the ratification action. This will ensure that the appropriate management level is kept informed of the volume and nature of agency ratification actions on an ongoing basis.

B. Executive Order 12866

This is not a significant regulatory action for purposes of Executive Order 12866; therefore, no review is required at the Office of Information and Regulatory Affairs, within the Office of Management and Budget (OMB).

C. Paperwork Reduction Act

The Paperwork Reduction Act does not apply because this rule does not contain information collection requirements for the approval of OMB under the Paperwork Reduction Act of 1980 (44 U.S.C. 3501, et. seq.)

D. Regulatory Flexibility Act (RFA), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), 5 U.S.C. 601 et. seq.

The RFA generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act or any other statute unless the Agency certifies that the rule will not have a significant impact on a substantial number of small entities. Small entities include small businesses, small organizations, and small governmental jurisdictions.

For purposes of assessing the impact of this rule on small entities, small entity is defined as: (1) A small business that meets the definition of a small business found in the Small Business Act and codified at 13 CFR 121.201; (2) a small governmental jurisdiction that is a government of a city, county, town, school district or special district with a population of less than 50,000; and (3) a small organization that is any not-for-profit enterprise which is independently

owned and operated and is not dominant in its field.

After considering the economic impacts of today's direct final rule on small entities, I certify that this action will not have a significant economic impact on a substantial number of small entities. In determining whether a rule has a significant economic impact on a substantial number of small entities, the impact of concern is any adverse economic impact on small entities, since the primary purpose of the regulatory flexibility analyses is to identify and address regulatory alternatives "which minimize any significant economic impact of the proposed rule on small entities." 5 U.S.C. 603 and 604. Thus, an agency may certify that a rule will not have a significant economic impact on a substantial number of small entities if the rule relieves regulatory burden, or otherwise has a positive economic effect on all of the small entities subject to the rule. This direct final rule does not have a significant impact on a substantial number of small entities. The requirements under the rule impose no reporting, record-keeping, or compliance costs on small entities.

E. Unfunded Mandates

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) Public Law 104-4, establishes requirements for Federal agencies to assess their regulatory actions on State, local and Tribal governments and the private sector. This direct final rule does not contain a Federal mandate that may result in expenditures of \$100 million or more for State, local, and Tribal governments, in the aggregate, or the private sector in any one year. Any private sector costs for this action relate to paperwork requirements and associated expenditures that are far below the level established for UMRA applicability. Thus, the rule is not subject to the requirements of sections 202 and 205 of the UMRA.

F. Executive Order 13045

Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks (6 FR 19885, April 23, 1997), applies to any rule that: (1) Is determined to be economically significant as defined under Executive Order 12866; and (2) concerns an environmental health or safety risk that EPA has reason to believe may have disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children, and explain why the planned regulation is

preferable to other potentially effective and reasonably feasible alternatives considered by the Agency.

This rule is not subject to Executive Order 13045 because it is not a significant rule as defined by E.O. 12866, and because it does not involve decisions on environmental health or safety risks.

G. Executive Order 13084

Under Executive Order 13084, EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian Tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay for the direct compliance costs incurred by the Tribal governments, or EPA consults with those governments. If EPA complies by consulting, E.O. 13084 requires EPA to provide to OMB, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected Tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected and other representatives of Indian tribal governments "to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities."

This rule does not significantly or uniquely affect the communities of Indian Tribal governments. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

H. National Technology Transfer and Advancement Act of 1995

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note), directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent

with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures and business practices) that are developed or adopted by voluntary consensus standards bodies. The NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards.

This rule does not involve technical standards. Therefore, EPA did not consider the use of any voluntary consensus standards.

I. Executive Order 13132

Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999), requires EPA to develop an accountable process to ensure "meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications." "Policies that have federalism implications" are defined in the Executive Order to include regulations that have "substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government."

Under Section 6 of Executive Order 13132, EPA may not issue a regulation that has federalism implications, that imposes substantial direct compliance costs, and that is not required by statute, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by State and local governments, or EPA consults with State and local officials early in the process of developing the proposed regulation. EPA also may not issue a regulation that has federalism implications and that preempts State law, unless the Agency consults with State and local officials early in the process of developing the proposed regulation.

This direct final rule does not have federalism implications. It will not have substantial direct effect on the States, on the relationship between the national

government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132. The rule amends the EPA Acquisition Regulation to revise the Agency definition of "Chief of the Contracting Office" for purposes of delegation of ratification authority procedures specified in FAR 1.602-3(b)(2).

J. Submission to Congress and the General Accounting Office

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U. S. Senate, the U. S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

Authority: The provisions of this regulation are issued under 5 U.S.C. 301; section 205(c), 63 Stat. 390, as amended 40 U.S.C. 486(c); 41 U.S.C. 418b.

List of Subjects in 48 CFR Parts 1501 and 1502

Government procurement.

Therefore, 48 CFR Chapter 15 is amended as set forth below:

1. The authority citation for parts 1501 and 1502 continues to read as follows:

Authority: Sec. 205(c), 63 Stat. 390 as amended, 40 U.S.C. 486(c); 41 U.S.C. 418b.

2. In section 1501.602-3, paragraph (b) is redesignated as paragraph (b)(1) and paragraph (b)(2) is added to read as follows:

1501.602-3 Ratification of unauthorized commitments.

* * * * *

(b) * * *

(2) The CCOs defined in 1502.100 for purposes of ratification authority of \$2,500 or less must meet the following criteria:

- (i) Must possess a contracting officer's warrant and be in the 1102 job series;
- (ii) Are prohibited from re-delegating their ratification authority;
- (iii) Must submit copies of ratification actions to the cognizant Office of Acquisition Management Division Director at Headquarters; and

(iv) As with other ratifying officials, must abide by the other limitations on ratification of unauthorized commitments set forth in FAR 1.602-3(c) and the EPAAR.

* * * * *

3. Section 1502.100 is amended by revising the definition of Chief of the Contracting Office (CCO) to read as follows:

1502.100 Definitions.

Chief of the Contracting Office (CCO) means the Office of Acquisition Management Division Directors at Headquarters, Research Triangle Park

and Cincinnati. For the purposes of ratification authority of \$2,500 or less, CCO is also defined as Regional Contracting Officer Supervisors and OAM Service Center Managers. See 1501.602-3(b)(2) for the limits of this ratification authority.

* * * * *

Dated: December 13, 2000.

Judy S. Davis,

Acting Director, Office of Acquisition Management.

[FR Doc. 00-32562 Filed 12-21-00; 8:45 am]

BILLING CODE 6560-50-U

Proposed Rules

Federal Register

Vol. 65, No. 247

Friday, December 22, 2000

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2000-NM-156-AD]

RIN 2120-AA64

Airworthiness Directives; Boeing Model 737, 747, and 777 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes the adoption of a new airworthiness directive (AD) that is applicable to certain Boeing Model 737, 747, and 777 series airplanes. This proposal would require replacement of the seat track fittings on all passenger seats with new, improved fittings. This action is necessary to prevent unrestrained movement of the passenger seats during high forward deceleration of the airplane, which could result in injury to the passengers or crew members during an emergency landing. This action is intended to address the identified unsafe condition.

DATES: Comments must be received by February 5, 2001.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM-114, Attention: Rules Docket No. 2000-NM-156-AD, 1601 Lind Avenue, SW., Renton, Washington 98055-4056. Comments may be inspected at this location between 9:00 a.m. and 3:00 p.m., Monday through Friday, except Federal holidays. Comments may be submitted via fax to (425) 227-1232. Comments may also be sent via the Internet using the following address: 9-anm-nprmcomment@faa.gov. Comments sent via fax or the Internet must contain "Docket No. 2000-NM-156-AD" in the subject line and need not be submitted in triplicate. Comments sent via the

Internet as attached electronic files must be formatted in Microsoft Word 97 for Windows or ASCII text.

The service information referenced in the proposed rule may be obtained from Boeing Commercial Airplane Group, P.O. Box 3707, Seattle, Washington 98124-2207. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington.

FOR FURTHER INFORMATION CONTACT: Jan Risheim, Aerospace Engineer, Airframe Branch, ANM-120S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue, SW., Renton, Washington; telephone (425) 227-1675; fax (425) 227-1181.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications shall identify the Rules Docket number and be submitted in triplicate to the address specified above. All communications received on or before the closing date for comments, specified above, will be considered before taking action on the proposed rule. The proposals contained in this action may be changed in light of the comments received.

Submit comments using the following format:

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

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

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this action

must submit a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket Number 2000-NM-156-AD." The postcard will be date stamped and returned to the commenter.

Availability of NPRMs

Any person may obtain a copy of this NPRM by submitting a request to the FAA, Transport Airplane Directorate, ANM-114, Attention: Rules Docket No. 2000-NM-156-AD, 1601 Lind Avenue, SW., Renton, Washington 98055-4056.

Discussion

The FAA has received reports from the manufacturer indicating that, on certain Model 737, 747, and 777 series airplanes, the shear plunger screws of certain seat track fittings broke during installation. Analysis of the broken screws revealed that various modifications had weakened the shear plunger screws. Further analysis revealed that high torque during seat installation resulted in broken shear plunger screws and subsequent disengagement of the shear plunger from the seat track. This condition, if not corrected, could result in unrestrained movement of the passenger seats during high forward deceleration of the airplane, and possible injury to the passengers or crew members during an emergency landing.

Explanation of Relevant Service Information

The FAA has reviewed and approved Boeing Service Bulletins 737-25-1371, Revision 2, dated December 9, 1999 (for Model 737 series airplanes); 747-25-3196, Revision 1, dated May 13, 1999 (for Model 747 series airplanes); and 777-25-0111, Revision 1, dated May 13, 1999 (for Model 777 series airplanes). These service bulletins describe procedures for a one-time examination (inspection) to detect damaged or broken seat track fittings of the passenger seats, and replacement of the seat track fittings with serviceable or new, improved fittings. Boeing Service Bulletin 737-25-1407, dated December 9, 1999, describes procedures for replacement of the seat track fittings of the passenger seats with new, improved fittings. Accomplishment of the actions specified in the service bulletins is intended to adequately address the identified unsafe condition.

Explanation of Requirements of Proposed Rule

Since an unsafe condition has been identified that is likely to exist or develop on other products of this same type design, the proposed AD would require accomplishment of the actions specified in the service bulletins described previously, except as discussed below.

Differences Between Service Bulletins and This Proposed AD

Operators should note that, although the service bulletins specify replacement of the seat track fittings as soon as manpower, facilities and materials are available, the FAA has determined that an 18-month compliance for replacement of the seat track fittings would address the identified unsafe condition in a timely manner. In developing an appropriate compliance time for this AD, the FAA considered not only the manufacturer's recommendation, but the degree of urgency associated with addressing the subject unsafe condition, the average utilization of the affected fleet, and the time necessary to perform the replacement. In light of all of these factors, the FAA finds an 18-month compliance time for completion of the replacement to be warranted, in that it represents an appropriate interval of time allowable for affected airplanes to continue to operate without compromising safety.

For certain airplanes, certain service bulletins provide for inspection and replacement of certain fittings with serviceable fittings if discrepancies are detected, then at a later date replacement with new, improved fittings. This proposed AD would mandate replacement of all seat track fittings on all the passenger seats of all affected airplanes with new, improved fittings. The FAA has determined that, due to the probability of defective shear plunger screws of the seat track fittings developing over time, mandating this replacement is necessary in order to maintain fleet safety.

Cost Impact

There are approximately 46 Model 737, 747, and 777 series airplanes of the affected design in the worldwide fleet.

For Model 737 series airplanes (2 U.S.-registered airplanes): It would take approximately 10 work hours per airplane to accomplish the proposed replacement, at an average labor rate of \$60 per work hour. Required parts would cost approximately \$15,100 per airplane. Based on these figures, the cost impact of the replacement proposed by

this AD on U.S. operators is estimated to be \$31,400, or \$15,700 per airplane.

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

Currently, there are no affected Model 747 series airplanes on the U.S. Register. However, should an affected airplane be imported and placed on the U.S. Register in the future, it would require approximately 29 work hours to accomplish the proposed replacement, at an average labor rate of \$60 per work hour. Required parts would cost approximately \$43,000. Based on these figures, the cost impact of the replacement proposed by this AD would be \$44,740 per airplane.

Currently, there are no affected Model 777 series airplanes on the U.S. Register. However, should an affected airplane be imported and placed on the U.S. Register in the future, it would require approximately 24 work hours to accomplish the proposed replacement, at an average labor rate of \$60 per work hour. Required parts would cost approximately \$36,400. Based on these figures, the cost impact of the replacement proposed by this AD would be \$37,840 per airplane.

Regulatory Impact

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

For the reasons discussed above, I certify that this proposed regulation: (1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) if promulgated, will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A copy of the draft regulatory evaluation prepared for this

action is contained in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption ADDRESSES.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

Boeing: Docket 2000–NM–156–AD.

Applicability: Model 737, 747, and 777 series airplanes; certificated in any category; as specified in the Boeing service bulletins listed below:

For Model 737 series airplanes: 737–25–1371, Revision 2, dated December 9, 1999;

For Model 737 series airplanes: 737–25–1407, dated December 9, 1999;

For Model 747 series airplanes: 747–25–3196, Revision 1, dated May 13, 1999; or For Model 777 series airplanes: 777–25–0111, Revision 1, dated May 13, 1999.

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

Compliance: Required as indicated, unless accomplished previously.

To prevent unrestrained movement of the passenger seats during high forward deceleration of the airplane, which could result in injury to the passengers or crew members during an emergency landing, accomplish the following:

Replacement

(a) Within 18 months after the effective date of this AD: Replace all the seat track fittings on all the passenger seats with new, improved fittings, in accordance with the

Accomplishment Instructions specified in Boeing Service Bulletin 737-25-1371 or 737-25-1407, both dated December 9, 1999 (for Model 737 series airplanes); Boeing Service Bulletin 747-25-3196, Revision 1, dated May 13, 1999 (for Model 747 series airplanes), or Boeing Service Bulletin 777-25-0111, Revision 1, dated May 13, 1999 (for Model 777 series airplanes); as applicable.

Alternative Methods of Compliance

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

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

Special Flight Permit

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

Issued in Renton, Washington, on December 18, 2000.

Dorenda D. Baker,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 00-32764 Filed 12-21-00; 8:45 am]

BILLING CODE 4910-13-U

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2000-NM-309-AD]

RIN 2120-AA64

Airworthiness Directives; Boeing Model 767 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes the adoption of a new airworthiness directive (AD) that is applicable to certain Boeing Model 767 series airplanes. For certain airplanes this proposal would require rework of the bonding jumper assemblies. For certain other airplanes, this proposal would require repetitive inspections of the drain tube assemblies of the slat track housing of the wings to find discrepancies, and corrective actions, if necessary. This proposal also provides for terminating action for the repetitive

inspections. This action is necessary to find and fix discrepancies of the bonding jumper assemblies, which could result in electrostatic discharge and an in-tank ignition source. This action also is necessary to find and fix discrepancies of the fuel drain tubes, which could result in fuel migrating into the tubes and leaking onto an engine or exhaust nozzle, and consequent risk of a fire when the airplane is stationary or during low speed taxiing. This action is intended to address the identified unsafe conditions.

DATES: Comments must be received by February 5, 2001.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM-114, Attention: Rules Docket No. 2000-NM-309-AD, 1601 Lind Avenue, SW., Renton, Washington 98055-4056. Comments may be inspected at this location between 9:00 a.m. and 3:00 p.m., Monday through Friday, except Federal holidays. Comments may be submitted via fax to (425) 227-1232. Comments may also be sent via the Internet using the following address: 9-anm-nprmcomment@faa.gov. Comments sent via fax or the Internet must contain "Docket No. 2000-NM-309-AD" in the subject line and need not be submitted in triplicate. Comments sent via the Internet as attached electronic files must be formatted in Microsoft Word 97 for Windows or ASCII text.

The service information referenced in the proposed rule may be obtained from Boeing Commercial Airplane Group, P.O. Box 3707, Seattle, Washington 98124-2207. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington.

FOR FURTHER INFORMATION CONTACT: Dennis Kammers, Aerospace Engineer, Propulsion Branch, ANM-140S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue, SW., Renton, Washington 98055-4056; telephone (425) 227-2956; fax (425) 227-1181.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications shall identify the Rules Docket number and be submitted in triplicate to the address specified above. All communications received on or before the closing date for comments, specified above, will be considered before taking action on the

proposed rule. The proposals contained in this action may be changed in light of the comments received.

Submit comments using the following format:

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

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

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this action must submit a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket Number 2000-NM-309-AD." The postcard will be date stamped and returned to the commenter.

Availability of NPRMs

Any person may obtain a copy of this NPRM by submitting a request to the FAA, Transport Airplane Directorate, ANM-114, Attention: Rules Docket No. 2000-NM-309-AD, 1601 Lind Avenue, SW., Renton, Washington 98055-4056.

Discussion

The FAA has received reports on certain Boeing Model 767 series airplanes that a new drain tube assembly was installed during production, and the manufacturer determined that the bonding jumper assembly on the installation did not meet the current bonding specifications. Such discrepancies of the bonding jumper assemblies could result in electrostatic discharge and an in-tank ignition source.

For certain other airplanes, the FAA has received reports of the detection of fuel leaks from the number 5 and number 8 drain locations of the slat track housing near the engine exhaust nozzles of the wings. One report showed that the fuel leak originated from a drain tube fitting that had loosened over time. The other reports showed that the fuel leaks originated from a crack in each of the drain tubes due to improper

installation. Such discrepancies of the fuel drain tubes could result in fuel migrating into the tubes and leaking onto an engine or exhaust nozzle, and consequent risk of a fire when the airplane is stationary or during low speed taxiing.

Explanation of Relevant Service Information

The FAA has reviewed and approved Boeing Service Bulletin 767-57A0060, Revision 1, dated December 31, 1998, which describes procedures for repetitive visual inspections of the drain tube assemblies of the slat track housing of the wings to find discrepancies (loose fittings and/or cracking of the fuel drain tubes); rework of the drain tube assemblies if any discrepancies are found; and eventual replacement of the drain tube assemblies, which would constitute terminating action for the repetitive inspections.

The FAA also has reviewed and approved Boeing Service Bulletin 767-57-0068, dated September 16, 1999, which describes procedures for rework of the bonding jumper assembly of the number 5 and number 8 drain tube assemblies of the inboard slat track that were installed before per a production change (PRRB12900-133) that was incorporated at the manufacturer's facility. The rework includes, but is not limited to, replacement of the fasteners common to the drain doubler assembly; installation of bonding jumper brackets to the rib stiffeners, and installation of bonding jumpers between the drain tube assemblies and the brackets installed on the rib panels.

Accomplishment of the actions specified in the service bulletins is intended to adequately address the identified unsafe conditions.

Explanation of Requirements of Proposed Rule

Since two unsafe conditions have been identified that are likely to exist or develop on other products of this same type design, the proposed AD would require accomplishment of the actions specified in the service bulletins described before, except as discussed below.

Differences Between Boeing Service Bulletin 767-57A0060, Revision 1, and This Proposed Rule

Operators should note that the service bulletin does not direct operators to do the initial and repeat visual inspections of the drain tube assemblies of the slat track housing of the wings to find leakage, if the inspection recommended in the Boeing 767 Maintenance Planning Document (MPD), Section 57-59-00-A,

has been accomplished. This proposed rule would require accomplishment of the initial and repeat visual inspections regardless of earlier accomplishment of the inspection specified in the MPD.

Operators also should note that this AD proposes to mandate, within 6,000 flight hours or 18 months, whichever occurs first, the replacement of the drain tube assemblies of the slat track housing of the wings described in the service bulletin as terminating action for the repetitive inspections. (The service bulletin states that incorporation of the terminating action specified is optional.) The FAA has determined that long-term continued operational safety will be better assured by design changes to remove the source of the problem, rather than by repetitive inspections. Long-term inspections may not be providing the degree of safety assurance necessary for the transport airplane fleet. This, coupled with a better understanding of the human factors associated with numerous continual inspections, has led the FAA to consider placing less emphasis on inspections and more emphasis on design improvements. The proposed replacement is consistent with these conditions.

Part IV of the Accomplishment Instructions of the service bulletin identifies certain rework specified in the "Validation Copy 1" release of the service bulletin as part of the corrective action. The FAA does not recognize work done using a validation copy of the service bulletin because it is not an FAA-approved document and, therefore, Part IV of the service bulletin is not required by this proposed rule.

Cost Impact

There are approximately 745 airplanes of the affected design in the worldwide fleet. The FAA estimates that 275 airplanes of U.S. registry would be affected by this proposed AD.

For airplanes listed in Boeing Service Bulletin 767-57A0060, Revision 1 (228 U.S.-registered airplanes): It would take approximately 1 work hour per airplane to accomplish the proposed inspection, at an average labor rate of \$60 per work hour. Based on these figures, the cost impact of the proposed inspection on U.S. operators is estimated to be \$13,680, or \$60 per airplane, per inspection cycle.

It would take approximately 12 work hours per airplane to accomplish the proposed replacement of the drain tube assemblies specified in Boeing Service Bulletin 767-57A0060, Revision 1, at an average labor rate of \$60 per work hour. Required parts would cost approximately \$5,236 per airplane. Based on these figures, the cost impact

of the proposed replacement on U.S. operators is estimated to be \$1,357,968, or \$5,956 per airplane.

For airplanes listed in Boeing Service Bulletin 767-57-0068, (47 U.S.-registered airplanes): It would take approximately 4 work hours per airplane to accomplish the proposed rework of the bonding jumper assemblies, at an average labor rate of \$60 per work hour. Required parts would cost approximately \$322 per airplane. Based on these figures, the cost impact of the proposed rework on U.S. operators is estimated to be \$26,414, or \$562 per airplane.

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

Regulatory Impact

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

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

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

Boeing: Docket 2000–NM–309–AD.

Applicability: Model 767 series airplanes, line numbers 1 through 757 inclusive, certificated in any category.

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

Compliance: Required as indicated, unless accomplished before.

To find and fix discrepancies (bonding, loose fittings, cracking) of the bonding jumper assemblies, which could result in electrostatic discharge and an in-tank ignition source; and of the fuel drain tubes, which could result in fuel migrating into the tubes and leaking onto an engine or exhaust nozzle, and consequent risk of a fire when the airplane is stationary or during low speed taxiing; accomplish the following:

Repetitive Inspections/Corrective Action

(a) For airplanes listed in Boeing Service Bulletin 767–57A0060, Revision 1, dated December 31, 1998; within 500 flight hours after the effective date of this AD: Do a general visual inspection of the drain tube assemblies of the slat track housings of the wings to find discrepancies (loose fittings, cracked tubes, fuel leaks), per Part I of the Accomplishment Instructions of the service bulletin.

(1) If any discrepancies are found, before further flight, rework the drain tube assembly per Part II of the Accomplishment Instructions of the service bulletin; repeat the inspection at intervals not to exceed 500 flight hours until accomplishment of the requirements in paragraph (b) of this AD.

(2) If no discrepancies are found, repeat the inspection thereafter at intervals not to

exceed 500 flight hours, until accomplishment of the requirements in paragraph (b) of this AD.

Note 2: For the purposes of this AD, a general visual inspection is defined as: “A visual examination of an interior or exterior area, installation, or assembly to find obvious damage, failure, or irregularity. This level of inspection is made under normally available lighting conditions such as daylight, hangar lighting, flashlight, or drop-light and may require removal or opening of access panels or doors. Stands, ladders, or platforms may be required to gain proximity to the area being checked.”

Terminating Action for Repetitive Inspections

(b) For airplanes specified in paragraph (a) of this AD; within 6,000 flight hours or 18 months after the effective date of this AD, whichever occurs first: Replace the drain tube assemblies of the slat track housings of the wings (including general visual inspection and repair) per Part III of the Accomplishment Instructions of Boeing Service Bulletin 767–57A0060, Revision 1, dated December 31, 1998. Any applicable repair must be accomplished prior to further flight. Accomplishment of this paragraph terminates the repetitive inspections required by paragraph (a) of this AD.

Rework of Bonding Jumper Assemblies

(c) For airplanes listed in Boeing Service Bulletin 767–57–0068, dated September 16, 1999; within 5,000 flight cycles or 22 months after the effective date of this AD, whichever occurs first: Rework the bonding jumper assembly of the drain tube assemblies of the slat track housing of the wings (including general visual inspection and repair) per the Accomplishment Instructions of the service bulletin. Any applicable repair must be accomplished prior to further flight. Accomplishment of this paragraph terminates the requirements of this AD.

Alternative Methods of Compliance

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

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

Special Flight Permit

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

Issued in Renton, Washington, on December 18, 2000.

Dorenda D. Baker,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 00–32765 Filed 12–21–00; 8:45 am]

BILLING CODE 4910–13–U

FEDERAL TRADE COMMISSION

16 CFR Part 432

Trade Regulation Rule Relating to Power Output Claims for Amplifiers Utilized in Home Entertainment Products

AGENCY: Federal Trade Commission.

ACTION: Supplemental notice of proposed rulemaking.

SUMMARY: The Federal Trade Commission (“Commission” or “FTC”) is issuing a supplemental notice of proposed rulemaking to amend its Rule relating to Power Output Claims for Amplifiers Utilized in Home Entertainment Products (“Amplifier Rule” or “Rule”). The Commission proposes amending the Rule to specify the channels of amplification that are to be considered “associated” under the Rule and, therefore, subject to simultaneous operation during the Rule-required power measurements of multichannel audio/video receivers and separate power amplifiers. The Commission is conducting this supplemental rulemaking proceeding because of comments filed in response to a Notice of Proposed Rulemaking (“NPR”) published in the **Federal Register** on July 19, 1999, and other information discussed in this document. The notice includes a description of the procedures to be followed, an invitation to submit written comments, a list of questions and issues upon which the Commission particularly desires comments, and instructions for prospective witnesses and other interested persons who desire to participate in a hearing where oral testimony could be presented.

DATES: Written comments must be submitted on or before February 23, 2001. Notifications of interest in testifying must be submitted on or before February 23, 2001. If interested parties request the opportunity to present testimony, the Commission will publish a document in the **Federal Register**, stating the time and place at which the hearings will be held and describing the procedures that will be followed in conducting the hearings. In addition to submitting a request to testify, interested parties who wish to

present testimony must submit, on or before February 23, 2001, a written comment or statement that describes the issues on which the party wishes to testify and the nature of the testimony to be given. If there is no interest in a hearing, the Commission will base its decision on the written rulemaking record.

ADDRESSES: Written comments and requests to testify should be submitted to Office of the Secretary, Federal Trade Commission, Room H-159, 600 Pennsylvania Ave., NW., Washington, DC 20580. Comments and requests to testify should be identified as "16 CFR part 432 Comment—Amplifier Rule" and "16 CFR part 432 Request to Testify—Amplifier Rule," respectively. If possible, submit comments both in writing and on a personal computer diskette in Word Perfect or other word processing format (to assist in processing, please identify the format and version used). Written comments should be submitted, when feasible and not burdensome, in five copies.

FOR FURTHER INFORMATION CONTACT: Dennis Murphy, Economist, Division of Consumer Protection, Bureau of Economics, (202) 326-3524, or Neil Blickman, Attorney, Division of Enforcement, Bureau of Consumer Protection, (202) 326-3038, Federal Trade Commission, Washington, DC 20580.

SUPPLEMENTARY INFORMATION:

Part A—Introduction

This Supplemental Notice of Proposed Rulemaking ("SNPR") is published pursuant to section 18 of the Federal Trade Commission Act, 15 U.S.C. 57a *et seq.*, the provisions of part 1, Subpart B of the Commission's Rules of Practice, 16 CFR 1.7 *et seq.*, and 5 U.S.C. 551 *et seq.* This authority permits the Commission to promulgate, modify, and repeal trade regulation rules that define with specificity acts or practices that are unfair or deceptive in or affecting commerce within the meaning of section 5(a)(1) of the FTC Act, 15 U.S.C. 45(a)(1).¹

The Amplifier Rule was promulgated on May 3, 1974 (39 FR 15387), to assist consumers in purchasing power amplification equipment for home entertainment purposes by standardizing the measurement and disclosure of various performance

characteristics of the equipment. On July 19, 1999, the Commission published in the **Federal Register** a Notice of Proposed Rulemaking that proposed amending the Rule to (1) exempt sellers who make power output claims in media advertising from the requirement to disclose total rated harmonic distortion and the associated power bandwidth and impedance ratings; (2) clarify the manner in which the Rule's testing procedures apply to self-powered subwoofer-satellite combination speaker systems; and (3) reduce the preconditioning power output requirement from one-third of rated power to one-eighth of rated power (64 FR 38610).

On September 21, 1999, the Commission published in the **Federal Register** its decision granting an extension of the public comment period on the NPR until October 15, 1999 (64 FR 51087). The extension was granted to allow the Consumer Electronics Manufacturers Association ("CEMA"), the principal trade association of the U.S. electronics industry, additional time to elicit information from its members concerning the testing and performance of certain multichannel audio/video receivers and amplifiers, such as those used in home theater installations. These receivers and amplifiers, which incorporate five or more discrete channels of amplification, are designed to decode and/or amplify digitally encoded multichannel movie soundtracks or music program material recorded on video cassette tapes, laser discs, or digital video disks. CEMA informed Commission staff that marketers of such equipment are not interpreting the Rule's testing procedures in a uniform fashion, and that certain advertised power specifications might mislead consumers.²

Audio/video receivers with digital decoding circuitry and five or more discrete channels of amplification were not available to consumers when the Commission initiated its review of the Amplifier Rule in 1997 to determine the Rule's current effectiveness and impact.³ The Commission has tentatively concluded that such components raise unique interpretational issues under the Rule that were not addressed in the 1997 review or in the subsequent NPR. The Commission has determined, therefore,

to publish this SNPR commencing a supplementary rulemaking proceeding, and inviting interested persons to submit written comments addressing the issues raised in this notice. In a separate document published elsewhere in today's **Federal Register**, the Commission announces a final rule resolving the three issues that were the subject of the NPR.

Part B—Analysis of Proposed Amendment to Designate "Associated Channels" for Multichannel Audio/Video Receivers and Power Amplifiers

Section 432.2(a) of the Rule requires that an amplifier's rated continuous power output per channel be "[m]easured with all *associated* channels fully driven to rated per channel power." [Emphasis added.] When the Rule was promulgated in 1974, virtually all amplifiers available to consumers incorporated either one channel of amplification ("monophonic" amplifiers), or two channels in a left and right "stereophonic" configuration. For such amplifiers, interpretation of the term "all associated channels" in section 432.2(a) is self evident. By definition, a monophonic amplifier can be measured only with its single channel driven to full rated power. For stereophonic amplifiers, the left and right channels clearly are associated presentations of the same musical performance and, in any event, are the only channels that could be considered "associated" under the Rule.

In recent years, multichannel audio/video receivers and power amplifiers with five or more channels of amplification have accounted for an increasingly large share of consumer audio equipment sales. This equipment is designed to reproduce digitally encoded cinema soundtracks and musical program material recorded on video cassette tapes, laser discs, and digital video discs. Current digital audio/video receivers and amplifiers typically incorporate a pair of front left and right stereophonic amplification channels, a center channel designed to reproduce the dialog portion of cinema soundtracks, and two discrete rear amplification channels that may reproduce special sound effects or ambient sound information encoded in cinema soundtracks or music program material. Some home theater amplifiers may also provide one or more "subwoofer" amplification channels that are dedicated to reproducing only deep bass frequencies (below approximately 100 Hertz). Future developments may include additional

¹ In accordance with section 18 of the FTC Act, 15 U.S.C. 57a, the Commission submitted this SNPR to the Chairman of the Committee on Commerce, Science, and Transportation, United States Senate, and the Chairman of the Committee on Commerce, United States House of Representatives, 30 days prior to its publication in the **Federal Register**.

² CEMA, (5), pp. 6-7. All Rule NPR comments are on the public record and are available for public inspection in the Public Reference Room, Room 130, FTC, 600 Pennsylvania Ave., NW, Washington, DC, from 8:30 a.m. to 5:00 p.m., Monday through Friday, except holidays.

³ 62 FR 16500 (April 7, 1997).

surround or special effects channels placed around the listening room.

Manufacturers of multichannel audio/video receivers and amplifiers who wish to rate power output under section 432.2 of the Rule must decide which of the five or more discrete channels of amplification are to be considered "associated" and, therefore, subject to simultaneous operation at full rated power. Under the strictest interpretation of section 432.2(a), all available channels would be considered associated and all channels would be driven to full rated power simultaneously during testing. Such a regimen might severely tax the common power supply utilized in many home theater receivers, and the resulting per channel power ratings might be considerably below those that would be obtained if, for example, only the specific set of channels being rated (*e.g.*, surround channels) were driven to full power simultaneously. The controlling consideration in determining the proper interpretation of "associated channels" is whether audio/video receivers and amplifiers would, when operated by consumers in the home at high playback volume, be required to deliver full rated power output in all channels simultaneously, or whether such maximum stress conditions would more likely be restricted at any given moment of time to certain sub-groupings of available channels.

The Commission already has reached a determination relevant to the appropriate treatment of any subwoofer channels of amplification that might be provided in audio/video receivers. This determination, which the Commission announced in a separate section of today's **Federal Register**, applies to self-powered combination subwoofer-satellite loudspeaker systems, such as those used with personal computers and in home theater installations. Specifically, the Commission amended section 432.2 of the Rule to specify that:

* * * when measuring maximum per channel output of self-powered combination speaker systems that employ two or more amplifiers dedicated to different portions of the audio frequency spectrum, such as those incorporated into combination subwoofer-satellite speaker systems, only those channels dedicated to the same audio frequency should be considered associated channels that need be fully driven simultaneously to rated per channel power.

In reaching this determination, the Commission concluded that, under actual in-home use of such combination systems, maximum power demands typically would not occur precisely in the crossover region of frequencies that would be reproduced both by the

subwoofer and satellite amplifiers. Rather, simultaneous demands would more likely occur in portions of the audio spectrum that would be assigned primarily either to the subwoofer amplifier or the satellite amplifier.⁴ A similar conclusion would appear to hold for home theater receivers that incorporate a separate amplified subwoofer channel(s) and an internal crossover network.

The Commission tentatively concludes, therefore, that subwoofer amplifiers in combination self-powered subwoofer-satellite speaker systems and subwoofer amplifiers in audio/video receivers should be treated consistently under section 432.2(a) of the Rule. That is, the amplified subwoofer channel(s) of digital home theater receivers and the remaining amplified channels need not be considered "associated" channels that must be fully driven to rated per channel power when rating the power output of the subwoofer channel(s).

The Commission is unable, however, to make any tentative determination at this time concerning the appropriate designation of associated channels for the remaining amplified channels in multichannel audio/video receivers and amplifiers, since the comments on the NPR contained no evidence relevant to this issue. The Commission, therefore, is soliciting public comment on three alternative methods of grouping associated channels for multichannel audio/video receivers. These alternatives would govern power ratings applicable when an audio/video receiver is used in full multichannel mode. The proposed alternative amendments would not affect power ratings for the main left and right front channels that apply when the receiver's intended use is restricted to conventional stereo mode. For such conventional stereo ratings, only the two front stereo channels need be driven simultaneously to full rated power.

Commission adoption of the first alternative ("Alternative A") would designate all amplified channels other than the subwoofer channel(s) as "associated," and would require that all such channels be driven simultaneously to full rated output during power output measurements. Thus, for example, a technician rating the maximum per channel output of the main front left and right channels would be required to drive both front channels, the center channel, and the surround channels to full rated power while performing these measurements. The basis for this designation of associated channels

would be a determination by the Commission that multichannel audio/video receivers and power amplifiers commonly would be required to generate full rated power simultaneously in all channels (other than the subwoofer channel(s)) when reproducing multichannel program material in the home at high playback volume.

Commission adoption of the second alternative ("Alternative B") would designate the front left and right channels and the front center channel as one set of associated channels, and all surround channels as a separate set of associated channels. Accordingly, all front channels would have to be driven to full rated power during measurements of rated per channel power output for either the front stereo channels or the center channel. Similarly, all surround channels (but none of the front channels) would have to be driven simultaneously to full rated power during measurements of the rated per channel power output of the surround channels. The basis for this designation of associated channels would be a Commission determination that multichannel audio/video receivers and power amplifiers commonly would be required to deliver full rated power simultaneously to the front stereo and front center channels when reproducing multichannel program material in the home at high volume, but that such full power demands are not likely to occur simultaneously with full power demands in the surround channels.

Commission adoption of the third alternative ("Alternative C") would designate the front left and right channels as one set of associated channels, the center channel(s) as a second associated set, and all surround channels as a third set of associated channels. Thus, only the two front stereo channels would have to be driven simultaneously to full rated power during measurements of rated per channel power output for these channels; similarly, only the front center channel(s) would have to be driven to full rated power during power measurement of rated per channel output for that channel set; and only the surround channels would have to be driven simultaneously to full rated power during measurements of rated per channel output of those channels. The basis for this designation of associated channels would be a Commission determination that multichannel audio/video receivers and power amplifiers commonly would be required to deliver full rated per channel power output simultaneously to either the front stereo channels, front center channel(s), or

⁴ See, *e.g.*, 64 FR 38610, 38613 (July 19, 1999).

surround channels, but not simultaneously to any two or more sets of these channels, when reproducing multichannel program material in the home at high volume.

Part C—Rulemaking Procedures

The Commission finds that the public interest will be served by using expedited procedures in this proceeding. Using expedited procedures will support the Commission's goals of clarifying existing regulations, when necessary, and eliminating obsolete or unnecessary regulation without an undue expenditure of resources, while ensuring that the public has an opportunity to submit data, views and arguments on whether the Commission should amend the Rule.

The Commission, therefore, has determined, pursuant to 16 CFR 1.20, to use the procedures set forth in this notice. These procedures include: (1) Publishing this Supplemental Notice of Proposed Rulemaking; (2) soliciting written comments on the Commission's proposals to amend the Rule; (3) holding an informal hearing, if requested by interested parties; (4) obtaining a final recommendation from staff; and (5) announcing final Commission action in a notice published in the **Federal Register**.

Part D—Request For Public Hearings

Because written comments appear adequate to present the views of all interested parties, a public hearing has not been scheduled. If any person would like to present testimony at a public hearing, he or she should follow the procedures set forth in the **DATES** and **ADDRESSES** sections of this notice.

Part E—Description of Proposed Amendment and Alternatives Relating to Designation of "Associated Channels" for Multichannel Audio/Video Receivers and Power Amplifiers

The Commission proposes to amend section 432.2 to define the term "associated channels" for multichannel audio/video receivers such as those used in home theater systems. The Commission solicits public comment on the following three alternative designations of "associated channels" for such audio equipment:

Alternative A: When measuring maximum per channel output of multichannel audio/video receivers and power amplifiers, the front stereo channels, the center channel(s), and the surround channels should be considered associated channels that need be fully driven simultaneously to rated per channel power. The subwoofer

channels should be considered as a second group of associated channels.

Alternative B: When measuring maximum per channel output of multichannel audio/video receivers and power amplifiers, the front stereo channels and the center channel(s) should be considered one group of associated channels; the surround channels should be considered a second group of associated channels; and the subwoofer channels should be considered a third group of associated channels.

Alternative C: When measuring maximum per channel output of multichannel audio/video receivers and power amplifiers, the front stereo channels should be considered one group of associated channels; the center channel(s) should be considered a second group of associated channels; the surround channels should be considered a third group of associated channels; and the subwoofer channels should be considered a fourth group of associated channels.

Part F—Preliminary Regulatory Analysis and Regulatory Flexibility Act Requirements

Under section 22 of the FTC Act, 15 U.S.C. 57b, the Commission must issue a preliminary regulatory analysis for a proceeding to amend a rule only when it (1) estimates that the amendment will have an annual effect on the national economy of \$100,000,000 or more; (2) estimates that the amendment will cause a substantial change in the cost or price of certain categories of goods or services; or (3) otherwise determines that the amendment will have a significant effect upon covered entities or upon consumers. The Commission has preliminarily determined that the proposed amendment to the Rule will not have such effects on the national economy, on the cost of sound amplification equipment, or on covered businesses or consumers. The Commission, however, requests comment on the economic effects of the proposed amendment.

The Regulatory Flexibility Act ("RFA"), 5 U.S.C. 601–12, requires that the agency conduct an analysis of the anticipated economic impact of the proposed amendment on small businesses. The purpose of a regulatory flexibility analysis is to ensure that the agency considers impact on small entities and examines regulatory alternatives that could achieve the regulatory purpose while minimizing burdens on small entities. Section 605 of the RFA, 5 U.S.C. 605, provides that such an analysis is not required if the agency head certifies that the regulatory

action will not have a significant economic impact on a substantial number of small entities.

Because the Amplifier Rule covers manufacturers and importers of power amplification equipment for use in the home, the Commission believes that any amendments to the Rule may affect a substantial number of small businesses. Nevertheless, the proposed amendment would not appear to have a significant economic impact upon such entities.

Depending upon which of the three proposed alternative amendments is adopted, the clarification of testing procedures for multichannel audio/video receivers and separate power amplifiers would have either no impact or a modest impact on the overall cost of producing affected amplification equipment. Proposed Alternative A, which would require all channels of multichannel audio/video receivers and amplifiers to be driven to full rated power during the power rating tests of either the satellite, center, or surround channels, might lead some manufacturers to install more costly power supplies in order to maximize the power output ratings that could be achieved with this testing procedure. Any such upgrading of electronic components would not, however, require substantial investments in capital equipment or other investments involving high fixed costs (such as expansion of record keeping systems) that could have a disproportionate impact on small businesses. Proposed Alternatives B and C, which would place lower demands on the power supplies of multichannel receivers and amplifiers, would have little or no impact on any business decisions for either large or small businesses.

Based on available information, therefore, the Commission certifies that amending the Amplifier Rule as proposed will not have a significant economic impact on a substantial number of small businesses. To ensure that no significant economic impact is being overlooked, however, the Commission requests comments on this issue. The Commission also seeks comments on possible alternatives to the proposed amendment to accomplish the stated objectives. After reviewing any comments received, the Commission will determine whether a final regulatory flexibility analysis is appropriate.

Part G—Paperwork Reduction Act

The Amplifier Rule contains various information collection requirements for which the Commission has obtained clearance until August 31, 2002, under the Paperwork Reduction Act, 44 U.S.C.

3501 *et seq.*, Office of Management and Budget ("OMB") Control Number 3084-0105. As noted above, for purposes of performing the tests necessary for affected entities to make the disclosures required under the Rule, section 432.2(a) of the Rule requires that an amplifier's rated continuous power output per channel be measured with all associated channels fully driven to rated per channel power.

The amendment proposed by the Commission would not increase or alter the Rule's paperwork requirements. Consequently, there are no additional "collection of information" requirements included in the proposed amendment to submit to OMB for clearance under the Paperwork Reduction Act.

The proposed amendment to designate the channels of amplification that are to be considered "associated" under the Rule and, therefore, subject to simultaneous operation during the Rule-required power measurements of multichannel audio/video receivers and separate power amplifiers would not increase the Rule's paperwork burden. Further, it would not alter the Rule's requirements, but merely would clarify the test procedure that should be followed in applying the Rule's continuous power rating protocol to multichannel audio/video receivers and amplifiers.

Thus, the Commission concludes that the proposed amendment would not increase the paperwork burden associated with compliance with the Rule. To ensure that no significant paperwork burden is being overlooked, however, the Commission requests comments on this issue.

Part H—Additional Information For Interested Persons

1. Motions or Petitions

Any motions or petitions in connection with this proceeding must be filed with the Secretary of the Commission.

2. Communications by Outside Parties to Commissioners or Their Advisors

Pursuant to Commission Rule 1.18(c)(1), 16 CFR 1.18(c)(1), the Commission has determined that communications with respect to the merits of this proceeding from any outside party to any Commissioner or Commissioner advisor shall be subject to the following treatment. Written communications and summaries or transcripts of oral communications shall be placed on the rulemaking record if the communication is received before the end of the comment period. They

shall be placed on the public record if the communication is received later. Unless the outside party making an oral communication is a member of Congress, such communications are permitted only if advance notice is published in the Weekly Calendar and Notice of "Sunshine" Meetings.⁵

Part I—Invitation to Comment and Questions For Comment

Members of the public are invited to comment on any issues or concerns they believe are relevant or appropriate to the Commission's consideration of the proposed amendment to the Amplifier Rule. The Commission requests that factual data upon which the comments are based be submitted with the comments. In addition to the issues raised above, the Commission solicits public comment on the costs and benefits to industry members and consumers of each of the proposals, as well as the specific questions identified below. These questions are designed to assist the public and should not be construed as a limitation on the issues on which public comment may be submitted.

The written comments submitted will be available for public inspection in accordance with the Freedom of Information Act, 5 U.S.C. 552, and Commission regulations, on normal business days between the hours of 8:30 a.m. to 5:00 p.m. at the Federal Trade Commission, 600 Pennsylvania Ave., NW., Room 130, Washington, DC 20580, (202) 326-2222.

Questions

(1) What are the various testing procedures used currently by manufacturers of multichannel audio/video receivers and power amplifiers to determine full rated per channel power of the front left and right channels, center channel(s), surround channels, and subwoofer channels? Which channels of amplification are most frequently driven simultaneously to full rated power when performing such measurements?

(2) Would multichannel audio/video receivers and power amplifiers commonly be required to deliver full rated power simultaneously to all channels (other than the subwoofer channel(s)) when reproducing multichannel cinema soundtracks and other multichannel program material in the home at high playback volume? If not, to which channels would audio/video receivers and power amplifiers commonly be required to deliver full

rated power simultaneously when reproducing multichannel program material in the home at high volume?

(3) Should the Commission adopt "Alternative A" to define "associated channels" for multichannel audio/video receivers and power amplifiers? Why or why not?

(4) Should the Commission adopt "Alternative B" to define "associated channels" for multichannel audio/video receivers and power amplifiers? Why or why not?

(5) Should the Commission adopt "Alternative C" to define "associated channels" for multichannel audio/video receivers and power amplifiers? Why or why not?

(6) Are there any other definitions of "associated channels" that would be preferable to any of the three proposed alternative designations? If so, why?

Authority: 15 U.S.C. 41-58.

List of Subjects in 16 CFR Part 432

Amplifiers, Electronic products, Trade practices.

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 00-32393 Filed 12-21-00; 8:45 am]

BILLING CODE 6750-01-P

FEDERAL TRADE COMMISSION

16 CFR Part 600

Fair Credit Reporting Act Interpretations

AGENCY: Federal Trade Commission.

ACTION: Proposed interpretations of the Fair Credit Reporting Act.

SUMMARY: The Federal Trade Commission (Commission) is publishing for comment proposed interpretations of the provisions of the Fair Credit Reporting Act (FCRA) that permit companies to communicate consumer information to their affiliates (affiliate information sharing) without incurring the obligations of consumer reporting agencies. These interpretations clarify that institutions may communicate among their affiliates: Information as to transactions or experiences between the consumer and the person making the communication (transaction or experience information); and "other" information (that is, information covered by the FCRA but not transaction or experience information), provided that the institution has given notice to the consumer that the other information may be communicated, the institution has provided the consumer an opportunity to "opt out" (i.e., to direct

⁵ See 15 U.S.C. 57a(i)(2)(A); 45 FR 50814 (1980); 45 FR 78626 (1980).

that the information not be communicated), and the consumer has not opted out. The proposed interpretations provide guidance on compliance with the affiliate information sharing provisions, addressing such matters as the content and delivery of the notice to consumers that "other" information may be communicated (opt out notice). The proposed interpretations are substantively parallel to the proposed regulations issued by the Board of Governors of the Federal Reserve System, Federal Deposit Insurance Corporation, Office of the Comptroller of the Currency, and Office of Thrift Supervision (collectively the "Federal banking agencies"), in a Notice of Proposed Rulemaking published in the **Federal Register** on October 20, 2000 (65 FR 63120). For the most part, these proposed interpretations allow companies to provide notices and process opt-out elections in a manner similar to the final regulations implementing the privacy provisions of the Gramm-Leach-Bliley Act.

DATES: Comments must be received on or before January 31, 2001.

ADDRESSES: Comments should be addressed to: Secretary, Federal Trade Commission, Room H-159, 600 Pennsylvania Avenue, NW., Washington, DC 20580.

FOR FURTHER INFORMATION CONTACT: Clarke Brinckerhoff or Christopher Keller, Attorneys, Division of Financial Practices, Federal Trade Commission, Washington, DC 20580, 202-326-3224.

SUPPLEMENTARY INFORMATION:

I. Background

A. The Fair Credit Reporting Act

The Fair Credit Reporting Act ("FCRA") (15 U.S.C. 1681-1681u) sets forth legal standards governing the collection, use, and communication of credit and other information about consumers. The Consumer Credit Reporting Reform Act of 1996 (Pub. L. 104-208) amended the FCRA extensively ("1996 Amendments"). The 1996 Amendments gave consumers many new protections, such as a requirement that consumer reporting agencies ("CRAs") such as credit bureaus complete reinvestigations of disputed file data within a thirty-day period, while also providing some greater flexibility to business in some areas.

The subject of these interpretation is one of the 1996 Amendments that allowed businesses to share information with affiliated companies without becoming CRAs, as long as they

followed prescribed procedures to allow consumers to "opt out" of such information sharing. Specifically, it excluded specified types of information sharing with affiliates from the definition of "consumer report," relieving companies making these communications (under certain circumstances) from the obligations of CRAs imposed by the FCRA.¹ It excluded from the definition of "consumer report" the sharing of "other information" among affiliates, so long as the consumer, having been given notice and an opportunity to opt out, did not opt out. "Other information" refers to information that is covered by the FCRA and that is not a report containing information solely as to transactions or experiences between the consumer and the person making the report.

From its original enactment in 1970 to the present, the FCRA has assigned enforcement authority to the Commission.² The only significant exception is for banks and similar financial institutions regulated by federal agencies.³ The 1996 Amendments specifically prohibited all agencies, including the Commission, from issuing regulations implementing the FCRA.⁴ The Gramm-Leach-Bliley Act ("GLBA") repealed this prohibition in November 1999 and added a new section authorizing the Federal banking agencies to jointly prescribe such regulations as necessary to carry out the purposes of the FCRA as to the financial institutions under their jurisdiction.⁵ However, the GLBA did not grant such regulatory authority to the Commission. Pursuant to their authority, the Federal banking agencies issued proposed FCRA regulations in a Notice of Proposed Rulemaking published in the **Federal Register** on October 20, 2000 (65 FR 63120).

¹ The FCRA creates substantial obligations for CRAs. Most importantly, CRAs must make reports only to parties with permissible purposes listed in section 604, limit reporting negative information that is older than the times set out in section 605, maintain reasonable procedures to ensure accuracy of reports as required by section 607(b), make file disclosures to consumers required by section 609, and reinvestigate disputes using the procedures set forth in section 611.

² Section 621(a), 15 U.S.C. 1681s(a).

³ Section 621(b)(1-3), 15 U.S.C. 1681s(b)(1-3). Also, Section 621(b)(4-6) assigns FCRA regulatory authority to the Departments of Transportation and Agriculture over entities under their jurisdiction.

⁴ 15 U.S.C. 1681s(a)(4), repealed by section 506(b) of Pub. L. 106-102.

⁵ Section 621(e)(1), 15 U.S.C. 1681s(e)(1), added by section 506(a) of Pub. L. 106-102.

B. The Gramm-Leach-Bliley Act, its privacy regulations, and financial institutions

The GLBA sets standards for financial institutions' disclosure of nonpublic personal information to nonaffiliated third parties ("privacy provisions"). Pub. L. 106-102, 15 U.S.C. 6802; see also 12 U.S.C. 6803. The Commission published timely final regulations implementing these privacy provisions ("privacy regulations"), 65 FR 33646, May 24, 2000, as did the Federal banking agencies. 65 FR 35162 June 1, 2000.

The GLBA privacy regulations do not "modify, limit, or supersede the operation of the Fair Credit Reporting Act." 15 U.S.C. 6806. Thus, both the privacy regulations and the FCRA may apply to a financial institution's disclosure of certain consumer information. Moreover, if a financial institution provides an opt out notice under the FCRA, that notice must be included in certain notices mandated by the privacy regulations, including annual notices to customers. 15 U.S.C. 6803. Therefore, the Commission anticipates that financial institutions will design their information-sharing policies and practices taking into account both the GLBA (and its privacy regulations) and the FCRA. The Federal banking agencies have stated their intent to conform their privacy regulations and FCRA regulations where appropriate (65 FR 63120, 63121).

C. This proposal, and prior Commission interpretations of the FCRA

Some entities subject to the enforcement authority of the Commission, rather than the Federal banking agencies, also share information with their affiliates. The Commission believes it is important for such entities to be aware of the Commission's interpretations of the FCRA as to issues on which the Federal banking agencies propose to issue regulations, and to be afforded an opportunity to comment on them. The Commission encourages all such entities to submit comments to the Commission in response to this notice. Although Section 603(d)(2)(A)(iii) of the FCRA has been effective since September 30, 1997, the Commission plans to enforce that provision in accord with any interpretations it may issue in this proceeding only after any similar final regulations issued by the Federal banking agencies have become effective.

In 1990, the Commission issued a comprehensive Commentary on the FCRA. The Commentary does not address the extensive changes and additions made in the 1996

Amendments. However, the Commission believes the Commentary will continue to be of use to the public because of its guidance in areas not affected by the 1996 Amendments or not included in the proposed new interpretations. Therefore, the Commission does not plan to withdraw the Commentary at this time. The proposed interpretations would be added as Appendix B to 16 CFR part 600 following the Commentary, which would be re-designated as Appendix A. The Commission staff will continue to respond to requests for informal opinion letters interpreting FCRA provisions and make them available to the public on its web site (www.ftc.gov).

II. Questions for comment

The Commission solicits comment on all aspects of the proposed interpretations (16 CFR Part 600, Appendix B), including but not limited to those highlighted below.

A. Examples.

Should the interpretations include additional or different examples? More fundamentally, are examples appropriate and useful?

B. Defined terms

1. *Affiliate.* Several FCRA provisions apply to information sharing with persons "related by common ownership or affiliated by corporate control," "related by common ownership or affiliated by common corporate control," or "affiliated by common ownership or common corporate control." *E.g.*, FCRA, sections 603(d)(2), 615(b)(2), and 624(b)(2). Section 3(b) of the proposed interpretations uses the term "affiliate" to refer to all of these relationships between and among companies. It uses the phrase "related or affiliated by common ownership or affiliated by corporate control or common corporate control" to mean controlling, controlled by, or under common control with another company. As used in the proposed interpretations, is the term "affiliate" appropriate in scope?

Consistent with definitions in the privacy regulations, the proposed interpretation uses the term "control" to apply exclusively to the control of a "company." Is the term "control" in proposed Section 3(i), including the proposed 25 percent ownership benchmark, useful or appropriate? Is the term "company" in proposed Section 3(e), which includes any corporation, limited liability company, business trust, general or limited partnership, association, or similar organization (but omits other entities such as individuals,

estates, cooperatives, governments, and governmental subdivisions or agencies) useful or appropriate, in the context of these interpretations concerning sharing of consumer information by affiliates?

2. *Clear and conspicuous.* Section 3(c) states that "clear and conspicuous" refers to a notice that is reasonably understandable and designed to call attention to the nature and significance of the information it contains. Companies have flexibility in determining how to make their notices clear and conspicuous, consistent with the approach in the privacy regulations. Is this an appropriate interpretation of the term for FCRA compliance? How should the term be interpreted to ensure "clear and conspicuous" disclosures under both the GLBA and the FCRA for those entities sharing protected information with affiliates and third parties?

3. *Opt out information.* As described above, the 1996 Amendments to the FCRA excluded from the definition of "consumer report" the sharing of "other information" among affiliates, so long as the consumer, having been given notice and an opportunity to opt out, did not opt out. "Other information" refers to information that is covered by the FCRA, and that is not a report containing information solely as to transactions or experiences between the consumer and the person making the report. (The FCRA's definition of "consumer report," reflected in proposed Section 3(g)(2)(i), has always excluded communication of information solely as to transactions or experiences between the consumer and the person making the report, regardless of whether the parties are affiliated.⁶)

Proposed Section 3(k) uses the term "opt out information" to describe this category of information. It describes it as information that (i) bears on a consumer's credit worthiness, credit standing, credit capacity, character, general reputation, personal characteristics, or mode of living, (ii) is used or expected to be used or collected for one of the permissible purposes listed in the FCRA (e.g., credit transaction, insurance underwriting, employment purposes), and (iii) is not solely transaction or experience information. Is "opt out information" a useful term in the proposed

interpretations? Is the definition accurate in this context? In the event that consumer information is shared with both affiliates and third parties, subject to both GLBA and FCRA provisions, is the use of this term likely to result in confusion? If so, how might any such confusion be avoided? Would the term "FCRA opt-out information" be a better term for these interpretations? Is proposed Section 3(k)(2) that refers to the permissible purposes for which the information is used or expected to be used, which is part of the statutory definition of "consumer report" in Section 603(d) of the FCRA, useful in analyzing the affiliate information sharing exception?

C. Application of the exclusion—general

Section 603(d)(2)(A)(iii) of the FCRA excludes from the definition of "consumer report" the sharing of opt out information among affiliates if:

it is clearly and conspicuously disclosed to the consumer that the information may be communicated among such persons and the consumer is given the opportunity, before the time that the information is initially communicated, to direct that such information not be communicated among such persons. * * *

Proposed Section 4 states that opt out information may be communicated among affiliates without the communication being a consumer report if: (i) the company has provided an opt out notice; (ii) the company has given the consumer a reasonable opportunity and means, before the time that it communicates the information, to opt out; and (iii) the consumer has not opted out. Is this interpretation, when combined with others proposed in this publication, sufficient to encompass the opt out notice and procedure provided in Section 603(d)(2)(A)(iii)?

D. Application of the exclusion—mergers and acquisitions

Under proposed Section 4, in a merger or acquisition situation, the exclusion applies and the surviving company need not provide new notices, if the notices previously given to those customers accurately reflect the policies and practices of the surviving entity. Does that interpretation properly reflect Section 603(d)(2)(A)(iii) of the FCRA in these situations? Should this point be specifically included in the text of Section 4?

E. Contents of opt out notice

Proposed Section 5(a) states that an opt out notice must accurately explain (i) the categories of opt out information about the consumer that the company communicates, (ii) the categories of

⁶ Prior to the 1996 amendments to the FCRA, each affiliate could disclose its own transaction or experience information directly to another affiliate, but could not pool such information in a common database, without being considered a consumer reporting agency. The 1996 amendments facilitated the disclosure of such information among affiliates. However, the affiliates will still become CRAs if they share pooled data outside the affiliate family.

affiliates to which the company communicates the information, (iii) the consumer's ability to opt out, and (iv) a reasonable means to opt out. Section 5(d) sets forth four categories of information sources and six examples of types of information that a company may use to describe the information it may share with affiliates. Section 5(e) provides three categories of affiliates (financial service providers, non-financial companies, and others), with illustrative examples for each, that a company may use to describe the parties with which the company may share the information. Are these categories and examples appropriate and sufficient to guide compliance with the portion of section 603(d)(2)(A)(iii) that calls for a disclosure that "clearly" informs consumers of their "opportunity" to "direct that *such information* not be communicated among *such persons*" (emphasis added)? Is it clear from these interpretations that the Commission views as insufficient a very general notice that states that the company may share any information it obtains on the consumer with any of its affiliates?

The descriptions of the categories of information set out in proposed Section 5(d)(2) differ somewhat from those in the privacy regulations that appear at 16 CFR 313.6(c)(2). To what extent should the categories in (d)(2) be considered consistent with similar categories in the privacy regulations (such as disclosures of information from consumer reporting agencies) in order to reduce compliance burden and consumer confusion?

Should the interpretations also state that companies must also state in their FCRA notices how long a consumer has to respond to the opt out notice before the company may begin disclosing information about that consumer to its affiliates, as well as the fact that a consumer can opt out at any time? (These disclosures are not required in the privacy regulations.) Should the interpretations state that companies must disclose that they will wait a specified time (such as 30 days) in every instance before sharing consumer information with affiliates? (See proposed Section 6, below, for additional discussion on reasonable opportunity to opt out.) Is either or both of those disclosures, in an opt out notice, necessary for a company to have "clearly * * * disclosed" the consumer's "opportunity" to opt out Section 603(d)(2)(A)(iii) of the FCRA?

F. Reasonable opportunity to opt out

Proposed Section 6(a) states that companies must provide a reasonable period of time for the consumer to opt out from the time that the notice is

delivered. Proposed Section 6(b) sets out examples of what is a reasonable period of time when notices are provided in person, by mail, or by electronic means. Are there other situations that would suggest a different reasonable period that the Commission should note by example? Is it clear, from Section 6(b) and other authorities, that a consumer must agree to receive notices electronically before a company can provide notices in that manner? Proposed Section 6(c) explains that a consumer may opt out at any time. Are the interpretations in proposed Section 6 appropriate descriptions of the opt out "opportunity" afforded by Section 603(d)(2)(A)(iii) to consumers?

Is the 30-day period cited in the examples in Section 6(b) appropriate? Should the period vary depending on the means of delivery or other factors? If so, what factors merit a different minimum "opportunity" for the consumer to opt out, and how long should it be in each case? Should Section 6(b) include an "isolated transaction" example similar to that set forth at 16 CFR 313.10(a)(3)(iii), the Commission rule implementing the GLBA, which states that it is reasonable for a company to provide an opt-out notice and request the consumer to decide, as a necessary part of the transaction, whether to opt out before completion of the transaction?

G. Reasonable methods of exercising opt out opportunity

Proposed Section 7 states that a company must provide a reasonably convenient method to the consumer to opt out, and sets forth examples of reasonable and unreasonable methods of opting out when notices are provided in person, by mail, or by electronic means. It states that a company may require each consumer to opt out through a specific means as long as that means is reasonable to the consumer. Are the situations and examples appropriate and sufficient for guidance as to opt out methods that the Commission views as providing or not providing the opt out "opportunity" afforded by Section 603(d)(2)(A)(iii) to consumers?

H. Delivery of opt out notices

Proposed Section 8(a) states that opt out notices must be delivered in a manner such that each consumer can reasonably be expected to receive actual notice. The company may give notice in writing or, if the consumer agrees, electronically. Proposed Section 8(b) sets forth examples of the types of notice that the Commission believes would meet the "reasonably be expected" standard. Are the examples

appropriate and sufficient for this purpose? Is the proposed delivery standard, which does not require actual notice, faithful to the statutory exclusion that applies only if the opt out right is "disclosed to the consumer?" The Commission invites comment on how Section 603(d)(2)(A)(iii) of the FCRA, relating to the delivery of opt out notices by companies to consumers, should be applied to electronic communications in light of the Electronic Signatures in Global and National Commerce Act (the E-SIGN Act).⁷

Proposed Section 8(d) explains that a company must provide the notice so that the consumer can retain it or obtain it at a later time, and gives examples that would meet this standard. Is this a proper interpretation of the statutory requirement that the right to opt out right, which the Commission interprets as an ongoing right, must be "clearly * * * disclosed to the consumer?" Are the examples appropriate and sufficient for guidance as to what companies must do to ensure that the consumer can retain the notice, or obtain it at a later time? Is this interpretation inconsistent with or more burdensome than the GLBA, which requires financial institutions to provide notices in form that can be retained (or later accessed) only to those consumers with whom they have a customer relationship?

Proposed Section 8(f) sets out a range of appropriate methods for delivery of opt out notices and processing of opt out elections, in those situations where two or more consumers jointly obtain a product or service from a company. Does this section fairly apply Section 603(d)(2)(A)(iii) to those circumstances?

I. Time by which opt out must be honored

Proposed Section 10 explains that if a company provides a consumer with an opt out notice, and the consumer opts out, the company must comply as soon as reasonably practicable after receiving the consumer's direction. Is this general standard for compliance appropriate and sufficient, or should Section 603(d)(2)(A)(iii) of the FCRA be interpreted to require a fixed number of days to comply with a consumer's opt

⁷ The E-SIGN Act, Pub. L. 106-299, which became effective October 1, 2000, addresses the use of electronic records and signatures for interstate and foreign commerce. This Act contains general rules governing the use of electronic records for providing required information to consumers (such as disclosures and acknowledgments required by the GLBA). The legal requirement that consumer disclosures be in writing may be satisfied by an electronic record if the consumer affirmative by consents and certain other requirements of the E-SIGN Act are met.

out direction? Is it clear that a company cannot share any opt out information with affiliates without first providing consumers with a reasonable period of time to opt out as described in Section 6 above, but that the standard described in Section 10 applies when a consumer elects to opt out after that time has expired?

J. Duration of opt out

Proposed Section 11 provides that an opt out continues to apply to the information and affiliates described in the applicable opt out notice until revoked by the consumer in writing, or if the consumer agrees, electronically, as long as the consumer continues to have a relationship with the institution. It states that if the consumer's relationship with the institution terminates, the opt out will continue to apply to this information. If that consumer subsequently establishes a new relationship with the company, a company may either treat the previous opt out as continuing in effect, or provide the consumer with a new notice and opportunity to opt out. Are these interpretations an accurate reflection of the duration of opt out elections (where consumers "direct that such information not be communicated") provided in Section 603(d)(2)(A)(iii)? Should the Commission provide guidance as to what constitutes a "relationship" in the context of Section 11? If so, to what extent should that term parallel the definition of a "customer relationship" under the GLBA?

K. Sample form

Proposed Section 12 sets forth a sample notice, part or all of which may be used to facilitate the portion of Section 603(d)(2)(A)(iii) concerning clear and conspicuous disclosure to consumers that information may be shared among affiliates unless they "opt out" of such communications. Is the term "corporate family" or some other alternative more communicative to consumers than the term "affiliates" used in the statute and the sample notice?

Does this sample adequately convey to consumers that the company may continue to share certain information with its affiliates, even if a consumer exercises his or her opt out option? Specifically, should it specify that the company may continue to share information about its own transactions and experiences with the consumer, or any other type of information not subject to the definition of "consumer

report" in Section 603(d) of the FCRA. Is it helpful as a guide to describing the information that may be shared among affiliates? Is it helpful as a guide to describing the affiliated companies with which the information may be shared? Is it helpful as a guide to describing to the consumer how to exercise the opt out right?

L. Costs and Benefits of the Proposal

What benefits and costs to consumers and businesses would result from the proposed interpretations? What compliance burdens are anticipated in providing the FCRA opt-out notice in the context of the GLBA notice and opt-out requirements? Would the proposal have a significant economic impact on a substantial number of small businesses? Can that impact be quantified? Would compliance with the proposal impose costs on any entities that are not financial institutions subject to the GLBA, but wish to share consumer information with affiliates without becoming consumer reporting agencies under the FCRA? If so, describe any likely costs and the entities on which they would be imposed. Would the proposal reduce the compliance costs of financial institutions that must comply with both the GLBA's financial privacy provisions and the FCRA's affiliate information sharing provisions in order to share consumer information with affiliates without becoming consumer reporting agencies? Would the proposal benefit consumers by using similar standards for opting out of information sharing among affiliates under the FCRA and opting out of disclosures of nonpublic personal information to unaffiliated third parties under the GLBA? Do these benefits and savings outweigh the costs that might be imposed on entities that are not financial institutions under the FCRA?

List of Subjects in 16 CFR Part 600

Credit, Trade practices.

Pursuant to 15 U.S.C. 1681s and 16 CFR 1.73, the Commission proposes to amend 16 CFR Part 600 as follows:

PART 600—STATEMENTS OF GENERAL POLICY OR INTERPRETATIONS

1. The title of the existing Appendix is revised to read as follows:

Appendix A to Part 600—Commentary on the Fair Credit Reporting Act

2. A new Appendix B is added to read as follows:

Appendix B to Part 600—Commentary on the Amended Fair Credit Reporting Act (Affiliate Information Sharing)

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Introduction

Official status. This Appendix B has the same status as Appendix A. Comments issued in Appendix A continue to reflect the Commission's interpretations of the Fair Credit Reporting Act (FCRA) as it existed in 1990, whereas comments issued in Appendix B are the Commission's interpretations of affiliate information sharing resulting from the removal of such information from the definition of "consumer report" in Section 603(d)(2)(A) when the FCRA was amended by the Consumer Credit Reporting Reform Act of 1996.

Issuance of staff interpretations. The Commission staff's policy remains unchanged from that described in the preamble to Appendix A. Because of the 1996 amendments to the FCRA, the staff received a substantially increased volume of requests for informal staff opinions. Recent informal FCRA staff opinion letters have been placed on the Commission Web site at www.ftc.gov.

1. Purpose and scope

(a) *Purpose.* This Appendix applies to the collection, communication, and use of certain information bearing on a consumer's credit worthiness, credit standing, credit capacity, character, general reputation, personal characteristics, or mode of living.

(b) *Scope.* This Appendix applies to information that is used or expected to be used or collected in whole or in part for the purpose of serving as a factor in establishing a consumer's eligibility for credit, insurance, employment, or any other purpose authorized under Section 604 of the FCRA (15 U.S.C. 1681b).

2. Examples

The examples used in these interpretations, and the sample notice in Section 12, are not exclusive. Conformity with an example or use of

the sample notice, to the extent applicable, constitutes conformity with the Commission view expressed in an interpretation.

3. Definitions

As used in this Appendix, unless the context requires otherwise:

(a) *Act* means the Fair Credit Reporting Act (15 U.S.C. 1681 *et seq.*).

(b) *Affiliate*. (1) *In general*. The term means any company that is related or affiliated by common ownership, or affiliated by corporate control or common corporate control, with another company.

(2) *Related or affiliated by common ownership or affiliated by corporate control or common corporate control*. The term means controlling, controlled by, or under common control with, another company.

(c) *Clear and conspicuous*. (1) *In general*. The term means that a notice is reasonably understandable and is designed to call attention to the nature and significance of the information it contains.

(2) *Examples*. (i) *Reasonably understandable*. A company makes its notice reasonably understandable if it:

(A) Presents the information in the notice in clear and concise sentences, paragraphs, and sections;

(B) Uses short explanatory sentences or bullet lists whenever possible;

(C) Uses definite, concrete, everyday words and active voice whenever possible;

(D) Avoids multiple negatives;

(E) Avoids legal and highly technical business terminology whenever possible; and
(F) Avoids explanations that are imprecise and are readily subject to different interpretations.

(ii) *Designed to call attention*. A company designs its notice to call attention to the nature and significance of the information it contains if it:

(A) Uses a plain-language heading to call attention to the notice;

(B) Uses a typeface and type size that are easy to read;

(C) Provides wide margins and ample line spacing;

(D) Uses boldface or italics for key words; and

(E) In a form that combines the company's notice with other information, uses distinctive type sizes, styles, and graphic devices, such as shading or sidebars.

(iii) *Notice on a web page*. If a company provides a notice on a web page, the company designs its notice to call attention to the nature and significance of the information it contains if the company:

(A) Places either the notice, or a link that connects directly to the notice and that is labeled appropriately to convey the importance, nature, and relevance of the notice, on a page that consumers access often, such as a page on which transactions are conducted;

(B) Uses text or visual cues to encourage scrolling down the page if necessary to view the entire notice; and

(C) Ensures that other elements on the web page (such as text, graphics, links, or sound) do not detract attention from the notice.

(d) *Communication* includes any written and oral communication. It also includes an electronic communication to a consumer, if the consumer agrees to receive the communication electronically.

(e) *Company* means any corporation, limited liability company, business trust, general or limited partnership, association, or similar organization.

(f) *Consumer* means an individual.

(g) *Consumer report*. (1) *In general*. The term means any written, oral, or other communication of any information by a consumer reporting agency bearing on a consumer's credit worthiness, credit standing, credit capacity, character, general reputation, personal characteristics, or mode of living which is used or expected to be used or collected in whole or in part for the purpose of serving as a factor in establishing the consumer's eligibility for:

(i) Credit or insurance to be used primarily for personal, family, or household purposes;

(ii) Employment purposes; or

(iii) Any other purpose authorized under section 604 of the Act (15 U.S.C. 1681b).

(2) *Exclusions*. The term does not include:

(i) Any report containing information solely as to transactions or experiences between the consumer and the person making the report;

(ii) Any communication of transaction or experience information among affiliates;

(iii) Any communication among affiliates of opt out information if the conditions in sections 4 through 9 are satisfied;

(iv) Any authorization or approval of a specific extension of credit directly or indirectly by the issuer of a credit card or similar device;

(v) Any report in which a person who has been requested by a third party to make a specific extension of credit directly or indirectly to a consumer conveys his or her decision with respect to such request, if the third party advises the consumer of the name and address of the person to whom the request was made, and the person makes the

disclosures to the consumer required under section 615 of the Act (15 U.S.C. 1681m); or

(vi) A communication described in section 603(o) of the Act (15 U.S.C. 1681a(o)).

(h) *Consumer reporting agency* means any person which, for monetary fees, dues or on a cooperative nonprofit basis, regularly engages in whole or in part in the practice of assembling or evaluating consumer credit information or other information on consumers for the purpose of furnishing consumer reports to third parties, and which uses any means or facility of interstate commerce for the purpose of preparing or furnishing consumer reports.

(i) *Control* of a company means:

(1) Ownership, control, or power to vote 25 percent or more of the outstanding shares of any class of voting security of the company, directly or indirectly, or acting through one or more other persons;

(2) Control in any manner over the election of a majority of the directors, trustees, or general partners (or individuals exercising similar functions) of the company; or

(3) The power to exercise, directly or indirectly, a controlling influence over the management or policies of the company.

(j) *Opt out* means a direction by a consumer that a company not communicate opt out information about the consumer to one or more of its affiliates.

(k) *Opt out information* means information that:

(1) Bears on a consumer's credit worthiness, credit standing, credit capacity, character, general reputation, personal characteristics, or mode of living;

(2) Is used or expected to be used or collected in whole or in part to serve as a factor in establishing the consumer's eligibility for credit or another purpose listed in section 604 of the Act (15 U.S.C. 1681b); and

(3) Is not a report containing information solely as to transactions or experiences between the consumer and the person reporting or communicating the information.

(l) *Person* means any individual, partnership, corporation, trust, estate, cooperative, association, government or governmental subdivision or agency, or other entity.

4. Communication of opt out information to affiliates

A company's communication to its affiliates of opt out information about a consumer is not a consumer report if:

- (a) The company has provided the consumer with an opt out notice;
- (b) The company has given the consumer a reasonable opportunity and means, before the company communicates the information to its affiliates, to opt out; and
- (c) The consumer has not opted out.

5. *Contents of opt out notice*

(a) *In general.* An opt out notice must be clear and conspicuous, and must accurately explain:

- (1) The categories of opt out information about the consumer that a company communicates to its affiliates;
- (2) The categories of affiliates to which the company communicates the information;
- (3) The consumer's ability to opt out; and
- (4) A reasonable means for the consumer to opt out.

(b) *Future communications.* A company's notice may describe:

- (1) Categories of opt out information about the consumer that the company reserves the right to communicate to its affiliates in the future but does not currently communicate; and
- (2) Categories of affiliates to which the company reserves the right in the future to communicate, but to which the company does not currently communicate, opt out information about the consumer.

(c) *Partial opt out.* A company may allow a consumer to select certain opt out information or certain affiliates, with respect to which the consumer wishes to opt out.

(d) *Examples of categories of information that a company communicates.* (1) A company satisfactorily explains the categories of opt out information that it communicates to affiliates if the company lists the categories in paragraph (d)(2) of this section, as applicable, and examples to illustrate the types of information in each category. These examples may include those in paragraph (d)(3) of this section, if applicable.

(2) Categories of opt out information may include information:

- (i) From a consumer's application;
- (ii) From a consumer credit report;
- (iii) Obtained by verifying representations made by a consumer; or
- (iv) Provided by another person regarding its employment, credit, or other relationship with a consumer.

(3) Examples of information within a category listed in paragraph (d)(2) include a consumer's:

- (i) Income;
- (ii) Credit score or credit history with others;
- (iii) Open lines of credit with others;

- (iv) Employment history with others;
- (v) Marital status; and
- (vi) Medical history.

(4) A company that communicates or reserves the right to communicate individually identifiable health information (as described in section 1171(6)(B) of the Social Security Act (42 U.S.C. 1320d(6)(B)) satisfactorily describes this type of information, if it provides illustrative examples of the health information it communicates or reserves the right to communicate.

(e) *Examples of categories of affiliates.* (1) A company satisfactorily categorizes the affiliates to which it communicates opt out information if it lists the categories in paragraph (e)(2) of this section, as applicable, and examples to illustrate the types of affiliates in each category.

(2) Categories of affiliates may include:

- (i) Financial service providers, followed by illustrative examples such as mortgage bankers, securities broker-dealers, and insurance agents; and
- (ii) Non-financial companies, followed by illustrative examples such as retailers, magazine publishers, airlines, and direct marketers; and
- (iii) Others, followed by examples such as nonprofit organizations.

(f) *Sample notice.* A sample notice is included in section 12.

6. *Reasonable opportunity to opt out*

(a) *In general.* A company provides a reasonable opportunity to opt out if it provides a reasonable period of time following the delivery of the opt out notice for the consumer to opt out.

(b) *Examples of reasonable periods of time for different means of delivery:* (1) *In person.* A company hand-delivers an opt out notice to the consumer and provides at least 30 days from the date it delivered the notice.

(2) *By mail.* A company mails an opt out notice to a consumer and provides at least 30 days from the date it mailed the notice.

(3) *By electronic means.* A company notifies the consumer electronically and provides at least 30 days after the date that the consumer acknowledges receipt of the electronic notice.

(c) *Continuing opportunity to opt out.* A consumer may opt out at any time.

7. *Reasonable means of opting out*

(a) *General rule.* A company provides a consumer with a reasonable means of opting out if it provides a reasonably convenient method to opt out.

(b) *Reasonably convenient methods.* Examples of reasonably convenient methods include:

(1) Designating check-off boxes in a prominent position on the relevant forms included with the opt out notice;

(2) Including a reply form that includes the address to which the form should be mailed, together with the opt out notice;

(3) Providing an electronic means to opt out, such as a form that can be electronically mailed or a process at the company's web site, if the consumer agrees to the electronic delivery of information; or

(4) Providing a toll-free telephone number that consumers may call to opt out.

(c) *Methods not reasonably convenient.* Examples of methods that are not reasonably convenient include:

(1) Requiring a consumer to write his or her own letter to a company; or

(2) Referring in a revised notice to a check-off box that a company included with a previous notice but that the company does not include with the revised notice.

(d) *Requiring specific means of opting out.* A company may require each consumer to opt out through a specific means, as long as that means is reasonable for that consumer.

8. *Delivery of opt out notices*

(a) *In general.* A company must deliver an opt out notice so that each consumer can reasonably be expected to receive actual notice in writing or, if the consumer agrees, electronically.

(b) *Examples of expectation of actual notice.* (1) A company may reasonably expect that a consumer will receive actual notice if it:

- (i) Hand-delivers a printed copy of the notice to the consumer;
- (ii) Mails a printed copy of the notice to the last known mailing address of the consumer; or
- (iii) For the consumer who conducts transactions electronically, posts the notice on its electronic site and requires the consumer to acknowledge receipt of the notice as a necessary step to obtaining a particular product or service;

(2) A company may *not* reasonably expect that a consumer will receive actual notice if it:

- (i) Only posts a sign in its branch or office or generally publishes advertisements presenting its notice; or
- (ii) Sends the notice via electronic mail to a consumer who does not obtain a product or service from the company electronically.

(c) *Oral description insufficient.* A company may not provide an opt out notice solely through an oral explanation of the notice, either in person or over the telephone.

(d) *Retention or accessibility.* (1) *In general.* A company clearly discloses the consumer's opportunity to opt out if it provides an opt out notice so that it can be retained or obtained at a later time by the consumer in writing or, if the consumer agrees, electronically.

(2) *Examples of retention or accessibility.* A company provides the notice so that it can be retained or obtained at a later time if the company:

- (i) Hand-delivers a printed copy of the notice to the consumer;
- (ii) Mails a printed copy of the notice to the last known address of the consumer upon request of the consumer; or
- (iii) Makes the company's current notice available on a web site (or a link to another web site) for the consumer who obtains a product or service electronically and who agrees to receive the notice at the web site.

(e) *Joint notice with affiliates.* A company may provide a joint notice with one or more affiliates as long as the notice identifies each person providing it and is accurate with respect to each.

(f) *Joint relationships.* (1) *In general.* If two or more consumers jointly obtain a product or service from a creditor or other company (joint consumers), the following principles apply:

- (i) The company may provide a single notice to all of the joint consumers.
- (ii) Any of the joint consumers has the opportunity to opt out.
- (iii) The company may treat an opt out direction by a joint consumer either as:
 - (A) Applying to all of the joint consumers; or
 - (B) Applying to that particular joint consumer.
- (iv) The company must explain in its opt out notice which of the two policies set forth in paragraph (f)(1)(iii) of this section it will follow.

(v) If the company follows the policy set forth in paragraph (f)(1)(iii)(B) of this section, by treating the opt out of a joint consumer as applying to that particular joint consumer, the company must also permit:

- (A) A joint consumer to opt out on behalf of other joint consumers; and
- (B) One or more joint consumers to notify the company of their opt out directions in a single response.

(vi) A company may not require all joint consumers to opt out before it implements any opt out direction.

(vii) If a company receives an opt out by a particular joint consumer that does not apply to the others, the company may disclose information about the others as long

as no information is disclosed about the consumer who opted out.

(2) *Example.* If consumers A and B, who have different addresses, have a joint account with a creditor and arrange for the creditor to send statements to A's address, the creditor may do any of the following, but it must explain in its opt out notice which opt out policy the creditor will follow. The creditor may send a single opt out notice to A's address and:

- (i) Treat an opt out direction by A as applying to the entire account. If the creditor does so and A opts out, the creditor may not require B to opt out as well before implementing A's opt out direction.
- (ii) Treat A's opt out direction as applying to A only. If the creditor does so, it must also permit:

- (A) A and B to opt out for each other; and
- (B) A and B to notify the creditor of their opt out directions in a single response (such as on a single form) if they choose to give separate opt out directions.

(iii) If A opts out only for A, and B does not opt out, the creditor may disclose opt out information only about B, and not about A and B jointly.

9. Revised opt out notice

If a company has provided a consumer with one or more opt out notices and plans to communicate opt out information to its affiliates about the consumer other than as described in those notices, the communication will not be a "consumer report" if the company provides the consumer with a revised opt out notice that complies with sections 4 through 8.

10. Time by which opt out must be honored

If a company provides a consumer with an opt out notice and the consumer opts out, the company must comply with the opt out as soon as reasonably practicable after the company receives it.

11. Duration of opt out

An opt out remains effective until revoked by the consumer in writing or electronically, as long as the consumer continues to have a relationship with the company. If the consumer's relationship with the company terminates, the opt out will continue to apply to this information. However, a new notice and opportunity to opt out must be provided if the consumer establishes a new relationship with the company.

12. Sample notice

This section contains a sample notice. A company may use applicable examples in this sample to provide disclosures to

consumers about the sharing of information with its affiliates.

Notice of Your Opportunity To Opt Out of Information Sharing With Our Affiliates

Information we can share with our affiliates about you—unless you tell us not to

What Information: Unless you tell us not to, [Company] may share with our affiliated companies information about you, including:

- Information we obtain from your application, such as [provide illustrative examples, such as "your income" or "your marital status"];
- Information we obtain from a consumer report, such as [provide illustrative examples, such as "your credit score or credit history"];
- Information we obtain to verify representations made by you, such as [provide illustrative examples, such as "your open lines of credit"]; and
- Information we obtain from a person regarding its employment, credit, or other relationship with you, such as [provide illustrative examples, such as "your employment history"].

Shared With Whom: Our affiliated companies who may receive this information are:

- Financial service providers, such as [provide illustrative examples, such as "mortgage lenders or brokers"];
- Non-financial companies, such as [provide illustrative examples, such as "retailers, direct marketers, airlines, and publishers"];
- Others [provide illustrative examples, such as "nonprofit organizations"].

How to tell us not to share this information with our affiliated companies

If you prefer that we not share this information with our affiliated companies, you may direct us not to share this information by doing the following [insert one or more of the reasonable means of opting out listed below*]: [call us toll free at {insert toll free number}]; or [visit our web site at {insert web site address} and {provide further instructions on how to use the web site option}]; or [e-mail us at {insert the e-mail address}]; or [fill out and tear off the bottom of this sheet and mail to the address shown there]; or [check the appropriate box on the attached form

* If the company is using its web site or an e-mail address as the only method by which a consumer may opt out, the consumer must agree to the electronic delivery of information.

{attach form}; and mail to the following address: {insert address}].

Note: Your direction in this paragraph covers certain information about you that we might otherwise share with our affiliated companies. We may share other information about you with our affiliated companies as permitted by law.

By direction of the Commission.

Donald S. Clark,
Secretary.

[FR Doc. 00-32391 Filed 12-21-00; 8:45 am]

BILLING CODE 6750-01-P

DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

37 CFR Parts 1 and 104

RIN 0651-AB22

Legal Processes

AGENCY: Office of the General Counsel, United States Patent and Trademark Office, Commerce.

ACTION: Proposed rule.

SUMMARY: The United States Patent and Trademark Office proposes rules relating to civil actions and claims involving the Office. Specifically, the rules will provide procedures for service of process, for obtaining Office documents and employee testimony, for indemnifying employees, and for making a claim against the Office under the Federal Tort Claims Act.

DATES: Submit comments on or before January 22, 2001.

ADDRESSES: Send all comments:

1. Electronically to "PBORulemaking@uspto.gov", Subject: "Legal Process Rules";
2. By mail to Director of the United States Patent and Trademark Office, Box 8, Washington, DC 20231, ATTN: Legal Process Rules; or
3. By facsimile to 703-305-9373, ATTN: Legal Process Rules.

A copy of any comments regarding the information collection requirements may instead be sent to the Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, 725 17th Street, NW., Room 10235, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Richard Torczon, 703-305-9035.

SUPPLEMENTARY INFORMATION:

Comment format

The Office prefers to receive comments in electronic form, either via the Internet or on a 3¼ inch diskette.

Comments submitted in electronic form should be submitted as ASCII text. Special characters and encryption should not be used.

Background

The Patent and Trademark Office Efficiency Act (PTOEA) (Public Law 106-113, 113 Stat. 1501A-572 (1999)) reestablished the Patent and Trademark Office as the United States Patent and Trademark Office, a performance-based organization with responsibility for its own operations. Consequently, the Office has responsibility for many functions formerly provided by the Department of Commerce. The rules proposed in this notice adopt the substance and scope of the existing Department of Commerce rules, but where possible the proposed rules have been streamlined and tailored to reflect the practices of the Office and its constituencies. These proposed rules have been organized into a single part for convenience.

General Provisions

The general provisions supply definitions, addresses, and a rule waiver provision that are generally applicable to the rules in this part. Filing of a petition to waive a rule will not in itself stay any action required of the petitioner. Section 1.17(h) of title 37 of the Code of Federal Regulations is amended to provide for a petition fee.

Service of Process

The Patent and Trademark Office had rules for the service of process. 37 CFR part 15 (1996). In recent years, however, the Patent and Trademark Office instead relied on the rules of the Department of Commerce, 15 CFR part 15, subpart A, which were substantially the same as the former Patent and Trademark Office rules. The Office will again issue its own rules to tailor the rules to the specific practices of the Office and to simplify the structure of the rules. The proposed rules ensure that service intended for the Office and its employees will be properly handled.

When the Office accepts service of process for an employee in an official capacity, the Marshal's or server's return of service form or receipt for registered or certified mail should be endorsed with the following statement: "Service accepted in official capacity only." The Office will not accept service for an employee in his or her individual capacity.

Employee Testimony and Production of Documents

The Patent and Trademark Office had rules for employee testimony and

document production. 37 CFR part 15a (1996). Those rules were specifically tailored to the practices of the Patent and Trademark Office and reflected case law regarding the quasi-judicial nature of many Patent and Trademark Office employees' positions. *Western Elec. Co. v. Piezo Technology, Inc.*, 860 F.2d 428, 431, 8 USPQ2d 1853, 1856 (Fed. Cir. 1988). The Patent and Trademark Office subsequently relied on Department of Commerce rules. 15 CFR part 15, subpart B. The Commerce rules materially differ from the former Patent and Trademark Office rules in two respects. First, the Department of Commerce rules do not address specific and recurrent problems associated with taking testimony from quasi-judicial officials at the Patent and Trademark Office. Second, the Department of Commerce rules include former employees within their scope. The Office will again issue its own rules tailored to the practices of the Office, but will follow the example of the Department of Commerce in including former employees within the scope of the rules (§ 104.2).

The inclusion of former employees within the scope of the rules is appropriate since, in many cases, the rules serve to preserve privileges of the Office. The Office's privileges are not waived simply because an employee leaves the Office. Moreover, testimony by former employees may raise other legal issues that might be avoided or resolved if the Office is involved early in the process. *Cf. Friedman v. Lehman*, 40 USPQ2d 1206 (D.D.C. 1996) (affirming a sanction against a former Patent and Trademark Office employee for testifying about a patent on which he had worked). The scope of this subpart has been defined to exclude (§ 104.21(b)) testimony unrelated to official business and, for former employees, expert testimony that is not likely to involve an Office privilege. The exception for expert testimony by former employees is based on the policies of 18 U.S.C. 207(a)(1) and (j)(6), but the scope of the exception is not the same as the scope of this criminal statute. The exception has no effect on the scope of the criminal statute or the disciplinary rules. *Cf.* 37 CFR 10.111; *Friedman, supra*.

The former Patent and Trademark Office rules listed questions that employees would not be authorized to answer because the questioning would be impermissibly directed to

discovering the mental processes or expertise of a quasi-judicial official. 37 CFR 15a.6(b) (1996). These questions included:

- (1) Information about that employee's:
 - (i) Background.
 - (ii) Expertise.
 - (iii) Qualifications to examine or otherwise consider a particular patent or trademark application.
 - (iv) Usual practice or whether the employee followed a procedure set out in any Office manual of practice in a particular case.
 - (v) Consultation with another Office employee.
 - (vi) Understanding of:
 - (A) A patented invention, an invention sought to be patented, or patent application, patent, reexamination or interference file.
 - (B) Prior art.
 - (C) Registered subject matter, subject matter sought to be registered, or a trademark application, registration, cancellation, opposition, interference, or concurrent use file.
 - (D) Any Office manual of practice.
 - (E) Office regulations.
 - (F) Patent, trademark, or other law.
 - (G) The responsibilities of another Office employee.
 - (vii) Reliance on particular facts or arguments.
- (2) To inquire into the manner in and extent to which the employee considered or studied material in performing the quasi-judicial function.
- (3) To inquire into the bases, reasons, mental processes, analyses, or conclusions of that Office employee in performing the quasi-judicial function.

While all of these prohibitions remain valid, they are necessarily incomplete because it would be impossible to list every kind of question that would be considered impermissible under the case law. For instance, in *Western Electric*, fact questions were also deemed impermissible because they were "disruptive of the decisionmaking process and thereby interfere with the PTO's administrative functions" and also because they were inherently prejudicial. 860 F.2d at 432-33, 8 USPQ2d at 1857. Consequently, rather than codify an incomplete list of impermissible questions, the Office will rely on the case law and this notice as its basis for declining to authorize testimony in response to impermissible questions. The Office will not authorize testimony on the validity or enforceability of a patent or registered trademark.

The proposed rules require an employee who receives a subpoena to

forward the subpoena to the General Counsel immediately (§ 104.23(a)). The General Counsel will determine the extent to which the employee will comply with the subpoena. The General Counsel may instruct the employee, orally or in writing, not to give testimony or produce documents.

The proposed rules require (§ 104.23(c)(3)) that an affidavit accompany the subpoena to assist the General Counsel in making an informed decision regarding whether testimony or the production of a document should be authorized. The General Counsel may consult or negotiate with an attorney for a party, or with the party if not represented by an attorney, to refine or limit a demand so that compliance is less burdensome or to obtain information necessary to determine whether to authorize testimony or produce documents.

Whenever, in any proceeding involving the United States, a request is made by an attorney representing or acting under the authority of the United States, the General Counsel will make all necessary arrangements for the employee to give testimony on behalf of the United States (§ 104.25(a)(2)). Where appropriate, the General Counsel may require reimbursement to the Office of the expenses associated with an employee giving testimony on behalf of the United States.

The proposed rules on production of documents (especially § 104.29) do not affect rights under, and procedures governing public access to records pursuant to, the Freedom of Information Act (5 U.S.C. 552), the Privacy Act (5 U.S.C. 552a), or the Trade Secrets Act (18 U.S.C. 1905). Moreover, the proposed rules in this subpart do not create any right or benefit, substantive or procedural, enforceable by any party against the United States.

Employee Indemnification

The Patent and Trademark Office operated under Department of Commerce rules for employee indemnification, 15 CFR part 15, subpart D. The Office will issue its own rules to tailor the rules to the specific practices of the Office and to simplify the structure of the rules. Essentially, the Office adopts the requirements of the lead agency, the Department of Justice (28 CFR part 14), for filing requests for indemnification.

Federal Tort Claims Act Claims

The Patent and Trademark Office operated under Department of Commerce rules (15 CFR part 2) for claims under the Federal Tort Claims Act (28 U.S.C. 2672). The Office will

issue its own rules to tailor the rules to the specific practices of the Office and to simplify the structure of the rules.

The Federal Tort Claims Act provides a limited waiver of the United States Government's sovereign immunity contingent, in part, on submission of a tort claim to the affected agency for an administrative determination. The Office of the General Counsel will record the time and date the claim was received. The claim may then be forwarded to the business unit involved in the claim or another appropriate business unit within the Office and request that an investigation be conducted. The business unit will conduct an investigation, prepare a file, obtain additional information as necessary, and prepare a recommendation for award or denial of the claim. If the amount of the proposed award exceeds \$25,000 (in which case, approval by the Attorney General is required), or if consultation with the Department of Justice is appropriate (28 CFR 14.6), the General Counsel will provide liaison with the Department of Justice.

Regulatory Flexibility Act

The Office's Acting General Counsel certified to the Chief Counsel for Advocacy, Small Business Administration, that the changes proposed in this notice, if adopted, would not have a significant impact on a substantial number of small entities (Regulatory Flexibility Act, 5 U.S.C. 605(b)). This rulemaking substantially adopts rules in effect for the Department of Commerce, but modifies the rules to make them more specific to the United States Patent and Trademark Office, which in some cases simplifies the structure of the rules. Since few proceedings within the scope of this rulemaking typically arise over the course of a year, and since very few involve small businesses, the Office anticipates only a slight impact on a minimal number of small businesses annually.

Executive Order 13132

Federalism Assessment

This rulemaking does not contain policies with federalism implications sufficient to warrant preparation of a Federalism Assessment under Executive Order 13132 (August 4, 1999).

Executive Order 12866

Regulatory Planning and Review

This rulemaking has been determined to be not significant for purposes of Executive Order 12866 (September 30, 1993).

Paperwork Reduction Act

This notice of proposed rulemaking contains information collection requirements subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). The Office's Records Officer is submitting an information collection package to the Office of Management and Budget (OMB) for review and approval of the proposed information collections.

Section 104.4 authorizes petitions to waive rules under this part. Such petitions are expected to be rare (assumed to be one each year for the purposes of this analysis). Section 104.12 sets requirements for addressing and forwarding service of process. Section 104.23 sets requirements for addressing and explaining demands for testimony. Section 104.25 requires employees giving unauthorized testimony to provide written summary of the testimony to the General Counsel. Section 104.33 sets requirements for requesting indemnification. Section 104.42 sets addressing requirements for tort claims.

The title, description, and respondent description of the information collection is shown below with an estimate of the annual reporting burdens. Included in this estimate is the time for reviewing instructions, gathering, and maintaining the data needed, and completing and reviewing the collection of information. The principal impact of the changes in this notice of proposed rulemaking is to tailor Department of Commerce rules to the specific context of the United States Patent and Trademark Office.

OMB Number: 0651-00xx.

Title: Legal processes.

Form Numbers: None.

Type of Review: New collection.

Affected Public: Individuals or households, businesses or other for-profit, not-for-profit institutions, Federal Government, and state, local, or tribal governments.

Estimated Number of Respondents: 186.

Estimated Time Per Response: 0.16 hours.

Estimated Total Annual Burden Hours: 29.2 hours.

Needs and Uses: The information is necessary to settle claims under the Federal Tort Claims Act (28 U.S.C. 2672), to indemnify employees involved in Office-related litigation (28 U.S.C. part 14), and to determine whether and how to respond to litigation or to requests for discovery involving the Office or its employees.

Comments are invited on: (1) whether the collection of information is necessary for proper performance of the

functions of the agency; (2) the accuracy of the agency's estimate of the burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information to respondents.

Interested persons are requested to send comments regarding these information collections, including suggestions for reducing this burden, to Richard Torczon, c/o Office of the General Counsel, United States Patent and Trademark Office, Washington, DC 20231, or to the Office of Information and Regulatory Affairs of OMB, New Executive Office Building, 725 17th Street, NW, Room 10235, Washington, DC 20503, ATTN: Desk Officer for the United States Patent and Trademark Office.

Notwithstanding any other provision of law, no person is required to respond to nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a currently valid OMB control number.

List of Subjects

37 CFR Part 1

Administrative practice and procedure, Claims, Courts, Freedom of information, Inventions and patents, Tort claims, Trademarks.

37 CFR Part 104

Administrative practice and procedure, Claims, Courts, Inventions and patents, Tort claims.

For the reasons stated in the preamble, the United States Patent and Trademark Office amends 37 CFR chapter I as follows:

PART 1—RULES OF PRACTICE IN PATENT CASES

1. The authority citation for 37 CFR part 1 is revised to read as follows:

Authority: 35 U.S.C. 2(b)(2), unless otherwise noted.

2. Section 1.17 is amended by revising paragraph (h) to read as follows:

§ 1.17 Patent application processing fees.

* * * * *

(h) For filing a petition to the Commissioner under one of the following sections which refers to this paragraph: 130.00

§ 1.12—for access to an assignment record.

§ 1.14—for access to an application.

§ 1.47—for filing by other than all the inventors or a person not the inventor.

§ 1.53(e)—to accord a filing date.

§ 1.59—for expungement and return of information.

§ 1.84—for accepting color drawings or photographs.

§ 1.91—for entry of a model or exhibit.

§ 1.102—to make an application special.

§ 1.103(a)—to suspend action in an application.

§ 1.138(c)—to expressly abandon an application to avoid publication.

§ 1.182—for decision on a question not specifically provided for.

§ 1.183—to suspend the rules.

§ 1.295—for review of refusal to publish a statutory invention registration.

§ 1.313—to withdraw an application from issue.

§ 1.314—to defer issuance of a patent.

§ 1.377—for review of decision refusing to accept and record payment of a maintenance fee filed prior to expiration of a patent.

§ 1.378(e)—for reconsideration of decision on petition refusing to accept delayed payment of maintenance fee in an expired patent.

§ 1.644(e)—for petition in an interference.

§ 1.644(f)—for request for reconsideration of a decision on petition in an interference.

§ 1.666(b)—for access to an interference settlement agreement.

§ 1.666(c)—for late filing of an interference settlement agreement.

§ 1.741(b)—to accord a filing date to an application under 1.740 for extension of a patent term.

§ 5.12—for expedited handling of a foreign filing license.

§ 5.15—for changing the scope of a license.

§ 5.25—for a retroactive license.

§ 104.4—for waiver of a rule in part 104 of this title.

* * * * *

3. Revise the heading of subchapter B to read as follows:

SUBCHAPTER B—ADMINISTRATION

4. Add part 104 to subchapter B to read as follows:

PART 104—LEGAL PROCESSES

Subpart A—General Provisions

Sec.

104.2 Definitions.

104.3 Address for mail and service; telephone number.

104.4 Waiver of rules.

Subpart B—Service of Process

104.11 Scope and purpose.

104.12 Acceptance of service of process.

Subpart C—Employee Testimony and Production of Documents in Legal Proceedings

104.21 Scope and purpose.

104.23 Demand for testimony or production of documents.

104.25 Expert or opinion testimony.

104.29 Demands or requests in legal proceedings for records protected by confidentiality statutes.

Subpart D—Employee Indemnification

104.31 Scope.

104.33 Procedure for requesting indemnification.

Subpart E—Tort Claims

104.42 Procedure for filing claims.

104.44 Finality of settlement or denial of claims.

Authority: 35 U.S.C. 2(b)(2), 10, 23, 25; 44 U.S.C. 3101, except as otherwise noted.

PART 104—LEGAL PROCESSES

Subpart A—General Provisions

§ 104.2 Definitions.

Demand means a request, order, or subpoena for testimony or documents for use in a legal proceeding.

Director means the Director of the United States Patent and Trademark Office.

Document means any record, paper, and other property held by the Office, including without limitation, official letters, telegrams, memoranda, reports, studies, calendar and diary entries, maps, graphs, pamphlets, notes, charts, tabulations, analyses, statistical or informational accumulations, any kind of summaries of meetings and conversations, film impressions, magnetic tapes, and sound or mechanical reproductions.

Employee means any current or former officer or employee of the Office, including any individual subject to the jurisdiction, supervision, or control of the Office.

Legal proceeding means any pretrial, trial, and posttrial stages of existing or reasonably anticipated judicial or administrative actions, hearings, investigations, or similar proceedings before courts, commissions, boards or other tribunals, foreign or domestic. This phrase includes all phases of discovery as well as responses to formal or informal requests by attorneys or others involved in legal proceedings.

Office means the United States Patent and Trademark Office, including any operating unit in the United States Patent and Trademark Office, and its predecessors, the Patent Office and the Patent and Trademark Office.

Official business means the authorized business of the Office.

General Counsel means the General Counsel of the Office.

Testimony means a statement in any form, including personal appearances before a court or other legal tribunal, interviews, depositions, telephonic, televised, or videotaped statements or any responses given during discovery or similar proceedings, which response would involve more than the production of documents, including a declaration under 35 U.S.C. 25 or 28 U.S.C. 1746.

United States means the Federal Government, its departments and agencies, individuals acting on behalf of the Federal Government, and parties to the extent they are represented by the United States.

§ 104.3 Address for mail and service; telephone number.

(a) Mail under this part should be addressed to General Counsel, United States Patent and Trademark Office, P.O. Box 15667, Arlington, VA 22215.

(b) Service by hand should be made during business hours to the Office of the General Counsel, Crystal Park Two, Suite 714, 2121 Crystal Drive, Arlington, Virginia.

(c) The Office of the General Counsel may be reached by telephone at 703–305–9035 during business hours.

§ 104.4 Waiver of rules.

In extraordinary situations, when the interest of justice requires, the General Counsel may waive or suspend the rules of this part, sua sponte or on petition of an interested party to the Director, subject to such requirements as the General Counsel may impose. Any petition must be accompanied by the petition fee set forth in § 1.17(h) of this title.

Subpart B—Service of Process

§ 104.11 Scope and purpose.

(a) This subpart sets forth the procedures to be followed when a summons or complaint is served on the Office or on the Director or an employee in his or her official capacity.

(b) This subpart is intended, and should be construed, to ensure the efficient administration of the Office and not to impede any legal proceeding.

(c) This subpart does not apply to subpoenas, the procedures for which are set out in subpart C of this part.

(d) This subpart does not apply to service of process made on an employee personally on matters not related to official business of the Office or to the official responsibilities of the employee.

§ 104.12 Acceptance of service of process.

(a) Any summons or complaint to be served in person or by registered or certified mail or as otherwise authorized by law on the Office, on the Director, or on an employee in his or her official capacity, shall be served as indicated in § 104.3.

(b) Any employee of the Office served with a summons or complaint shall immediately notify, and shall deliver the summons or complaint to, the Office of the General Counsel.

(c) Any employee receiving a summons or complaint shall note on the

summons or complaint the date, hour, and place of service and whether service was by hand or by mail.

(d) When a legal proceeding is brought to hold an employee personally liable in connection with an action taken in the conduct of official business, rather than liable in an official capacity, the employee by law is to be served personally with process. Service of process in this case is inadequate when made only on the General Counsel. An employee sued personally for an action taken in the conduct of official business shall immediately notify and deliver a copy of the summons or complaint to the General Counsel.

(e) An employee sued personally in connection with official business may be represented by the Department of Justice at its discretion (28 CFR 50.15 and 50.16).

(f) The Office will only accept service of process for an employee in the employee's official capacity.

Subpart C—Employee Testimony and Production of Documents in Legal Proceedings

§ 104.21 Scope and purpose.

(a) This subpart sets forth the policies and procedures of the Office regarding the testimony of employees as witnesses in legal proceedings and the production or disclosure of information contained in Office documents for use in legal proceedings pursuant to a demand.

(b) Exceptions. This subpart does not apply to any legal proceeding in which:

(1) An employee is to testify regarding facts or events that are unrelated to official business; or

(2) A former employee is to testify as an expert in connection with a particular matter in which the former employee did not participate personally while at the Office.

§ 104.23 Demand for testimony or production of documents.

(a) Whenever a demand for testimony or for the production of documents is made upon an employee, the employee shall immediately notify the General Counsel at the telephone number or addresses in § 104.3 and make arrangements to send the subpoena to the General Counsel promptly.

(b) An employee may not give testimony, produce documents, or answer inquiries from a person not employed by the Office regarding testimony or documents subject to a demand or a potential demand under the provisions of this subpart without the approval of the General Counsel. The General Counsel may authorize the provision of certified copies not

otherwise available under part 1 of this title subject to payment of applicable fees under § 1.19 of this chapter.

(c)(1) *Demand for testimony or documents.* A demand for the testimony of an employee under this subpart shall be addressed to the General Counsel as indicated in § 104.3.

(2) *Subpoenas.* A subpoena for employee testimony or for a document shall be served in accordance with the Federal Rules of Civil or Criminal Procedure or applicable state procedure, and a copy of the subpoena shall be sent to the General Counsel as indicated in § 104.3.

(3) *Affidavits.* Except when the United States is a party, every demand shall be accompanied by an affidavit or declaration under 28 U.S.C. 1746 or 35 U.S.C. 25(b) setting forth the title of the legal proceeding, the forum, the requesting party's interest in the legal proceeding, the reason for the demand, a showing that the desired testimony or document is not reasonably available from any other source, and, if testimony is requested, the intended use of the testimony, a general summary of the desired testimony, and a showing that no document could be provided and used in lieu of testimony.

(d) Failure of the attorney to cooperate in good faith to enable the General Counsel to make an informed determination under this subpart may serve as a basis for a determination not to comply with the demand.

(e) A determination under this subpart to comply or not to comply with a demand is not a waiver or an assertion of any other ground for noncompliance, including privilege, lack of relevance, or technical deficiency.

(f) *Noncompliance.* If the General Counsel makes a determination not to comply, but the subpoena is not withdrawn or modified and Department of Justice representation cannot be arranged, the employee should appear at the time and place set forth in the subpoena. If legal counsel cannot appear on behalf of the employee, the employee should produce a copy of these rules and state that the General Counsel has advised the employee not to provide the requested testimony or to produce the requested document. If a legal tribunal rules that the demand in the subpoena must be complied with, the employee shall respectfully decline to comply with the demand, citing *United States ex rel. Touhy v. Ragen*, 340 U.S. 462 (1951).

§ 104.25 Expert or opinion testimony.

(a)(1) If the General Counsel authorizes an employee to give testimony in a legal proceeding not

involving the United States, the testimony, if otherwise proper, shall be limited to facts within the personal knowledge of the employee. Employees, with or without compensation, shall not provide expert testimony in any legal proceedings regarding Office information, subjects, or activities except on behalf of the United States or a party represented by the United States Department of Justice.

(2) The General Counsel may authorize an employee to appear and give the expert or opinion testimony upon the requester showing, pursuant to § 104.4 of this part, that exceptional circumstances warrant such testimony and that the anticipated testimony will not be adverse to the interest of the Office or the United States.

(b)(1) If, while testifying in any legal proceeding, an employee is asked for expert or opinion testimony regarding Office information, subjects, or activities, which testimony has not been approved in advance in writing in accordance with the regulations in this subpart, the witness shall:

(i) Respectfully decline to answer on the grounds that such expert or opinion testimony is forbidden by this subpart;

(ii) Request an opportunity to consult with the General Counsel before giving such testimony; and

(iii) Explain that upon such consultation, approval for such testimony may be provided.

(2) If the tribunal conducting the proceeding then orders the employee to provide expert or opinion testimony regarding Office information, subjects, or activities without the opportunity to consult with the General Counsel, the employee shall respectfully refuse to provide such testimony, citing *United States ex rel. Touhy v. Ragen*, 340 U.S. 462 (1951).

(c) If an employee is unaware of the regulations in this subpart and provides expert or opinion testimony regarding Office information, subjects, or activities in a legal proceeding without the aforementioned consultation, the employee shall, as soon after testifying as possible, inform the General Counsel that such testimony was given and provide a written summary of the expert or opinion testimony provided.

(d) Proceeding where the United States is a party. In a proceeding in which the United States is a party or is representing a party, an employee may not testify as an expert or opinion witness for any party other than the United States.

§ 104.29 Demands or requests in legal proceedings for records protected by confidentiality statutes.

Demands in legal proceedings for the production of records, or for the testimony of employees regarding information protected by the confidentiality provisions of the Patent Act (35 U.S.C. 122), the Privacy Act (5 U.S.C. 552a), the Trade Secrets Act (18 U.S.C. 1905), or any other confidentiality statute, must satisfy the requirements for disclosure set forth in those statutes and associated rules before the records may be provided or testimony given. Where the General Counsel determines an applicable confidentiality statute requires disclosure, this subpart will not apply.

Subpart D—Employee Indemnification

§ 104.31 Scope.

The procedure in this subpart shall be followed if a civil action or proceeding is brought, in any court, against an employee (including the employee's estate) for personal injury, loss of property, or death, resulting from the employee's activities while acting within the scope of the employee's office or employment. When the employee is incapacitated or deceased, actions required of an employee should be performed by the employee's executor, administrator, or comparable legal representative.

§ 104.33 Procedure for requesting indemnification.

(a) After being served with process or pleadings in such an action or proceeding, the employee shall within five (5) calendar days of receipt, deliver to the General Counsel all such process and pleadings or an attested true copy thereof, together with a fully detailed report of the circumstances of the incident giving rise to the court action or proceeding.

(b)(1) An employee may request indemnification to satisfy a verdict, judgment, or award entered against that employee only if the employee has timely satisfied the requirements of paragraph (a) of this section.

(2) No request for indemnification will be considered unless the employee has submitted a written request through the employee's supervisory chain to the General Counsel with:

(i) Appropriate documentation, including copies of the verdict, judgment, appeal bond, award, or settlement proposal;

(ii) The employee's explanation of how the employee was acting within the scope of the employee's employment; and

(iii) The employee's statement of whether the employee has insurance or any other source of indemnification.

Subpart E—Tort Claims

Authority: 28 U.S.C. 2672; 35 U.S.C. 2(b)(2); 44 U.S.C. 3101; 28 CFR part 14.

§ 104.42 Procedure for filing claims.

Administrative claims against the Office filed pursuant to the administrative claims provision of the Federal Tort Claims Act (28 U.S.C. 2672) and the corresponding Department of Justice regulations (28 CFR part 14) shall be filed with the General Counsel as indicated in § 104.3.

§ 104.44 Finality of settlement or denial of claims.

Only a decision of the Director or the General Counsel regarding settlement or denial of any claim under this subpart may be considered final for the purpose of judicial review.

Dated: December 11, 2000.

Q. Todd Dickinson,

Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.

[FR Doc. 00-32314 Filed 12-21-00; 8:45 am]

BILLING CODE 3510-16-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[CO-001-0044b; FRL-6875-4]

Approval and Promulgation of Air Quality Implementation Plans; State of Colorado; Colorado Springs Revised Carbon Monoxide Maintenance Plan and Approval of a Related Revision

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing approval of the revised Colorado Springs carbon monoxide (CO) maintenance plan, that is designed to keep the area in attainment for CO through 2010, and revisions to Colorado's Regulation No. 13 "Oxygenated Fuels Program" for the removal of the requirement for the implementation of the wintertime oxygenated fuels program in El Paso County and the Colorado Springs area. The revised maintenance plan and revisions to Regulation No. 13 were submitted by the Governor on May 10, 2000. In the Final Rules section of this **Federal Register**, EPA is approving the State's State Implementation Plan (SIP) revisions, involving the revised

maintenance plan and the changes to Regulation No. 13, as a direct final rule without prior proposal because the Agency views these SIP revisions as noncontroversial and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If no adverse comments are received in response to this rule, no further activity is contemplated in relation to this rule. If EPA receives adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. EPA will not institute a second comment period on this action. Any parties interested in commenting on this action should do so at this time.

DATES: Comments must be received in writing by January 22, 2001.

ADDRESSES: Written comments may be mailed to: Richard R. Long, Director, Air and Radiation Program, Mailcode 8P-AR, United States Environmental Protection Agency, Region VIII, 999 18th Street, Suite 300, Denver, Colorado 80202-2466.

Copies of the documents relevant to this action are available for public inspection between 8:00 a.m. and 4:00 p.m., Monday through Friday at the following office:

United States Environmental Protection Agency, Region VIII, Air Program, 999 18th Street, Suite 300, Denver, Colorado 80202-2466.

FOR FURTHER INFORMATION CONTACT: Tim Russ, Air and Radiation Program, Mailcode 8P-AR, United States Environmental Protection Agency, Region VIII, 999 18th Street, Suite 300, Denver, Colorado 80202-2466; Telephone number (303) 312-6479.

SUPPLEMENTARY INFORMATION: See the information provided in the Direct Final action of the same title which is located in the Rules section of this **Federal Register**.

Dated: September 14, 2000.

Patricia D. Hull,

Acting Regional Administrator, Region VIII.

[FR Doc. 00-32301 Filed 12-21-00; 8:45 am]

BILLING CODE 6560-50-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 216

[Docket No.000801223-0223-01; I.D. 062000A]

RIN 0648-AO24

Taking and Importing Marine Mammals; Taking Marine Mammals Incidental to Operation of a Low Frequency Sound Source by the North Pacific Acoustic Laboratory

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of proposed rulemaking; request for comments.

SUMMARY: NMFS has received a request from the University of California San Diego, Scripps Institution of Oceanography (Scripps), for a Letter of Authorization (LOA) to take a small number of marine mammals incidental to the continued operation of a low frequency (LF) sound source previously installed off the north shore of Kauai by the Acoustic Thermometry of Ocean Climate (ATOC) project. By this notice, NMFS is proposing regulations to govern that take. In order to grant the exemption and issue the regulations, NMFS must determine that these takings will have no more than a negligible impact on the affected species and stocks of marine mammals. NMFS invites comment on the application and the proposed regulations.

DATES: Comments and information must be postmarked no later than February 5, 2001. Comments will not be accepted if submitted via e-mail or the Internet.

Comments regarding the burden-hour estimate or any other aspect of the collection of information requirement contained in this rule should be sent to the Chief, and to the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Attention: NOAA Desk Officer, Washington, DC 20503.

ADDRESSES: Comments should be addressed to Donna Wieting, Chief, Marine Mammal Conservation Division, Office of Protected Resources, National Marine Fisheries Service, 1315 East-West Highway, Silver Spring, MD 20910-3226. A copy of the application, which contains the references used in this document, may be obtained by writing to this address or by telephoning the contacts listed here (see **FOR FURTHER INFORMATION CONTACT**). A copy

of the draft environmental impact statement (DEIS) may be obtained from Marine Acoustics Inc., 809 Aquidneck Ave., Middletown, RI 02842, attn. Kathy Vigness Reposa, 401-847-7508.

FOR FURTHER INFORMATION CONTACT:

Kenneth R. Hollingshead (301) 713-2055, ext. 128, and Margaret Dupree, 808-973-2935, ext. 210.

SUPPLEMENTARY INFORMATION:

Background

Section 101(a)(5)(A) of the Marine Mammal Protection Act (16 U.S.C. 1361 *et seq.*) (MMPA) directs the Secretary of Commerce (Secretary) to allow, upon request, the incidental, but not intentional, taking of small numbers of marine mammals by U.S. citizens who engage in a specified activity (other than commercial fishing) within a specified geographical region if certain findings are made and regulations governing the take are issued.

Permission may be granted for periods of 5 years or less if the Secretary finds that the taking will be small, will have no more than a negligible impact on the species or stock(s), and will not have an unmitigable adverse impact on the availability of the species or stock(s) for Arctic Ocean subsistence uses, and if regulations are prescribed setting forth the permissible methods of taking and the requirements pertaining to the monitoring and reporting of such taking.

Summary of Request

On May 21, 2000, NMFS received an application for an incidental, small take authorization under section 101(a)(5)(A) of the MMPA from Scripps to take a small number of marine mammals incidental to the continued operation of a LF sound source previously installed off the north shore of Kauai by the ATOC project. An alternative source location under consideration in the DEIS is for Midway Island. A final decision on whether to re-use the acoustic source (or to install a new source and cable at Midway), in order to combine a second phase of research on the feasibility and value of large-scale acoustic thermometry with long range underwater sound transmission studies and marine mammal monitoring and studies will be made based, in part, on findings and determinations made under the National Environmental Policy Act (NEPA). As the principal funding agency for the proposed action, a DEIS has been prepared by the Office of Naval Research (ONR). NMFS is a cooperating agency in the preparation of this DEIS.

Project Description

Acoustic thermometry is a method for obtaining information about the temperature field in the ocean from precise measurements of the travel times of sound pulses transmitted through the ocean. It is also a technique for acoustic remote sensing of the ocean interior, in which the properties of the ocean between the acoustic sources and receivers are determined, rather than the properties of the ocean at the instruments as is the case for conventional thermometers and current meters.

The purposes for conducting the proposed action are: (1) To perform the second phase of research on the feasibility and value of large-scale acoustic thermometry; and (2) to study the behavior of sound transmissions in the ocean over long distances. Large-scale acoustic thermometry is needed: (1) To study seasonal and interannual ocean variability associated with ocean phenomena such as El Nino, La Nina, and the Pacific Decadal Oscillation; (2) to use acoustic thermometry data in combination with a variety of other data types, including satellite altimeter data, surface drifter data, surface mooring data, and others to test and constrain computer models of ocean circulation in order to gain a better understanding of ocean variability and the earth's changing climate; and (3) to make an objective assessment of the value of acoustic methods for remote sensing of the ocean interior as one component of an integrated ocean observing system for ocean weather and climate.

Long-range underwater sound transmission studies are needed: (1) To improve the understanding of the basic principles of LF, long-range underwater sound transmission (i.e., acoustic propagation) in the ocean; (2) to determine the effects of ocean environmental variability on acoustic signal stability and coherence; (3) to study the seasonal and annual variations in acoustic conditions in the North Pacific and the impact of environmental variability on acoustic propagation; and (4) to determine the fundamental limits to acoustic signal processing at long-range imposed by the ocean environment.

This second phase of acoustic research requires longer time series of acoustic measurements in order to determine whether the acoustically-derived time series of large-scale ocean temperature and heat content variability prove to be as valuable as anticipated in studying seasonal and interannual ocean variability. It is anticipated that there will be a growing effort to monitor

the variability of the North Pacific using a combination of satellite altimeter data, surface and subsurface drifter data, surface moorings and bathythermograph data, in addition to acoustic thermometry data. Combining all of these different data types in computer models of the ocean circulation will allow testing and refinement of ocean general circulation and climate models in order to gain a better understanding of the earth's changing climate.

Under the proposed action, which is for Scripps to operate the sound source previously installed off the north shore of Kauai by the Acoustic Thermometry of Ocean Climate (ATOC) project, the seabed power cable and sound source from the ATOC project would remain in their present locations on Kauai, and transmissions would continue with approximately the same signal parameters and transmission schedule used in the earlier ATOC project. The typical schedule would consist of six 20-minute (min) transmissions (one every 4 hours), every fourth day, with each transmission preceded by a 5-min ramp-up period during which the signal intensity is gradually increased, representing an average duty cycle of 2 percent. With the possible exception of short duration testing with duty cycles of up to 8 percent, or equipment failure, this schedule would continue for a period of 5 years. The signals transmitted by the source would have a center frequency of 75 Hertz (Hz) and a bandwidth of approximately 35 Hz (i.e., sound transmissions are in the frequency band of 57.5-92.5 Hz). Approximately 260 watts of acoustic power would be radiated during transmission. According to Scripps, the signal parameters and source level in the ATOC project have been found to provide adequate, but not excessive, signal-to-noise ratios in the receiver ranges of interest. At 1 meter (m) (3.3 feet (ft)) from the source (at 807 m (2,648 ft) water depth at the Kauai location), sound intensity (i.e., source level) would be about 195 decibels (dB) referenced to the intensity of a signal with a sound pressure level (SPL) of 1 microPascal (1 μ Pa).

Average ambient noise levels in the 60-90 Hz band offshore central Kauai can be 76-98 dB (with various degrees of shipping traffic) and are expected to be higher (105 dB) when humpback whales are present. The received level from the NPAL source is not expected to exceed 137 dB at the water's surface anywhere in the vicinity of the sound source. The received level in the top 100 m (328.1 ft) has been measured to decrease to about 120 dB at 5 km (2.7 nm) shoreward of the source. The near-

surface received level is predicted to decrease to about 120 dB at 7.5 km (4 nm) seaward of the source. Underwater sound levels in the immediate vicinity of the source are expected to be: 140 dB at 245 m (804 ft) depth (562 m (1844 ft) from the source); 145 dB at 491 m (1611 ft) depth (316 m (1037 ft) from the source); 150 dB at 629 m (2064 ft) depth (178 m (584 ft) range around the source); and 165 dB at 775 m (2543 ft) (32 m (105 ft) range around source (ONR/NMFS, 2000; ARPA/NMFS, 1995).

While Scripps' preferred alternative to use the ATOC source off Kauai, HI involves the continued operation of the source installed at that location, an alternative under consideration in ONR's DEIS would be installing a sound source and cable at a location off the coast of Midway Island.

Comments and Responses

On August 24, 2000 (65 FR 51584), NMFS published a notice of receipt of Scripps' application for a small take exemption and requested comments, information, and suggestions concerning the request and the structure and content of regulations to govern the take. During the 30-day public comment period, NMFS received letters from the Office of Naval Research (ONR), the Marine Mammal Commission (MMC), the Humane Society of the United States (HSUS), Animal Welfare Institute (AWI), the Whale and Dolphin Conservation Society (WDCS), the Hawaiian Islands Humpback Whale National Marine Sanctuary, the State of Hawaii, and a number of U.S. citizens, including several form letters. Comments made regarding ONR's DEIS, that are not germane to the Scripps' application for taking marine mammals incidental to the activity will be addressed in ONR's Final EIS (FEIS). Comments postmarked after the close of the comment period are not addressed in this document.

Activity Concerns

Comment 1: The MMC notes that it is not clear whether the ATOC program will terminate in 5 years, as indicated in both the DEIS and the request for taking authorization, or continue further.

Response: NMFS understands that the authorization requested by Scripps, for the taking of marine mammals incidental to operating the NPAL acoustic source, will be for a single 5-year authorization and will not be renewed thereafter. Scripps notes that, by the time the next 5-year research and marine mammal monitoring program ends, the acoustic source will have been deployed for over 10 years, and therefore questions whether it will

continue to be usable after that time. NMFS notes, however, that if the project was continued thereafter, a new small take rulemaking would be required. Moreover, if the project were proposed to continue beyond 5 years at the Hawaii location (Kauai or Midway), NMFS strongly recommends that long-term monitoring studies be designed and carried out so that remaining issues regarding cumulative impacts can be addressed.

Comment 2: Several commenters noted that the application omitted discussion and comparison with the beaked whale stranding in the Bahamas. One commenter noted that, while the sonar applications are different, the application did not mention the beaked whale stranding which, the commenter asserted, was caused by a sonar experiment known as Littoral Warfare Advanced Deployment (LWAD) Sea Test 00-1. An important similarity may be found in the island habitats. Another commenter noted that NPAL was the world-wide deployment of the Surveillance Towed Array Sensor System Low Frequency Active (SURTASS LFA) sonar system with a different name.

Response: Naval ship sonars have signal and operational characteristics very different from those of the Kauai NPAL source. For example, in response to the stranding of beaked whales in the Bahamas on March 15, 2000, the Navy and NMFS are investigating the transit of several ships (not associated with the LWAD 00-1 Sea Test) using standard, hull-mounted sonar operations within normal frequency ranges, power outputs, and duty cycles, which are, respectively: 3.5 and 7.5 kHz, 235 dB (and lower) and "pings" of short duration (about one-tenth of a second or less duration on a standard duty cycle of 24 seconds. Since these sonars do not have signal and operational characteristics similar to the NPAL source, ONR does not believe it is appropriate for either the DEIS or the small take application to analyze those strandings. NMFS concurs.

The Bahamian beaked whale stranding could not have been caused by the LWAD 00-1 Sea Test, because these strandings began prior to the Navy's beginning that test. In addition, LWAD Sea Test 00-1 did not employ sonar around the time of the strandings. The U.S. Navy and NMFS are continuing the investigation into the cause of the beaked whale strandings and will report on their findings next summer at the conclusion of investigations.

In addition, NPAL should not be confused with the Navy's SURTASS

LFA sonar system, a ship-mounted LF sonar array for detecting submarines. The two systems have distinctly different operating systems, frequencies, duty cycles, and operating characteristics.

Marine Mammal Concerns

Comment 3: One commenter noted that the Hawaiian monk seal was not listed in the application for Kauai waters because preliminary studies by Scripps were totally outdated and inadequate. The request did not list earlier aerial surveys which reported numerous monk seals around Kauai and Niihau. The WDCS believes that Scripps has not given full consideration to the impacts of its actions on the marine environment, particularly the Hawaiian monk seal, noting that the species lives only in the Hawaiian Islands and is very sensitive to human disturbance.

Response: NMFS has been informed that ONR and Scripps will include information in the FEIS on the abundance of Hawaiian monk seals around Kauai, that was not available at the time the DEIS was written. In addition, ONR and Scripps have added the Hawaiian monk seal to the marine mammals species in the Acoustic Integration Model (AIM) for Kauai (it was previously modeled only for the Midway alternative). NMFS has added this species to the list of marine mammal species potentially affected off Kauai. However, NMFS does not believe that Hawaiian monk seals will be impacted by the NPAL source considering that monk seals are believed to be high-frequency-specialist hearers, the relatively low SPL of the NPAL source at the water surface in the offshore vicinity of the source (less than 136 dB), and the coastal nature of the Hawaiian monk seal where SPLs will be even lower.

Marine Mammal Impact Assessment Concerns

Comment 4: The HSUS finds that, while the AIM model may result academically in the best guesses possible for estimating received levels for free ranging animals, it is inadequate for management purposes. If cetaceans, or monk seals act contrary to the assumptions made in the model, the received levels to which the animals are exposed may in fact be far higher (or far lower) than the model predicts, thus invalidating the mitigation protocols established by Scripps.

Response: The MMPA requires NMFS to use the best scientific information available when making determinations of negligible impact from maritime activities. NMFS believes the AIM

model incorporates the best scientific information available on each species in order to predict the acoustic impact on these species. Independent of the AIM model, however, scientific information is available to NMFS from several other sources to assist NMFS in making its negligible impact determination for this activity. NMFS notes, for example, the limited duty cycle of the sound source (2 percent during humpback whale presence, 8 percent at other seasons), the depth of the sound source (few marine mammals could dive to depths that would put them in proximity to sound fields that could affect them), the amount of attenuation of the SPL by the time the sounds reach the upper water depths, and the LF of the NPAL source that many species of marine mammals are unlikely to hear. In addition, the California and Hawaii ATOC Marine Mammal Research Programs (MMRPs) did not find any overt or obvious short-term changes in the abundance or distribution of marine mammals in response to the transmissions of the ATOC sound sources. Costa et al. (1998) and Mobley et al. (1999) showed no significant changes in the abundance of humpback and sperm whales from the control periods, when the source was not operating, to the experimental periods, when it was on. While intensive statistical analyses of aerial survey data showed some subtle shifts in distribution of humpback (and possibly sperm) whales away from the Pioneer Seamount ATOC source during transmission periods, no statistically significant shifts in distribution were found for any other species of marine mammal. In addition, comparison of the 1993, 1995, and 1998 population estimates for humpback whales in Hawaii show an almost statistically significant increase in population size of approximately 8 percent annually.

Comment 5: The HSUS believes that the "single ping equivalent" (SPE) concept is based on assumptions that have not and cannot be verified. The calculation that 10 pings at 120 dB are equivalent to one ping at 130 dB is entirely speculative—no empirical data were used to establish this relationship.

Response: The SPE concept is explained in detail in ONR's DEIS. The purpose of the SPE is to take into account repeated exposure to sound. Richardson et al. (1995) discussed the relationship between repeated exposures of the human ear to impulsive sound and the temporary elevation in hearing sensitivity (referred to as temporary threshold shift (TTS)). While recognizing that no empirical data have been collected to establish this relationship, and there is no

guarantee that marine mammal behavioral responses exhibit patterns similar to human hearing, the human model is the best objective foundation for an assessment and is consistent with Crocker (1997).

Richardson et al. (1995) noted the risk threshold is lowered by 5 dB per tenfold increase in the number of sounds in the exposure. As such, an SPE RL will always be larger than the maximum RL of any single ping in a sequence. In addition, NMFS believes that dividing the single, 20-min NPAL source signal into 20 one-minute "pings" accurately represents the impact on the animals during diving and movement. For these two reasons, therefore, NMFS believes that the SPE concept, which is based on the best science currently available, is significantly more conservative than assumptions made for previous marine mammal impact assessments.

Comment 6: The HSUS express concern that the assumption that a RL of 180 dB would result in TTS for 95 percent of exposed baleen whales, far from being conservative, is completely unsubstantiated.

Response: As explained in ONR's DEIS, to date, there are no authoritative studies of TTS in mysticetes. However, as noted in the DEIS, studies of human hearing indicate that the normal process of hearing loss with age (termed presbycusis) can be accelerated by chronic exposure to sounds 80 dB above the absolute threshold of hearing (Richardson et al., 1995). Here chronic is interpreted as about 8 hours per day for about 10 years. While hearing thresholds are not known in mysticetes, the lowest value is speculated to be 80 dB (Ketten, 1998). This suggests that 10 years of exposure to 160 dB RL (i.e., 80 dB threshold plus 80 dB exposure level) for 8 hours per day would cause auditory damage. As a result, because TTS may result from a brief exposure to a loud sound, prolonged exposure to a faint sound, or intermediate exposure to a sound of intermediate loudness, sound duration and intensity can be considered to trade off with each other in causing TTS. Therefore, by estimating that 95 percent of baleen whales would experience TTS (a level which would not result in any hearing damage), after exposure to a 1-minute ping at 180 dB is considered conservative.

Comment 7: ONR believes that certain language found in the ANPR implies that the Navy and Scripps: (1) Categorized harm as the onset of TTS; (2) categorized the onset of TTS as the lower end of Level A harassment; (3) categorized TTS as the onset for a Level A harassment take; and (4) determined that a marine mammal would have to

receive one ping greater than or equal to 180 dB re 1 micro Pa in order to be considered to have received a non-serious injury, or many pings at a received level slightly lower than 180 dB re 1 micro Pa in order to potentially incur a significant biological response (Level B harassment). Each of these statements is inaccurate: Neither Navy nor Scripps state in the DEIS or application that TTS is the onset of Level A harassment, or that harm is the onset of TTS, or that TTS is a threshold for Level A harassment, or that marine mammals are considered to receive non-serious injury when exposed to a single ping of LF sound from NPAL at a receive level of 180 dB re 1 micro Pa, or that Level B harassment occurs when exposed to multiple pings at receive levels below 180 dB re 1 micro Pa.

Response: The model used by the Navy for the SURTASS LFA sonar, which is also used by Scripps and ONR for this action, establishes a single-ping RL of 180 dB as a scientifically reasonable estimate for the potential onset of non-serious injury to marine mammals (Navy, 1999). According to the Navy (1999), a marine mammal would have to receive a single ping greater than, or equal to, 180 dB, or many pings at a slightly lower RL to possibly incur non-serious injury. For serious injury, the marine mammal would need to be well within the 180-dB sound field at the onset of the sound transmission. While the ONR DEIS and the Scripps' application for a small take authorization do not go into the depth of analysis found in other documents (see Navy, 1999), their use of the same model requires acceptance of the same assumptions, unless it is made clear that different assumptions apply. At the time of publication of the ANPR for this action, such clarification had not been made by the Navy.

At a workshop on marine mammals and LF sound convened by the Minerals Management Service-sponsored High-Energy Seismic Survey (HESS) Team in 1997, an expert panel concluded that it was apprehensive about levels above 180 dB re 1 μPa rms regarding overt behavioral, physiological, and hearing effects on marine mammals in general (HESS, 1997). These concerns were expressed again at an Acoustic Criteria workshop convened by NMFS in 1998. The latter workshop clarified, that a safety zone for pinnipeds, for impulse sounds only, could be safely set at 190 dB, instead of 180 dB, due to their different ear structure from cetaceans and, secondarily, to their generally lower sensitivity to LF sounds. It must be clarified further however, that the 180/190 dB safety zones were

established for impulse noise, not intermittent noise, such as is under discussion in this document and elsewhere. Adopting the precautionary approach, safety zones need to be established for the marine mammal species most sensitive to the frequency of the sound source that has more than a remote potential to be in the area at the time of the activity. For LF sounds, the species most likely to be affected are the mysticete whales and sperm whales. At this time, there is no evidence that TTS would occur in marine mammals at an SPL of 180 dB, and, in fact, Schlundt *et al.* (2000) indicates that onset TTS, for at least some species, occurs at significantly higher SPLs.

NMFS scientists and other scientists are in general agreement that TTS is not an injury (i.e., does not result in tissue damage) but is an impairment to hearing (resulting in an increased elevation in hearing sensitivity) that may last for a few minutes to a few days, depending upon the level and duration of exposure. In this document, NMFS makes clear that, although TTS is not an injury (i.e., Level A harassment), because a permanent elevation in hearing sensitivity (termed permanent threshold shift (PTS)) is considered an injury (Level A harassment), and because scientists have noted that a range of only 15-20 dB may exist between the onset of TTS and the onset of PTS, TTS is considered by NMFS to be in the upper portion of the Level B harassment zone (near the lower end of the Level A harassment zone). Therefore, onset PTS, not onset TTS, is considered by NMFS to be the lower end of Level A harassment. NMFS believes that establishing TTS at the upper end of the Level B harassment zone is both precautionary and warranted by the science. However, mitigation measures, such as establishing safety zones, should be applied whenever a marine mammal has the potential to incur a TTS in hearing in order to prevent an animal incurring a PTS injury.

Therefore, while the commenter's statement is true, the Navy's precautionary approach for assessing impacts by using TTS as the onset of non-serious injury needs to be amended to better reflect current scientific findings that TTS does not result in injury to a marine mammal. For this action, NMFS understands that this clarification will be made by ONR in its FEIS on this action.

Comment 8: ONR further notes that it is not the view of the Navy that TTS constitutes injury, harm, or level A harassment under the MMPA. TTS is a method of determining when the level

of sound input temporarily reduces the ear's ability to respond fully (Schlundt *et al.*, 2000). TTS is defined as a reversible decrease in hearing sensitivity as a result, for example, of exposure to a loud noise (Green, 1976). The leading analysis of TTS in marine mammals was conducted by Schlundt *et al.* (2000), in a series of experiments involving bottlenose dolphins and white whales. That effort included and expanded on pure-tone TTS data collected by Ridgway *et al.* (1997). The analysis generally within the range of 192 to 201 dB re 1 micro Pa, for exposures to one-second tones at frequencies of 0.4, 3, 10, 20, and 75 kHz. The threshold shift was generally in the nature of a 6- to 17-dB masking in the animal's hearing and was of short duration and completely recoverable.

Response: Please see response to Comment 7.

Comment 9: The HSUS states that the acceptance of TTS as a working definition for Level B harassment, although not expressly stated in the LOA request, is implicit in its risk continuum analysis (where 95 percent of baleen whales are estimated to experience TTS at 180 dB).

Response: Although NMFS considers TTS to be Level B harassment, a sound source would not need to cause TTS in order to result in harassment. For impulse, intermittent, and continuous sounds, NMFS considers both TTS impairment and any significant behavioral response to the signal on the part of the mammal to constitute Level B harassment of marine mammals. (Non-significant behavioral responses include, but are not limited to, a heads up display by pinnipeds, and minor adjustments in course direction or swimming speed by a marine mammal). For impulse, intermittent, and continuous types of noise, maritime activities such as the one in this document need to consider the level of take due to their activities resulting in a significant behavioral response. However, for single explosive events, because of the extremely short duration of the signal, NMFS scientists and other scientists believe that marine mammals cannot have a significant behavioral response because of the transient nature of the signal. For explosives therefore, only TTS needs to be considered for determining the level of Level B impact.

As mentioned previously, the consensus of scientific opinion is that TTS is not an injury. The National Research Council (NRC)(NRC, 2000), supports this statement noting that animals that experience small levels of TTS are not injured, suggesting that TTS is a conservative standard for the

prevention of injury. However, the risk continuum estimates that 95 percent of the marine mammals exposed to a single 1-min sound at 180 dB could have the potential for a risk of TTS. If 180 dB is accepted as a precautionary de facto level for onset TTS (even though onset TTS probably occurs at a significantly higher SPL) and TTS itself is not an injury, the Scripps/ONR assumption for estimating risk is very conservative.

Comment 10: The HSUS notes that both the risk analysis and the AIM model require assumptions to be made for several key variables; if these assumptions are violated or are inaccurate or invalid to begin with, then the analysis and model are not valid.

Response: NMFS believes the AIM model has incorporated the best scientific information currently available on the levels of abundance of marine mammals in Hawaiian waters and on acoustic characteristics of both the ATOC source and surrounding waters. NMFS considers this information to be the best information currently available, especially since it allows NMFS to consider impacts in three dimensions as opposed to the usual two dimensions used in previous impact assessments. However, the AIM model is not the only source of information that NMFS intends to use in this action for the necessary determinations under the MMPA for levels of impacts.

Comment 11: The HSUS states that the principal assumption of the risk analysis is the use of the SPL "harm" criteria, which is not based on any empirical data. For example, determining these criteria requires gross speculation on baleen whale hearing thresholds, which are unknown.

Response: While NMFS agrees that baleen whale hearing thresholds are unknown empirically, until such time as this information becomes available, the AIM model uses assumptions on pre-industrial era ambient noise levels as a hearing threshold for low frequency sensitive marine mammals. This assumption was explained in ONR's DEIS.

Comment 12: The AWI strongly objects to the issuance of permits that allow the intentional infliction of suffering on marine mammals, especially by the propagation of sound. AWI believes that NMFS cannot issue the permit knowing that the sound intensity will reach 195 dB, a sound intensity 55 dB louder than the sound known to cause neurological damage in human beings, who are not nearly as sensitive to sound as cetaceans.

Response: The NPAL acoustic source operating at full intensity produces

approximately 260 Watts of acoustic power, resulting in a sound level of 195 dB re 1 micro Pa at one meter. NMFS does not believe that any marine mammals will be exposed to the source at this full intensity, since they would need to be immediately adjacent to the source, 807 m (2,648 ft) below the water surface during the 2-8 percent of the time the source was transmitting. This depth is approximately 550 m (1,804 ft) deeper than the deepest recorded humpback whale dive depth, the only deep-diving marine mammal species expected to be commonly found in the offshore NPAL waters.

Chapman and Ellis (1998) note that this comparison with humans is incorrect, for the following reasons: (1) The reference sound pressures used in underwater acoustics and in-air acoustics are not the same; (2) the statement compares a source level with a received level; and (3) there is no obvious connection between an annoying or harmful sound level for humans in air and an annoying or harmful sound level for a marine animal in water. NMFS recommends that reviewers unfamiliar with underwater acoustics read Appendix A of ONR's DEIS, and/or Richardson et al. (1995).

Comment 13: Several comments noted that the DEIS and the Scripps application did not cite several scientific papers relating to whale stranding events. Other commenters expressed concern about sperm whales and beaked whales, two species that, in addition to humpback whales, are deep divers and sensitive to LF sounds.

Response: NMFS and Scripps are unaware of any scientific reports regarding a relationship between transmissions of the ATOC source and marine mammal strandings in either California or Hawaii. Marine mammal stranding events elsewhere in the world that may be linked to acoustic noise, to date, have not been noted to be associated with LF sounds in the range of 60-90 Hz, but instead are more likely related to high intensity mid-frequency sounds. Please refer to the response to Comment 2 for discussion on the Bahamian beaked whale stranding event.

While audiograms are unavailable for beaked whales, they are believed to be mid-frequency hearers, not low-frequency hearers. Discussion on sperm whales, beaked whales, and other species and on the potential impact from the NPAL source on these species is provided in ONR's DEIS.

Comment 14: One commenter states that the risk assumptions in this action rely on the same information provided to NMFS as justification for the planned

LWAD Sea Test 00-2 off New Jersey. Those tests involved use of LF sonar devices. NMFS found justification insufficient to warrant NMFS concurrence with those tests and the Navy cancelled the acoustic portion of the tests.

Response: On April 23, 2000, the U.S. Navy submitted to NMFS an Environmental Assessment (EA) for LWAD 00-2 and requested NMFS concur that these tests were unlikely to adversely affect species listed as threatened or endangered under the Endangered Species Act (ESA). NMFS responded on May 19 and May 26, 2000, that, because of the complexity of the project and the fact that the information provided in the EA was incomplete, NMFS could not concur with the Navy that the proposed action was not likely to adversely affect listed species under NMFS' jurisdiction. As a result, NMFS recommended that the Navy initiate formal consultation under section 7 of the ESA. Because there was insufficient time to complete formal consultation before the date the LWAD 00-2 Sea Test was scheduled to begin, the Navy cancelled the acoustic portion of the testing. NMFS finds no basis to conclude that the risk assumptions made for LWAD 00-2 were the same ones used for assessing marine mammal/sea turtle impacts for NPAL. Moreover, for the action under discussion in this document, ONR has requested formal consultation under section 7 of the ESA. That consultation will be completed prior to final determinations being made by ONR and Scripps on whether to proceed with its proposed action.

Mitigation Concerns

Comment 15: The HSUS believes that authorizing the continued use of the sound source for the next 5 years with minimal mitigation is unwarranted and premature, especially with recent strandings and research strongly suggesting that some low to mid-frequency sounds can result in significant negative impacts to cetaceans.

Response: It should be understood that NMFS does not authorize the activity, only the taking of marine mammals incidental to that activity. NMFS believes that the NPAL acoustic source, which at 75 Hz and 195 dB is significantly lower in frequency and intensity than those of many other sound sources in the world's oceans and is anchored in water depths of 807 m (2,648 ft), does not warrant comparison with open-water, mobile sources using loud mid-frequency sonars. The mitigation measures proposed for NPAL

are listed in the application, the ONR's DEIS, and in this document. NMFS invites public comment on additional practical mitigation measures for this acoustic source located in deep water. NMFS also solicits comment on any relevant scientific information on impacts of LF sound on marine mammals, other than that cited in these documents. NMFS believes that the information obtained during the ATOC MMRP and the SURTASS LFA sonar Scientific Research Program (SRP) provide the best scientific information to date on this subject.

Comment 16: The WDSCS questioned mitigation measure 2 which stated that increases in duty cycle (of the NPAL's acoustic source) would not occur during the peak humpback whale breeding season, but that transmissions will be conducted during this season.

Response: The NPAL acoustic source has been proposed to transmit on a 2-percent duty cycle. The proposed duty cycle would be six 20-minute transmissions (one every 4 hours), every fourth day, with each transmission preceded by a 5-minute ramp-up period. This is the minimum duty cycle necessary to support the large-scale acoustic thermometry and long-range propagation objectives. The 20-minute transmission period is designed to spread the energy over time, at much lower source levels, than if the signals were sent as short, loud pulses of the same total energy. However, the duty cycle may be increased to 8-percent for up to two months out of each year, to support short-term, long-range acoustic propagation studies. The 8 percent duty cycle would not occur during the humpback whale season (January-April). The rationale supporting the conduction of transmission studies during the humpback whale season is explained in detail in Chapter 2.1.3 of ONR's DEIS.

Comment 17: The WDSCS notes that, to its knowledge, there is no research that supports the statement that "the five-minute ramp-up period would give all marine animals the opportunity to depart the immediate area of the source."

Response: NMFS recognizes that ramp-up may not be effective as a mitigation tool. However, NMFS notes that ramp-up is not the only mitigation measure proposed by the Navy and therefore, until such time as there is evidence that it is not effective, NMFS, Scripps, and ONR prefer to err on the side of caution and incorporate ramp-up into the mitigation program for NPAL's acoustic source.

Monitoring Concerns

Comment 18: The MMC notes that the DEIS and the application indicate only that a total of four aerial surveys would be conducted each year in the period from January through April. There is no indication of how or by whom the aerial surveys would be conducted or what area(s) would be surveyed. The Hawaiian Islands Humpback Whale National Marine Sanctuary (HIHWNMS) recommends the four aerial surveys be augmented by at least two additional surveys to assess seasonal trends in abundance and distribution.

Response: After review, Scripps now proposes to conduct eight surveys each year from February through early April, during the peak of the humpback whale season. In order to maintain a basis for comparison with previous aerial surveys conducted in the area off the north shore of Kauai, the proposed survey protocol would follow the protocol used in the earlier 1993-1998 surveys (see Mobley *et al.*, 1999). The surveys would be scheduled eight days apart to match the NPAL transmission schedule. Based on an average of seven humpback sightings per survey observed during the 1998 season and assuming a moderate-sized effect due to NPAL transmissions, eight surveys should produce a minimum of 56 sightings of humpback whales, which would result in an estimated power of 0.80 (i.e., there would be an 80-percent probability of detecting a change in distribution if an effect is present). The estimate of 56 sightings is presumed to be a minimum, given previously reported evidence that Hawaiian wintering population of humpback whales is increasing.

Comment 19: The MMC notes that there is no indication of the baseline information now available or the kinds of changes in distribution or abundance that would trigger a review and suspension or termination of the project.

Response: Protocols similar to those used during the ATOC project would be followed for the review, suspension, and termination of the project. If at any time a monitoring team member identifies the occurrence of an acute or short-term effect on marine mammals, the information would be immediately communicated to the Team's Principal Investigator (PI). If the PI ascertains that an acoustic transmission coincided with the observed acute response, Scripps would suspend the source immediately and contact NMFS.

In addition, NMFS and Scripps propose to coordinate closely with the Hawaiian stranding network and will investigate all strandings. While there is contradictory information in the

comments received on this rulemaking regarding the level of competency of the local stranding network, NMFS believes that the location of the NPAL source allows for an acceptable level stranding response. If an investigation by NMFS of a stranding event indicated that the NPAL acoustic source was responsible for causing the event, NMFS would suspend the LOA until such time as the cause was corrected, or Scripps applied, and obtained a new LOA that would authorize the incidental taking of marine mammals by mortality. NMFS however, continues to believe that the NPAL source would result not in any marine mammal strandings.

NMFS does not believe that the level of data from the monitoring program will allow determinations to be made that the NPAL acoustic source was responsible for any decreases in abundance of humpback whales or other marine mammals in the vicinity of the source. At this time, evidence indicates that the numbers of humpback whales and Hawaiian monk seals off Kauai are increasing, however, it is unclear whether this is due to total abundance increases or geographic shifts due to oceanographic changes. Similarly, a cause and effect between operation of the NPAL source and any decrease in abundance of marine mammals in the offshore Hawaiian Islands over the short-term period of 5 years is unlikely.

Comment 20: The HIHWNMS recommends boat-based surveys and, if possible, shore-based theodolite studies should be conducted. One citizen recommended additional aerial surveys year-round to assess impacts on dolphins and smaller whales.

Response: Scripps notes that additional aerial surveys, boat-based surveys, and theodolite studies are not an efficient use of NPAL's resources and believes that this additional monitoring is unlikely to provide NMFS and the public with better data than would be provided by the humpback whale aerial surveys. Under current funding levels for this project, conducting these additional studies would necessitate a reduced aerial survey effort for humpback whales. NMFS notes that boat-based surveys do not provide an encounter rate high enough to give statistically significant results. Theodolite studies, being shore based, are not near the NPAL source site, and therefore animals would show less reaction than animals closer to the source. While the proposed humpback whale aerial surveys will also detect other marine mammal species, because the smaller whales and dolphins are not expected to be sensitive (e.g., react) to the Kauai NPAL acoustic source

transmission, NMFS does not believe that conducting additional aerial monitoring for these species is warranted.

Reporting Concerns

Comment 21: The MMC recommends that any proposal to issue the requested authorization include a description of the proposed monitoring program, in sufficient detail, to enable reviewers to judge the likelihood that it will be capable of detecting biologically significant long-term effects in time to stop and reverse them.

Response: A description of the monitoring program has been provided in this document.

MMPA Concerns

Comment 22: The HSUS notes that the criterion of "prolonged disturbance of biologically important behavior" is not consistent with either Level A or Level B harassment in the MMPA. "Prolonged disturbance" is a criterion apparently invented for the purposes of this LOA request. It is of concern that applicants continue to create "take" definitions inconsistent with the MMPA.

Response: The NRC (2000) states that NMFS should promulgate uniform (noise) regulations based on their potential for a biologically significant impact on marine mammals. NMFS concurs. However, the term "prolonged," as used in ONR's DEIS and Scripps' application, implies an increase in time or duration beyond normal limits. This, NMFS believes, exceeds the criterion used by NMFS to note that harassment must refer to a reaction that is behaviorally significant on the part of the animal in the course of that animal's conducting a biologically important activity, such as breeding, feeding, migrating. In this context, it is the impact of the activity on the animal, not the duration of the disturbance, that is critical. NMFS requests additional comment on this criterion.

By further clarifying Level B harassment as being more than a momentary reaction on the part of a marine mammal that has no consequence to the animal's survival or reproduction, NMFS believes that Scripps and ONR are in compliance with both the MMPA definition and NMFS' guidance for calculating takings of small numbers of marine mammals incidental to a maritime activity. NMFS believes that interpretation of the definition of Level B harassment to include trivial reactions like a change in breathing rates is inappropriate and would greatly increase the affected

universe of activities that would need to apply for small take authorizations under the MMPA, including the U.S. shipping, recreational boating, and ecotourism industries.

Comment 23: The HSUS states that the concept that TTS is Level B harassment has seemingly been established de facto for some time now but never subject to public notice or comment. This is simply unacceptable, and in violation of the Administrative Procedure Act. The HSUS is disturbed at its continued appearance in documentation associated with Navy or ONR projects (such as the WINSTON S. CHURCHILL shock trial).

Response: Because part of this rulemaking is the criterion NMFS proposes to use to determine levels of harassment incidental to takings of small number of marine mammals by the continued operation of a LF sound source previously installed off the north shore of Kauai by the ATOC project there is no violation of section 553(b) of the APA. NMFS invites comment on the criterion for assessing impacts from explosives on marine mammals.

Comment 24: The AWI requests NMFS officially state its policy with regard to the requirement for researchers to apply for a small take permit if the levels of sound transmissions are under 180 dB. Do you currently require a permit if researchers subject marine mammals to Level B harassment? Does your agency currently consider sound of under 180 dB insignificant and therefore exempt from an incidental take permit?

Response: First, NMFS must clarify between different types of researchers. Researchers planning to conduct research directed at marine mammals need to apply for a scientific research permit under section 104 of the MMPA. This document does not discuss applications for scientific research under section 104 of the MMPA. Those researchers, and others, whose activity will have an incidental interaction with marine mammals can apply for a small take exemption under section 101(a)(5)(A) or (a)(5)(D) of the MMPA. That is the type of application under discussion in this document.

Secondly, NMFS must clarify that there is a difference between a source level of 180 dB and a sound level of 180 dB received at the marine mammal. While NMFS considers that a received level at the marine mammal of 180 dB or greater has the potential to result in a taking of marine mammals, in most cases, an underwater acoustic device or instrument with a source level of 180 dB or less, is likely to attenuate (e.g., reduce in intensity) within a few meters to insignificant levels. Therefore, unless

there is an abundance of marine mammals in close proximity to a source of this intensity, marine mammals are unlikely to be taken.

In that regard, several factors need to be considered by a potential applicant prior to applying for a small take authorization. That person needs to consider: (1) The SPL and the frequency of the acoustic source (the higher the frequency, the greater the loss in intensity relative to distance); (2) whether the source results in an explosive, impulse, or intermittent noise; (3) the location and the duty cycle of the source; (4) the duration of the activity; and (5) the relative abundance of those species of marine mammals in the area of the source whose hearing range coincides with the frequencies of the acoustic source.

However, it is the responsibility of the proponents of an activity to determine whether marine mammals will be harassed, injured, or killed by an activity. NMFS recommends that, if there is a potential for marine mammals to be harassed by an acoustic source and for the response on the part of the mammal(s) to be more than a simple alert, startle, or dive reaction, the responsible party should contact NMFS to ascertain whether a small take authorization should be obtained. NMFS believes that an animal simply hearing a noise and making a minor course correction to avoid the noise is not a behavioral reaction sufficient to warrant a small take application, provided the reaction does not result in a response on the part of the animal that is biologically significant. A biologically significant response is one that has the potential to affect reproduction and survival, including feeding and migration.

Comment 25: One citizen wanted to know why NMFS is considering this (incidental harassment) proposal which potentially threatens to deprive the whale watching business of its vital coastal environment? Why should NMFS favor acoustic polluters over and above environmentally friendly businesses?

Response: Under section 101(a)(5)(A) of the MMPA, NMFS is charged with determining that the total taking by a lawful maritime activity is having no more than a negligible impact on a small number of marine mammals. If that determination can be made, then an authorization can be issued (provided monitoring and reporting are carried out). However, because the Kauai MMRP demonstrated that no overt or obvious short-term change in abundance, distribution, or behavior of humpback whales occurred as a result

of the ATOC sound transmissions, no direct effects on the economy through a reduction in whale-watching are expected to occur from operation of this source over the next 5 years.

The intentional taking of marine mammals by whale watching and other recreational boating activities that seek out marine mammals for either business or personal enjoyment are an issue for discussion under NEPA. NMFS understands that the ONR FEIS will be expanded with new economic data on the tourism industry.

Comment 26: The same citizen asks whether NMFS has considered the combined influences that these high intensity acoustic sources will create?

Response: Unless one were also to consider vocalizing whales as being high intensity sources, NMFS does not believe that the NPAL source (at 195 dB) qualifies as a high intensity acoustic source. Under section 101(a)(5)(A) of the MMPA, NMFS is required to determine that the total taking by the specified activity is not having more than a negligible impact on affected marine mammal stocks. In this case, the specified activity under consideration is the operation of the NPAL acoustic source by Scripps. However, the cumulative impact on the marine environment from oceanic anthropogenic noise sources, such as Navy mid-frequency and LF sonars, commercial shipping, and recreational boating noise in the vicinity of Kauai, are subject to consideration by ONR in its EIS.

Other Concerns

Comment 27: The HSUS noted that they and the Natural Resources Defense Council (NRDC) submitted extensive comments in October 1999 on the Navy's DEIS on SURTASS LFA sonar and its use of SURTASS LFA SRP data. The HSUS incorporates herein by reference concerns noted in those comments.

Response: The proposed action in this document is the taking of marine mammals incidental to operation of the NPAL acoustic source that is stationary off Kauai, Hawaii, not the incidental taking of marine mammals by the world-wide deployment of SURTASS LFA sonar. Those comments will be addressed by the Navy in the FEIS for that activity. NMFS has reviewed the comments submitted by HSUS and the NRDC for the SURTASS LFA sonar DEIS and notes that most comments are not germane to this action.

Marine Mammals

A summary of the marine mammal species that may potentially be found in

the vicinity of the NPAL acoustic source at either Kauai or Midway is presented here. For more detail on marine mammal abundance, density, and the methods used to obtain this information, reviewers are requested to refer to ONR's DEIS. For general information on North Pacific Ocean marine mammals, reviewers may refer to Barlow *et al.* (1997).

Six species of baleen whales, humpback (*Megaptera novaengliae*), fin (*Balaenoptera physalus*), blue (*B. musculus*), Bryde's (*B. edeni*), minke (*B. acutorostrata*), and right (*Eubalaena glacialis*) whales, may occur in the Kauai or Midway Atoll areas. Although not reported near Midway Atoll, the humpback whale is the only balaenopterid whale known to be present in reasonably large numbers. Humpback whales are considered abundant in coastal waters of the main Hawaiian Islands from November through April. Fin whales and blue whales have the potential to occur in the area; however, their distribution and abundance in the region is believed to be uncommon (Balcomb, 1987), although only a single fin whale was observed during recent ATOC marine mammal research. Right whales in the North Pacific Ocean are extremely rare and therefore, would also be rare in the Hawaiian Islands. Bryde's whales, and minke whales may be occasionally seen in the area of Midway Atoll (Leatherwood *et al.*, 1988), but are not usually found off Kauai.

Sixteen species of odontocetes (toothed whales, dolphins and porpoises) may be found in the Kauai and Midway areas. These species are sperm whales (*Physeter macrocephalus*), short-finned pilot whales (*Globicephala macrorhynchus*), beaked whales (*Ziphius cavirostris*, *Berardius bairdi*, and *Mesoplodon spp.*), spinner dolphins (*Stenella longirostris*), spotted dolphins (*Stenella attenuata*), striped dolphins (*Stenella coeruleoalba*), bottlenose dolphins (*Tursiops truncatus*), rough-toothed dolphins (*Steno bredanensis*), pygmy sperm whales (*Kogia breviceps*), dwarf sperm whales (*Kogia simus*), killer whales (*Orcinus orca*), false killer whales (*Pseudorca crassidens*), pygmy killer whales (*Feresa attenuata*), and melon-headed whales (*Peponocephala electra*). It should be noted, however, that the latter 7 species were not sighted in or near the proposed Kauai area during marine mammal surveys conducted between 1993 and 1998.

The Hawaiian monk seal (*Monachus schauinslandi*) occurs in the area of the Leeward Hawaiian Islands and, more

recently in the main Hawaiian Islands, including the island of Kauai.

Potential Impacts on Marine Mammals

The effects of underwater noise on marine mammals are highly variable, and can be categorized as follows (based on Richardson *et al.*, 1995): (1) The noise may be too weak to be heard at the location of the animal (i.e. lower than the prevailing ambient noise level, the hearing threshold of the animal at relevant frequencies, or both); (2) the noise may be audible but not strong enough to elicit any overt behavioral response; (3) the noise may elicit behavioral reactions of variable conspicuousness and variable relevance to the well being of the animal; these can range from subtle effects on respiration or other behaviors (detectable only by statistical analysis) to active avoidance reactions; (4) upon repeated exposure, animals may exhibit diminishing responsiveness (habituation), or disturbance effects may persist (the latter is most likely with sounds that are highly variable in characteristics, unpredictable in occurrence, and associated with situations that the animal perceives as a threat); (5) any man-made noise that is strong enough to be heard has the potential to reduce (mask) the ability of marine mammals to hear natural sounds at similar frequencies, including calls from conspecifics and/or echolocation sounds, and environmental sounds such as ice or surf noise; and (6) very strong sounds have the potential to cause either a temporary or a permanent reduction in hearing sensitivity (i.e., TTS or PTS, respectively). Few data on the effects of non-explosive sounds on hearing thresholds of marine mammals have been obtained; however, in terrestrial mammals, and presumably in marine mammals, received sound levels must far exceed the animal's hearing threshold for there to be any TTS. Received levels must be even higher for there to be risk of PTS. In this proposed action, a marine mammal would have to receive one ping greater than, or equal to 180 dB in order to be considered receiving a non-serious injury, or many pings at an RL slightly lower than 180 dB in order to potentially incur a significant biological response (Level B harassment).

In order to understand the biological significance of the risk of Level A or Level B harassment, it is necessary to determine how this risk might affect a population of marine mammals, starting with acoustic criteria. First, the marine mammal must be able to hear LF sound. Second, the animal must incur a reaction to the LF sound that is more

than momentary. Third, any effect from LF sound must involve a significant behavioral change in a biologically important activity, such as feeding, breeding, or migration, all of which are potentially important for reproductive success of the population.

Based on California and Hawaii ATOC MMRPs, Scripps found no overt or obvious short-term changes: (1) In the abundance and distribution of marine mammals in response to the ATOC transmissions (intensive statistical analyses of aerial survey data showed some subtle shifts in distribution of humpback (and possibly sperm) whales away from the California site (Calambokidis *et al.*, 1998) and humpback whales away from the Kauai site); (2) in the behavior of humpback whales in response to the playback of ATOC-like sounds (intensive statistical analyses revealed some subtle changes in the behavior of humpback whales (Frankel and Clark, 1998; 1999b); or (3) in the singing behavior of humpback whales in the vicinity of the Kauai ATOC sound source. Bioacoustic experts concluded that these subtle effects would not adversely affect the survival of an individual whale or the status of the North Pacific humpback whale population (Frankel and Clark, 1999a).

To assess the potential environmental impact of the NPAL sound source on marine mammals, it was necessary for Scripps to predict the sound field that a given marine mammal species could be exposed to over time. This is a multi-part process involving (1) the ability to measure or estimate an animal's location in space and time, (2) the ability to measure or estimate the three-dimensional sound field at these times and locations, (3) the integration of these two data sets to estimate the potential impact of the sound field on a specific animal in the modeled population, and (4) the conversion of the resultant cumulative exposures for a modeled population into an estimate of the risk from a disruption of a biologically important behavior.

Next, a relationship for converting the resultant cumulative exposures for a modeled population into an estimate of the risk to the entire population of a significant disruption of a biologically important behavior and of injury was developed. This process assessed risk in relation to RL and repeated exposure. The resultant "risk continuum" is based on the assumption that the threshold of risk is variable and occurs over a range of conditions rather than at a single threshold.

Taken together, the recent results on marine mammals from LF sounds, the

acoustical modeling, and the risk assessment, provide an estimate of potential environmental impacts to marine mammals.

The acoustical modeling process was accomplished by Scripps using the U.S. Navy's standard acoustical performance prediction transmission loss model-Parabolic Equation (PE) version 3.4. The results of this model are the primary input to the AIM model. AIM was used in this analysis to estimate mammal sound exposures and integrate simulated characteristics of marine mammals (e.g., species distribution, density, dive profiles, and general movement, NPAL sound transmissions (e.g., duty cycle, transmission length), and the predicted sound field for each transmission to estimate acoustic exposure during a typical NPAL source transmission. A description of the PE and AIM models (including AIM input parameters for animal movement, diving behavior, and marine mammal distribution, abundance, and density) and the risk continuum analysis are described in detail in the Scripps application and ONR's DEIS and are not discussed further in this document. At this time, NMFS recommends reviewers read these documents if additional information is desired.

Scripps has drawn some general conclusions from the relative abundance of various marine mammal species in relationship to the NPAL sound field. Under the proposed alternative (utilizing the ATOC sound source at Kauai), the only mysticete (baleen) whale species expected in the area in substantial numbers is the humpback whale, and Scripps believes that because they usually prefer nearshore locations (inside the 100-fathom (188 m) depth contour), few are expected to be exposed to received levels greater than 120 dB (i.e., the SPL level presumed by Scripps to be zero for marine mammals having the potential to incur significant disturbance of biologically important behavior). Similarly, sperm whales are the most common deep-diving odontocete (toothed) whale in the area, but because they usually prefer offshore waters (i.e., water depths greater than 4,000 m (12,700 ft)), few are expected to be exposed to received levels greater than 120 dB. According to Scripps, these distributional preferences are supported by the Kauai ATOC MMRP (Mobley, 1999a).

Using the risk continuum and acoustic modeling, Scripps estimated the potential for biologically significant reactions by marine mammals under the proposed action. Scripps determined that only humpback whales that remain in the vicinity of the sound source for

a full day of transmissions may potentially experience any effect from the source transmissions. However, humpback whales typically travel parallel to the coast of Kauai, and, therefore, Scripps believes, would probably not receive sound from more than a single transmission.

At the Midway site, the mysticete whale expected in greatest abundance is the Bryde's whale. Because they usually prefer nearshore locations, Scripps expects few animals would be exposed to RLs greater than 120 dB. Similarly, sperm whales are the most common deep-diving odontocetes in the area, but because they usually prefer offshore waters (i.e., water depths greater than 4,000 m (12,700 ft)), few are expected to be exposed to received levels greater than 120 dB.

A much higher abundance of Hawaiian monk seals is expected near Midway Island than Kauai since this species prefers the small, mostly uninhabited chain of islands and atolls northwest of the main Hawaiian Islands.

Using the risk continuum and acoustic modeling Scripps determined that there would be no potential for biologically significant effects on marine mammals from source transmissions at Midway Island, although some subtle effects may occur.

Mitigation

Scripps' proposed action includes mitigation that would minimize the potential effects of the NPAL sound source to marine mammals. First, the sound source would operate at the minimum duty cycle necessary to support the large-scale acoustic thermometry and long-range propagation objectives. Transmissions would continue with approximately the same transmission schedule as that used during the first feasibility phase of the ATOC study. Second, any increases in the duty cycle beyond the nominal 2 percent (with a maximum of 8 percent) would not occur during the humpback whale season (January-April). The proposed action includes the possibility of an 8-percent duty cycle for up to 2 months out of each year; this action, however, would not occur during the period of time humpback whales inhabit Hawaiian waters. Third, the sound source would operate at the minimum power level necessary to support large-scale acoustic thermometry and long-range sound transmission objectives. The fourth mitigation measure proposed is to ramp-up the NPAL sound source transmissions over a 5-min period. This is believed to reduce the potential for startling marine mammals in the vicinity of the NPAL sound source and

provides them an opportunity to move away from the sound source before transmitting at the maximum power levels.

Monitoring and Reporting

In an effort to understand the potential for long-term effects of man-made sound on marine mammals, Scripps proposes to monitor the distribution and abundance of marine mammals in the vicinity of the sound source by conducting eight surveys each year from February through early April. In order to maintain a basis for comparison with previous aerial surveys conducted in the area off the north shore of Kauai, the proposed survey protocol would follow the protocol used in the earlier 1993-1998 surveys (see Mobley *et al.*, 1999). The surveys would be scheduled eight days apart to match the NPAL transmission schedule. Based on an average of seven humpback sightings per survey observed during the 1998 season, and assuming a moderate sized effect due to NPAL transmissions, eight surveys should produce a minimum of 56 sightings of humpback whales, which would result in an estimated power of 0.80 (i.e., there would be an 80-percent probability of detecting a change in distribution if an effect is present). The estimate of 56 sightings is presumed to be a minimum, given previously reported evidence that Hawaiian wintering population of humpback whales is increasing. Reports on the aerial survey results will be available to the public in reports. A report on activities will be provided to NMFS annually upon the conclusion of that year's aerial surveys.

Preliminary Determinations

Based on the scientific analyses detailed in Scripps' application and further supported by information and data contained in ONR's DEIS, NMFS concurs with Scripps and ONR that the incidental harassment of marine mammals incidental to the continued operation of an LF acoustic source previously installed off the north shore of Kauai by the ATOC project would result in only small numbers (as the term is defined in § 216.103) of marine mammals being taken, have no more than a negligible impact on the affected marine mammal stocks or habitats and not have an unmitigable adverse impact on Arctic subsistence uses of marine mammals.

In addition to the mitigation measures described previously, the following factors need to be considered when determining whether the taking by the NPAL acoustic source would be negligible: (1) The limited duty cycle of

the source (2-8 percent); (2) the information that most species of marine mammals are relatively insensitive to acoustic sounds as low as the NPAL source; (3) the fact that relatively few marine mammals that inhabit the acoustic source area that are known to dive to depths that would put them in the proximity to sound fields that could disrupt biologically significant behavior; and (4) the low potential for a marine mammal actually being within the acoustic sound field during sonar transmissions. In consideration of these factors, NMFS preliminarily concludes that the operation of the acoustic source at Kauai (or Midway) would result in no more than small numbers of marine mammals being affected, and that the proposed action would have a negligible impact on affected marine mammal species and stocks.

NEPA

The ONR has released a DEIS under NEPA (see **ADDRESSES**). The comment period for that document ended on July 24, 2000. NMFS is a cooperating agency, as defined by the Council on Environmental Quality (40 CFR 1501.6), in the preparation of this DEIS and the Final EIS, currently under preparation.

Endangered Species Act (ESA)

NMFS is in consultation with the ONR under section 7 of the ESA on this action. In that regard, the ONR has submitted to NMFS a Biological Assessment under the ESA. This consultation will be concluded prior to a determination on the issuance of a final rule and LOA.

Costs and Benefits

In addition to allowing Scripps to take a small number of marine mammals incidental to conducting scientific research using the NPAL acoustic source off Hawaii, this rule would require Scripps to provide NMFS and the public with information on the NPAL source's effect on certain species of marine mammals. Without an authorization under the MMPA, NMFS and the public may not receive this information. NMFS believes that obtaining this information is important because scientific findings resulting from the monitoring program is likely to be directly applicable to other oceanographic research activities that employ LF acoustic sources. The cost to ONR and Scripps cannot be fully determined at this time but these costs would be incurred through implementation of the aerial monitoring program that will be required under this proposed rule. Preliminarily, NMFS believes that this cost would be

approximately \$ 300,000 during the 5-year program.

Information Solicited

NMFS requests interested persons and organizations to submit comments, information, and suggestions concerning the content of the proposed regulations to authorize the taking. All commenters are requested to review the application prior to submitting comments and not submit comments solely on this Federal Register document. Because the comment period on the draft EIS has ended, comments on issues not relevant to either the potential impact of the NPAL acoustic source on marine mammals or NMFS' responsibilities under the MMPA will not be considered.

Classification

This action has been determined to be not significant for purposes of Executive Order 12866.

The Assistant General Counsel for Legislation and Regulation of the Department of Commerce has certified to the Chief Counsel for Advocacy of the Small Business Administration that this proposed rule, if adopted, would not have a significant economic impact on a substantial number of small entities since it would apply only to Scripps and would have no effect, directly or indirectly, on small businesses. It will also affect a small number of contractors providing services related to reporting the impact of the NPAL source on marine mammals. Some of the affected contractors may be small businesses, but the number involved would not be substantial. Further, since the monitoring and reporting requirements are what would lead to the need for their services, the economic impact on them would be beneficial. Because of this certification, a regulatory flexibility analysis is not required.

Notwithstanding any other provision of law, no person is required to respond to nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act (PRA) unless that collection of information displays a currently valid OMB control number. This proposed rule contains collection-of-information requirements subject to the provisions of the PRA. This collection has been approved previously by OMB under section 3504(b) of the PRA issued under OMB control number 0648-0151. These requirements include an application for an LOA and an annual report on monitoring. Other information requirements in the rule are not subject to the PRA since they apply

only to a single entity and, therefore, are not contained in a rule of general applicability.

The reporting burden for this collection is estimated to be approximately 80 hours, including the time for gathering and maintaining the data needed, and completing and reviewing the collection of information. It does not include time for monitoring the activity.

List of Subjects in 50 CFR Part 216

Administrative practice and procedure, Imports, Indians, Marine mammals, Penalties, Reporting and recordkeeping requirements, Transportation.

Dated: December 15, 2000.

William T. Hogarth,

Deputy Assistant Administrator for Fisheries, National Marine Fisheries Service.

For reasons set forth in the preamble, 50 CFR part 216 is proposed to be amended as follows:

PART 216—REGULATIONS GOVERNING THE TAKING AND IMPORTING OF MARINE MAMMALS

1. The authority citation for part 216 continues to read as follows:

Authority: 16 U.S.C. 1361 *et seq.*

2. Subpart P is added to read as follows:

Subpart P—Taking of Marine Mammals Incidental to Operating A Low Frequency Acoustic Source by the North Pacific Acoustic Laboratory

Sec.

- 216.170 Specified activity and specified geographical region.
- 216.171 Effective dates.
- 216.172 Permissible methods of taking.
- 216.173 Prohibitions.
- 216.174 Mitigation.
- 216.175 Requirements for monitoring and reporting.
- 216.176 Letter of Authorization.
- 216.177 Renewal of a Letter of Authorization.
- 216.178 Modifications to a Letter of Authorization.

Subpart P—Taking of Marine Mammals Incidental to Operating A Low Frequency Acoustic Source by the North Pacific Acoustic Laboratory

§ 216.170 Specified activity and specified geographical region.

(a) Regulations in this subpart apply only to the incidental taking of small numbers of marine mammals specified in paragraph (b) of this section by U.S. citizens engaged in conducting acoustic research using a moored, low-frequency acoustic source by the North Pacific

Acoustic Laboratory off either Kauai or Midway Islands, Hawaii.

(b) The incidental harassment of marine mammals under the activity identified in paragraph (a) of this section is limited to small numbers of the following species: humpback whales (*Megaptera novaengliae*), fin whales (*Balaenoptera physalus*), blue whales (*B. musculus*), Bryde's whales (*B. edeni*), minke whales (*B. acutorostrata*), North Pacific right whales (*Eubalaena glacialis*), sperm whales (*Physeter macrocephalus*), short-finned pilot whales (*Globicephala macrorhynchus*), beaked whales (*Ziphius cavirostris*, *Berardius bairdi*, and *Mesoplodon spp.*), spinner dolphins (*Stenella longirostris*), spotted dolphins (*Stenella attenuata*), striped dolphins (*Stenella coeruleoalba*), bottlenose dolphins (*Tursiops truncatus*), rough-toothed dolphins (*Steno bredanensis*), pygmy sperm whales (*Kogia breviceps*), dwarf sperm whales (*Kogia simus*), killer whales (*Orcinus orca*), false killer whales (*Pseudorca crassidens*), pygmy killer whales (*Feresa attenuata*), and melon-headed whales (*Peponocephala electra*), and Hawaiian monk seals (*Monachus schauinslandi*).

§ 216.171 Effective dates.

Regulations in this subpart are effective from April 1, 2001, through March 31, 2006.

§ 216.172 Permissible methods of taking.

(a) Under a Letter of Authorization issued pursuant to §§ 216.106 and 216.176, the Holder of this Letter of Authorization may incidentally, but not intentionally, take marine mammals by harassment within the area described in § 216.170(a), provided the activity is in compliance with all terms, conditions, and requirements of these regulations and the Letter of Authorization.

(b) The activities identified in § 216.170(a) must be conducted in a manner that minimizes, to the greatest extent practicable, any adverse impacts on marine mammals and their habitat.

§ 216.173 Prohibitions.

Notwithstanding takings authorized by § 216.170(b) and by a Letter of Authorization issued under §§ 216.106 and 216.176, no person in connection with the activities described in § 216.170(a) shall:

(a) Take any marine mammal not specified in § 216.170(b);

(b) Take any marine mammal specified in § 216.170(b) other than by incidental, unintentional harassment;

(c) Take a marine mammal specified in § 216.170(b) if such take results in more than a negligible impact on the

species or stocks of such marine mammal; or

(d) Violate, or fail to comply with, the terms, conditions, and requirements of these regulations or a Letter of Authorization issued under §§ 216.106 and 216.176.

§ 216.174 Mitigation.

As described in the Letter of Authorization issued under §§ 216.106 and 216.176, the North Pacific Acoustic Laboratory acoustic source must:

(a) Operate at the minimum duty cycle necessary for conducting large-scale acoustic thermometry and long-range propagation objectives.

(b) Not increase its duty cycle for long-range propagation studies during the months of January through April.

(c) Operate at the minimum power level necessary for conducting large-scale acoustic thermometry and long-range propagation objectives.

(d) Precede all transmissions from the acoustic source by a 5-minute ramp-up of the acoustic source's power.

§ 216.175 Requirements for monitoring and reporting.

(a) The holder of the Letter of Authorization is required to cooperate with the National Marine Fisheries Service and any other Federal, state or local agency monitoring the impacts of the activity on marine mammals. The holder must notify the Southwest Regional Administrator at least 2 weeks prior to commencing monitoring activities.

(b) The Holder of this Authorization must conduct a minimum of eight surveys each year from February through early April in the area off the north shore of Kauai, Hawaii.

(c) The Holder of this Authorization must, through coordination with marine mammal stranding networks in Hawaii, monitor strandings of marine mammals to detect long-term trends in stranding and the potential relationship to the North Pacific Acoustic Laboratory acoustic source.

(d) Activities related to the monitoring described in paragraphs (b) and (c) of this section, or in the Letter of Authorization issued under §§ 216.106 and 216.176 may be conducted without the need for a separate scientific research permit.

(e) In coordination and compliance with marine mammal researchers operating under this subpart, at its discretion, the National Marine Fisheries Service may place an observer on any aircraft involved in marine mammal surveys in order to monitor the impact on marine mammals.

(f) The holder of a Letter of Authorization must annually submit a

report to the Director, Office of Protected Resources, National Marine Fisheries Service, no later than 120 days after the conclusion of humpback whale aerial survey monitoring program. This report must contain all the information required by the Letter of Authorization, including the results, if any, of coordination with coastal marine mammal stranding networks.

(g) A final comprehensive report must be submitted to the Director, Office of Protected Resources, National Marine Fisheries Service no later than 240 days after completion of the final year of humpback whale aerial survey monitoring conducted under § 216.175. This report must contain all the information required by the Letter of Authorization.

§ 216.176 Letter of Authorization.

(a) A Letter of Authorization, unless suspended or revoked, will be valid for a period of time specified in the Letter of Authorization but may not exceed the period of validity of this subpart.

(b) A Letter of Authorization with a period of validity less than the period of validity of this subpart may be renewed subject to renewal conditions in § 216.177.

(c) A Letter of Authorization will set forth:

(1) Permissible methods of incidental taking;

(2) Authorized geographic area for taking;

(3) Means of effecting the least practicable adverse impact on the species of marine mammals authorized for taking and its habitat; and

(4) Requirements for monitoring and reporting incidental takes.

(d) Issuance of a Letter of Authorization will be based on a determination that the number of marine mammals taken by the activity will be small, and that the number of marine mammals taken by the activity, specified in § 216.170(b), as a whole will have no more than a negligible impact on the species or stocks of affected marine mammal(s).

(e) Notice of issuance or denial of a Letter of Authorization will be published in the **Federal Register** within 30 days of a determination.

§ 216.177 Renewal of a Letter of Authorization.

(a) A Letter of Authorization issued under § 216.106 and § 216.176 for the activity identified in § 216.170(a) will be renewed upon:

(1) Notification to the National Marine Fisheries Service that the activity described in the application for a Letter of Authorization submitted under

§ 216.176 will be undertaken and that there will not be a substantial modification to the described work, mitigation or monitoring undertaken during the upcoming season;

(2) Timely receipt of the monitoring reports required under § 216.175, which have been reviewed by the National Marine Fisheries Service and determined to be acceptable;

(3) A determination by the National Marine Fisheries Service that the mitigation, monitoring and reporting measures required under §§ 216.174 and 216.175 and the Letter of Authorization were undertaken and will be undertaken during the upcoming period of validity of a renewed Letter of Authorization; and

(4) Renewal of a Letter of Authorization will be based on a determination that the number of marine mammals taken by the activity continues to be small, and that the number of marine mammals taken by the activity, specified in § 216.170(b) will have no more than a negligible impact on the species or stock of affected marine mammal(s).

(b) A notice of issuance or denial of a renewal of a Letter of Authorization will be published in the **Federal Register** within 30 days of a determination.

§ 216.178 Modifications to a Letter of Authorization.

(a) In addition to complying with the provisions of §§ 216.106 and 216.176, except as provided in paragraph (b) of this section, no substantive modification (including withdrawal or suspension) to the Letter of Authorization issued pursuant to §§ 216.106 and 216.176 and subject to the provisions of this subpart shall be made by the National Marine Fisheries Service until after notification and an opportunity for public comment has been provided. For purposes of this paragraph, a renewal of a Letter of Authorization under § 216.177, without modification, except for the period of validity is not considered a substantive modification.

(b) If the Assistant Administrator determines that an emergency exists that poses a significant risk to the well-being of the species or stocks of marine mammals specified in § 216.170(b), a Letter of Authorization issued pursuant to §§ 216.106 and 216.176 may be substantively modified without prior notification and an opportunity for public comment. Notification will be published in the **Federal Register** within 30 days subsequent to the action. [FR Doc. 00-32725 Filed 12-21-00; 8:45 am]

BILLING CODE 3510-22-S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 622

[I.D. 121200K]

Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic; Shrimp Fishery of the Gulf of Mexico; Public Hearings

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of public hearings; request for comments.

SUMMARY: The Gulf of Mexico Fishery Management Council (Council) will convene additional public hearings to receive comments on Draft Amendment 11 to the Fishery Management Plan for the Gulf of Mexico Shrimp Fishery (Draft Amendment 11). Public hearings were previously held from Port Isabel, TX to Key West, FL.

DATES: Written comments will be accepted until 5 p.m., January 3, 2001. Public hearings will be held in January; for specific dates and times see

SUPPLEMENTARY INFORMATION.

ADDRESSES: Written comments should be sent to, and copies of Draft Amendment 11 are available from, the Gulf of Mexico Fishery Management Council, 3018 U.S. Highway 301, North, Suite 1000, Tampa, FL 33619; telephone: (813)228-2815. Public hearings will be held in Texas, Mississippi, Alabama, Louisiana, and Florida. For specific locations see

SUPPLEMENTARY INFORMATION.

FOR FURTHER INFORMATION CONTACT: Dr. Richard Leard, Senior Fishery Biologist, Gulf of Mexico Fishery Management Council; telephone: (813) 228-2815.

SUPPLEMENTARY INFORMATION: The Council held public hearings on Draft Amendment 11 throughout the Gulf of Mexico region from October 2, 2000, through October 26, 2000 (65 FR 57159). The Council will convene additional public hearings to review Draft Amendment 11. Draft Amendment 11 contains alternative measures for requiring shrimp vessel and boat permits, shrimp vessel and boat registration, and operator permits and for prohibiting trap gear in the royal red shrimp fishery in the Gulf exclusive economic zone (EEZ). Shrimp "vessels" refer to fishing craft usually over 5 net tons that carry a certificate-of-documentation issued by the U.S. Coast Guard (USCG); shrimp "boats" refer to

fishing craft under 5 net tons that do not carry a USCG certificate-of-documentation but that are issued a number by the appropriate state.

For its initial round of public hearings, it was the Council's belief that a major difference between vessel/boat permits and registrations, as noted in the earlier hearings, was that permits are subject to law enforcement sanctions, while vessel registrations are not. In a recent review of Draft Amendment 11, NOAA General Counsel determined that if a vessel/boat registration was required as a condition for participating in the shrimp fishery, then such vessel/boat registration is a permit, and would therefore be subject to law enforcement sanctions. This clarification is important because some persons may have previously supported vessel/boat registrations over permits in the belief that the former would not be subject to law enforcement sanctions. Further public hearings have been scheduled to give those persons a chance to change or retract their previous comments and to receive additional comments on a revised Draft Amendment 11.

Dates, Times, and Locations for Public Hearings

Public hearings for Draft Amendment 11 are scheduled as follows:

1. Wednesday, January 3, 2001, 7 p.m.—Laguna Madre Learning Center, Port Isabel High School, Highway 100, Port Isabel, TX 78578; telephone: 956-943-0052;
2. Thursday, January 4, 2001, 7 p.m.—Palacios Recreation Center, 2401 Perryman, Palacios, TX 77465; telephone: 361-972-3821;
3. Monday, January 8, 2001, 6 p.m.—MS Department of Marine Resources, 1141 Bayview Drive, Biloxi, MS 39530; telephone: 228-374-5000;
4. Tuesday, January 9, 2001, 7 p.m.—Bayou LaBatre Community Center, Padgett Switch Road, Bayou La Batre, AL 36509; telephone: 334-824-7918;
5. Wednesday, January 10, 2001, 7 p.m.—New Orleans Airport Hilton, 901 Airline Drive, Kenner, LA 70062; telephone: 504-469-5000; and
6. Wednesday, January 10, 2001, 7 p.m.—Madeira Beach City Hall, 300 Municipal Drive, Madeira Beach, FL 33708; telephone: 727-391-9951.

The Council will also hear public testimony at the January Council Meeting on January 17, 2001, before taking final action on Draft Amendment 11.

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for sign language

interpretation or other auxiliary aids should be directed to Anne Alford at the Council (see **ADDRESSES**) by December 27, 2000.

Dated: December 15, 2000.

Bruce C. Morehead,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 00-32724 Filed 12-21-00; 8:45 am]

BILLING CODE 3510-22-S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 660

[I.D. 121800E]

Pelagics Fisheries of the Western Pacific Region; Public Meetings

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of public meetings.

SUMMARY: On October 6, 1999, and on October 20, 1999, NMFS announced its intent to prepare an Environmental Impact Statement (EIS) on Federal management of the fishery for pelagic species in the U.S. exclusive economic zone (EEZ) waters of the western Pacific Region. The Draft Environmental Impact Statement (DEIS) has been prepared and is available to the public. The scope of the DEIS includes all activities related to the conduct of the fishery authorized by and managed under the Fishery Management Plan for the Pelagics Fisheries of the Western Pacific Region (FMP) and all amendments thereto. NMFS is holding public meetings to solicit public input on the range of actions, alternatives, and impacts addressed in the DEIS. In addition to holding the public meetings, NMFS is also accepting written comments on the DEIS.

DATES: Written comments will be accepted through January 29, 2001. See **SUPPLEMENTARY INFORMATION** for meeting times.

ADDRESSES: Written comments and requests to be included on a mailing list of persons interested in the DEIS/EIS should be sent to Marilyn Luipold, Pacific Islands Area Office, NMFS, 1601 Kapiolani Blvd., Suite 1110, Honolulu, HI 96814-4700. Comments also may be faxed to 808-973-2941. Comments will not be accepted if submitted via e-mail or the Internet. Public meetings will be held in Hawaii, Guam, American Samoa (AS), and the Commonwealth of the Northern Mariana Islands (CNMI). For specific meeting locations, see **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Marilyn Luipold (see **ADDRESSES**).

SUPPLEMENTARY INFORMATION: On October 6, 1999 (64 FR 54272), and on October 20, 1999 (64 FR 56479), NMFS announced its intent to prepare an EIS on Federal management of the fishery for pelagic species in the U.S. EEZ waters of the western Pacific Region. NMFS has prepared the DEIS and made it available to the public. The Notice of Availability of the DEIS was published on December 15, 2000, (65 FR 78485).

Dates, Times, and Locations for Public Meetings

1. Kahului, Maui, HI: January 3, 2001, 6 to 9 p.m., Maui Beach Hotel, Maui Room, 170 Kaahumanu Avenue, Kahului, Maui, HI 96732.

2. Lihue, Kauai, HI: January 4, 2001, 6 to 9 p.m., Wilcox Elementary School, 4319 Hardy St., Lihue, HI 96766.

3. Fagatogo, AS: January 6, 2001, 9 a.m. to noon, Department of Marine and Wildlife Resources (DMWR) conference room (behind market), Fagatogo, AS. Phone contact c/o DMWR (684-633-4456).

4. Waianae, Oahu, HI: January 10, 2001, 6 to 9 p.m., Waianae Public

Library, 85-625 Farrington Highway, Waianae, HI, 96792.

5. Haleiwa, Oahu, HI: January 11, 2001, 6 to 9 p.m., Haleiwa Alii Beach Park, Haleiwa, HI 96712.

6. Honolulu, Oahu, HI: January 12, 2001, 6 to 9 p.m., Ala Moana Hotel, Carnation Room, 410 Atkinson Boulevard, Honolulu, HI 96814.

7. Agana (Hagatna), Guam: January 16, 2001, 6 to 9 p.m., Guam Fishermen's Cooperative Association, Hagatna Boat Basin, Agana (Hagatna), Guam.

8. Susupe Village, Saipan, CNMI: January 17, 2001, 6 to 9 p.m., Saipan Diamond Hotel, Hibiscus Room. No street address, Susupe Village, P.O. Box 66, CNMI.

9. Kaunakakai, Molokai, HI: January 22, 2001, 6 to 9 p.m., Mitchell Pauole Center, 90 Ainoa St., Kaunakakai, HI 96748.

10. Kona, Hawaii, HI: January 23, 2001, 6 to 9 p.m., King Kamehameha Hotel, 75-5660 Palani Road, Kona, HI 96740.

11. Hilo, Hawaii, HI: January 24, 2001, 6 to 9 p.m. Cooperative Extension Services, College of Agriculture, Conference Room B, 875 Komohana Street, Hilo, HI 96720.

12. Lanai, HI: January 26, 2001, 6 to 9 p.m., Lanai Airport Conference Room, Lanai, HI 96763.

Special Accommodations

Requests for sign language interpretation or other auxiliary aids should be directed to Marilyn Luipold (see **ADDRESSES**), 808-973-2937 (voice) or 808-973-2941 (facsimile), at least 5 days prior to meeting date.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: December 19, 2000.

Bruce C. Morehead,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 00-32727 Filed 12-21-00; 8:45 am]

BILLING CODE 3510-22-S

Notices

Federal Register

Vol. 65, No. 247

Friday, December 22, 2000

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Commodity Credit Corporation

Request for Approval of an Information Collection

AGENCY: Commodity Credit Corporation, USDA.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the Commodity Credit Corporation's (CCC) intention to request a new information collection. This information collection will be used in support of the Pasture Recovery Program (PRP) which reimburses producers for drought-related losses on pasture during calendar year 1999 as authorized by the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act, 2000. Producers must agree to reestablish vegetation on pasture acreage destroyed by the drought in order to receive the disaster payment.

DATES: Comments on this notice must be received on or before February 20, 2001 to be assured consideration.

ADDITIONAL INFORMATION OR COMMENTS: Contact Clayton Furukawa, Agricultural Program Specialist, USDA, FSA, CEPD, STOP 0513, 1400 Independence Avenue, SW., Washington, DC 20250-0513; telephone (202) 690-0571; e-mail Clayton_Furukawa@wdc.usda.gov; or facsimile (202) 720-4619.

SUPPLEMENTARY INFORMATION:

Title: Pasture Recovery Program Contract.

OMB Control Number: 0560-NEW.

Type of Request: Approval of a new information collection.

Abstract: The PRP was authorized by the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act, 2000, to reimburse farmers and ranchers

for drought related losses to pasture during calendar year 1999. The information is necessary to ensure the integrity of the program and to ensure that only eligible producers are authorized contracts.

Producers requesting PRP payments from the CCC must provide specific data related to the disaster payment request. The form included in this information collection package requires farm and tract numbers, name and address, number of acres where vegetation will be reestablished, and similar information, in order to determine eligibility. Producers must also agree to the terms and conditions contained in the form. Without the collection of this information, CCC cannot ensure the integrity of the program.

Estimate of Respondent Burden: Public reporting burden for this collection of information is estimated to average .25 hours per response.

Respondents: Individuals producers, partnerships, corporations, tribal members, or other eligible agricultural producers.

Estimated Number of Respondents: 15,000.

Estimated Number of Annual Responses per Respondent: 1.

Estimated Total Annual Burden on Respondents: 1.25 hours (This estimate includes 60 minutes travel time for applicants to the local USDA service center office.)

Proposed topics for comment include:

(a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of burden, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of the information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology. Comments must be sent to the Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503, and to Clayton Furukawa, Agricultural Program Specialist, USDA-FSA-CEPD, STOP

0513, 1400 Independence Avenue, SW., Washington, DC 20250-0513; telephone (202) 690-0571; e-mail Clayton_Furukawa@wdc.fsa.usda.gov; or facsimile (202) 720-4619. Copies of the information collection may be obtained from Mr. Furukawa at the above address.

OMB is required to make a decision concerning the collection of information contained in these proposed regulations between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment to OMB is best assured of having its full effect if OMB receives it within 30 days of publication.

All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

Signed at Washington, DC, on December 13, 2000.

Keith Kelly,

Executive Vice President, Commodity Credit Corporation.

[FR Doc. 00-32713 Filed 12-21-00; 8:45 am]

BILLING CODE 3410-05-P

DEPARTMENT OF AGRICULTURE

Natural Resources Conservation Service

Notice of Proposed Change to the Natural Resources Conservation Service's National Handbook of Conservation Practices

AGENCY: Natural Resources Conservation Service (NRCS), Department of Agriculture, New York State Office.

ACTION: Notice of availability of proposed changes in the NRCS National Handbook of Conservation Practices, Section IV of the New York State NRCS Field Office Technical Guide (FOTG) for review and comment.

SUMMARY: It is the intention of NRCS to issue a revised conservation practice standard in its National Handbook of Conservation Practices. This revised standard is: Swaste Storage Facility (NY313).

DATES: Comments will be received on or before January 22, 2001.

FOR FURTHER INFORMATION CONTACT:

Inquire in writing to Wayne E. Maresch, State Conservationist, Natural Resources

Conservation Service, (NRCS), 441 S. Salina Street, Fifth Floor, Suite 354, Syracuse, New York, 13202-2450.

A copy of this standard is available from the above individual.

SUPPLEMENTARY INFORMATION: Section 343 of the Federal Agricultural Improvement and Reform Act of 1996 states that revisions made after enactment of the law to NRCS State Technical Guides used to carry out highly erodible land and wetland provisions of the law shall be made available for public review and comment. For the next 30 days the NRCS will receive comments relative to the proposed changes. Following that period a determination will be made by the NRCS regarding disposition of those comments and a final determination of change will be made.

Dated: December 7, 2000.

Wayne M. Maresch,

State Conservationist, Natural Resources Conservation Service, Syracuse, NY.

[FR Doc. 00-32737 Filed 12-21-00; 8:45 am]

BILLING CODE 3410-16-P

DEPARTMENT OF AGRICULTURE

Rural Utilities Service

Municipal Interest Rates for the First Quarter of 2001

AGENCY: Rural Utilities Service, USDA.

ACTION: Notice of municipal interest rates on advances for insured electric loans for the first quarter of 2001.

SUMMARY: The Rural Utilities Service hereby announces the interest rates for advances on municipal rate loans with interest rate terms beginning during the first calendar quarter of 2001.

DATES: These interest rates are effective for interest rate terms that commence during the period beginning January 1, 2001, and ending March 31, 2001.

FOR FURTHER INFORMATION CONTACT: Gail P. Salgado, Management Analyst, Office of the Assistant Administrator, Electric Program, Rural Utilities Service, U.S. Department of Agriculture, Room 4024-S, Stop 1560, 1400 Independence Avenue, SW, Washington, DC 20250-1560. Telephone: 202-205-3660. FAX: 202-690-0717. E-mail: GSalgado@rus.usda.gov.

SUPPLEMENTARY INFORMATION: The Rural Utilities Service (RUS) hereby announces the interest rates on advances made during the first calendar quarter of 2001 for municipal rate electric loans. RUS regulations at § 1714.4 state that each advance of funds on a municipal rate loan shall

bear interest at a single rate for each interest rate term. Pursuant to § 1714.5, the interest rates on these advances are based on indexes published in the "Bond Buyer" for the four weeks prior to the fourth Friday of the last month before the beginning of the quarter. The rate for interest rate terms of 20 years or longer is the average of the 20 year rates published in the Bond Buyer in the four weeks specified in § 1714.5(d). The rate for terms of less than 20 years is the average of the rates published in the Bond Buyer for the same four weeks in the table of "Municipal Market Data—General Obligation Yields" or the successor to this table. No interest rate may exceed the interest rate for Water and Waste Disposal loans.

The table of Municipal Market Data includes only rates for securities maturing in 2001 and at 5 year intervals thereafter. The rates published by RUS reflect the average rates for the years shown in the Municipal Market Data table. Rates for interest rate terms ending in intervening years are a linear interpolation based on the average of the rates published in the Bond Buyer. All rates are adjusted to the nearest one eighth of one percent (0.125 percent) as required under § 1714.5(a). The market interest rate on Water and Waste Disposal loans for this quarter is 5.500 percent.

In accordance with § 1714.5, the interest rates are established as shown in the following table for all interest rate terms that begin at any time during the first calendar quarter of 2001.

Interest rate term ends in (year)	RUS rate (0.000 percent)
2022	5.500 or later
2021	5.500
2020	5.500
2019	5.500
2018	5.500
2017	5.500
2016	5.500
2015	5.500
2014	5.500
2013	5.500
2012	5.375
2011	5.375
2010	5.250
2009	5.250
2008	5.125
2007	5.125
2006	5.000
2005	4.875
2004	4.750
2003	4.500
2002	4.375

Dated: December 18, 2000.

Christopher A. McLean,

Administrator, Rural Utilities Service.

[FR Doc. 00-32645 Filed 12-21-00; 8:45 am]

BILLING CODE 3410-15-P

DEPARTMENT OF AGRICULTURE

Rural Utilities Service

Notice of Funding Availability (NOFA); Treasury Rate Loan Program

AGENCY: Rural Utilities Service, USDA.

ACTION: Notice of funding availability (NOFA).

SUMMARY: This Notice of Funding Availability (NOFA) announces the availability of \$500 million in direct Treasury rate electric loans for fiscal year (FY) 2001. This document describes the eligibility and submission requirements, the criteria that will be used by the Rural Utilities Service (RUS) to select applications for funding, and the expectation that the current backlog of qualifying applications for loans from RUS under the Rural Electrification Act will exhaust all of the available funding. In the event this assumption proves to be incorrect, RUS intends to publish another NOFA on or before July 1, 2001, announcing the availability of any remaining direct Treasury rate electric loan funds and how they will be allocated. The intended effect of this NOFA is to enable RUS to approve all direct Treasury rate electric loans for FY 2001 prior to July 1, 2001.

DATES: RUS intends to treat all completed qualifying applications for direct electric loans at the municipal rate as pre-applications for direct electric loans at the Treasury rate. The closing date for receipt of pre-applications that will be considered is October 28, 2000; the date on which the direct Treasury rate electric loan program was established by Pub.L. 106-387.

ADDRESSES: Loan applicants that do not have outstanding loans from RUS should write to the Rural Utilities Service, United States Department of Agriculture, Washington, DC 20250-1500. A field or headquarters staff representative may be assigned by RUS to visit the applicant and discuss its financial needs and eligibility. Borrowers that have outstanding loans should contact their assigned RUS general field representative (GFR). Borrowers may consult with RUS field representatives and headquarters staff, as necessary.

FOR FURTHER INFORMATION CONTACT:

Robert O. Ellinger, Management Analyst, U.S. Department of Agriculture, Rural Utilities Service, Electric Program, Room 4023 South Building, Stop 1560, 1400 Independence Ave., SW., Washington, DC 20250-1560, Telephone: 202-720-0424.

SUPPLEMENTARY INFORMATION:**Programs Affected**

The Catalog of Federal Domestic Assistance Program number assigned to this program is 10.850.

Discussion of Notice*I. Authority and Distribution Methodology**a. Authority*

Section 4 of the Rural Electrification Act of 1936, (RE Act) (7 U.S.C. 904), among other things, provides RUS with the authority to make loans for rural electrification and for the purpose of furnishing and improving electric service in rural areas. Section 305 of the RE Act (7 U.S.C. 935) establishes the municipal rate electric loan program for these purposes. Title III of the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act, 2001 (Pub. L. 106-387) authorizes a direct Treasury rate electric loan program of \$500 million for FY 2001.

b. Distribution Methodology

RUS believes that Congress authorized the direct Treasury rate electric program to address the backlog of qualified loan applications for direct municipal rate electric loans from RUS. Such loans are generally allocated by RUS in the order that qualified applications are received. RUS will distribute direct Treasury rate electric loans by offering those municipal rate electric loan applicants whose qualified applications were pending at the time of the enactment of Pub.L. 106-387 the option of selecting the direct Treasury rate in lieu of the municipal rate for their loans. RUS will contact applicants in the order of priority that their applications for municipal rate loans would otherwise have been funded using the loan processing priorities published in 7 CFR 1710.119. In that order, RUS will allocate up to the original (as adjusted in accordance with this NOFA) qualifying municipal loan amount to each applicant who so elects. RUS will proceed in turn until such point as the \$500 million of authority has been exhausted. In the unlikely event that any of the authority remains unobligated on July 1, 2001, RUS plans

to publish a notice of the availability of the remaining portion and describe the manner in which it intends to proceed. RUS intends to obligate loans for the full amount by September 1, 2001.

II. Applications Process

Qualifying applications for direct municipal rate electric loans which have been submitted to RUS in accordance with 7 CFR part 1710 subpart I, before October 28, 2000 will be treated as pre-applications for direct Treasury rate electric loans. RUS will contact qualified applicants in the order which they are presently queued, and offer the applicant the opportunity to elect to receive its loan at the direct Treasury rate in lieu of the municipal rate. Applicants should notify RUS promptly in writing of their election. Only timely responses received by RUS and electing the direct Treasury rate will qualify for further loan processing by RUS at that rate. All other applicants will remain in the municipal rate loan queue without prejudice. RUS notes that a reduction of \$500 million of applications in the municipal rate loan queue will result in reaching municipal rate loan applications that otherwise would not be reached during FY 2001. Congress authorized a direct municipal rate electric loan program level of \$295 million for FY 2001. RUS estimates its current backlog of qualified applications for electric distribution loans as exceeding \$1.2 billion. Therefore, RUS anticipates that it will significantly reduce but not substantially eliminate its backlog of electric distribution loan applications.

III. Application Submission Requirements

Each application should include all of the information, materials, forms and exhibits required by 7 CFR part 1710 subpart I, as well as comply with the provisions of this NOFA. RUS believes that it currently has received sufficient pre-applications to exhaust all available FY 2001 funding for the direct Treasury rate electric program and therefore it is not soliciting additional applications for this rate category at this time.

IV. Differences Between Direct Municipal Rate Electric Loan Category and Direct Treasury Rate Electric Loan Category

Generally speaking, since the primary distinction between the established direct municipal rate electric loan program and the direct Treasury rate electric loan program is merely one of interest setting methodologies, RUS intends to administer the direct Treasury rate program during FY 2001

in a manner substantially the same as it administers the direct municipal rate program. General and pre-loan policies and procedures for electric loans made by RUS may be found in 7 CFR parts 1710 and 1714. It is intended that the use of established and highly successful direct electric loan program procedures will enable RUS to promptly make prudent loans to qualified applicants. These procedures have generally worked well and are familiar to both RUS staff and to the applicants. This approach helps assure that the funds authorized by Congress for FY 2001 are expended in a timely manner as Congress intended. The principal variances are as follows:

a. Interest Rates

1. The standard interest rate on direct Treasury rate loans will be established daily by the United States Treasury.

2. The interest rates for Treasury rate loans can be found on the Internet at www.federalreserve.gov/releases/H15/current/.

3. Selection of interest rate terms will be made by the borrower for each advance of funds. The minimum interest rate term shall be one year. Interest rate terms will be limited to terms published by the Treasury (*i.e.* 1, 2, 3, 5, 7, 10, 20, and 30). Interest rates for terms greater than 30 years will be at the 30-year rate.

4. There will be no interest rate cap on Treasury rate loans.

b. Prepayment

A direct Treasury rate electric loan may be repaid at par on its rollover maturity date if there is one. Such a loan may also be prepaid with no premiums or penalties at its "net present value" (NPV) as determined by RUS using the prepayment methodology in 7 CFR part 1786.

c. Supplemental Financing

The Administrator has elected not to impose any supplemental financing requirements in conjunction with direct Treasury rate electric loans made during FY 2001. Accordingly, the "original qualifying municipal amount" referred to in part I.B of this NOFA may be adjusted at the election of the applicant to include otherwise eligible amounts that would have been financed from other sources in accordance with 7 CFR 1710.110(c). Request for an adjustment in the "original" amount should specify the amount of the adjustment and accompany the applicant's election to use the Treasury rate category of direct electric loan. See part II of this NOFA.

V. Loan Documents

Successful applicants will be required to execute and deliver to RUS a promissory note evidencing the borrower's obligation to repay the loan. The note must be in form and substance satisfactory to RUS. RUS plans to require a form of note substantially in the form that it currently accepts for direct municipal rate electric loans, with such revisions as may be necessary or appropriate to reflect the different interest setting provisions and the terms of this NOFA. All notes will be secured in accordance with the terms of 7 CFR part 1718.

Dated: December 18, 2000.

Christopher A. McLean,

Administrator, Rural Utilities Service.

[FR Doc. 00-32714 Filed 12-21-00; 8:45 am]

BILLING CODE 3410-15-P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Additions and Deletion

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Additions to and Deletion from the Procurement List.

SUMMARY: This action adds to the Procurement List services to be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities, and deletes from the Procurement List a service previously furnished by such agencies.

EFFECTIVE DATE: January 22, 2001.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, Jefferson Plaza 2, Suite 10800, 1421 Jefferson Davis Highway, Arlington, Virginia 22202-3259.

FOR FURTHER INFORMATION CONTACT: Louis R. Bartalot (703) 603-7740

SUPPLEMENTARY INFORMATION: On September 29, October 20 and November 3, 2000, the Committee for Purchase From People Who Are Blind or Severely Disabled published notices (65 FR 58505, 63057 and 66231) of proposed additions to and deletion from the Procurement List:

Additions

After consideration of the material presented to it concerning capability of qualified nonprofit agencies to provide the services and impact of the additions on the current or most recent

contractors, the Committee has determined that the services listed below are suitable for procurement by the Federal Government under 41 U.S.C. 46-48c and 41 CFR 51-2.4.

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities other than the small organizations that will furnish the services to the Government.

2. The action will not have a severe economic impact on current contractors for the services.

3. The action will result in authorizing small entities to furnish the services to the Government.

4. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 46-48c) in connection with the services proposed for addition to the Procurement List.

Accordingly, the following services are hereby added to the Procurement List:

Services

Base Supply Center, Trident Refit Facility, Naval Submarine Base, Kings Bay, Georgia
Commissary Warehousing and Janitorial, United States Naval Academy, Annapolis, Maryland
Janitorial/Custodial, US Border Patrol Compound, Davis Monthan AFB, Arizona
Linen Service, Hickam Air Force Base, Hawaii
Moving Services, Department of the Interior, Washington, DC

This action does not affect current contracts awarded prior to the effective date of this addition or options that may be exercised under those contracts.

Deletion

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities.

2. The action will not have a severe economic impact on future contractors for the services.

3. The action will result in authorizing small entities to furnish the services to the Government.

4. There are no known regulatory alternatives which would accomplish

the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 46-48c) in connection with the services deleted from the Procurement List.

After consideration of the relevant matter presented, the Committee has determined that the service listed below is no longer suitable for procurement by the Federal Government under 41 U.S.C. 46-48c and 41 CFR 51-2.4.

Accordingly, the following service is hereby deleted from the Procurement List:

Service

Janitorial/Custodial, Drug Dependence Treatment Center, 2320 West Roosevelt Road, Chicago, Illinois

Louis R. Bartalot,

Deputy Director (Operations).

[FR Doc. 00-32720 Filed 12-21-00; 8:45 am]

BILLING CODE 6353-01-P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List Proposed Additions and Deletions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Proposed Additions to and Deletions from Procurement List.

SUMMARY: The Committee is proposing to add to the Procurement List commodities and a service to be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities, and to delete services previously furnished by such agencies.

COMMENTS MUST BE RECEIVED ON OR BEFORE: January 22, 2001.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, Jefferson Plaza 2, Suite 10800, 1421 Jefferson Davis Highway, Arlington, Virginia 22202-3259.

FOR FURTHER INFORMATION CONTACT: Louis R. Bartalot (703) 603-7740

SUPPLEMENTARY INFORMATION: This notice is published pursuant to 41 U.S.C. 47(a) (2) and 41 CFR 51-2.3. Its purpose is to provide interested persons an opportunity to submit comments on the possible impact of the proposed actions.

Additions

If the Committee approves the proposed addition, all entities of the Federal Government (except as otherwise indicated) will be required to procure the commodity and service

listed below from nonprofit agencies employing persons who are blind or have other severe disabilities.

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities other than the small organizations that will furnish the commodities and service to the Government.

2. The action will result in authorizing small entities to furnish the commodities and service to the Government.

3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 46-48c) in connection with the commodities and service proposed for addition to the Procurement List. Comments on this certification are invited. Commenters should identify the statement(s) underlying the certification on which they are providing additional information. The following commodities and service have been proposed for addition to Procurement List for production by the nonprofit agencies listed:

Commodities

Kit, Martial Arms Training, 7810-00-NSH-0001, 7810-00-NSH-0002, 7810-00-NSH-0003

NPA: Chautauqua County Chapter, NYSARC, Jamestown, New York

Service

Janitorial/Custodial, Illinois Air National Guard, 182nd Airlift Wing, Peoria, Illinois

NPA: Community Workshop & Training Center, Peoria, Illinois

Deletions

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities.

2. The action will result in authorizing small entities to furnish the services to the Government.

3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 46-48c) in connection with the services proposed for deletion from the Procurement List.

The following services have been proposed for deletion from the Procurement List:

Services

Administrative Services, Frank Hagel Federal Building, 1221 Nevin Avenue, Richmond, California
Grounds Maintenance, Mare Island Naval Complex and Roosevelt Terrence, and Combat Systems Technical School Command, Mare Island Naval Shipyard, Vallejo, California

Janitorial/Custodial, U.S. Federal Building and Courthouse, 110 S. 4th Street, Minneapolis, Minnesota
Parts Sorting, Kelly Air Force Base, Texas

Louis R. Bartalot,

Deputy Director (Operations).

[FR Doc. 00-32721 Filed 12-21-00; 8:45 am]

BILLING CODE 6353-01-P

DEPARTMENT OF COMMERCE

Bureau of Export Administration

President's Export Council Subcommittee on Encryption; Notice of Partially Closed Meeting

The President's Export Council Subcommittee on Encryption (PECSENC) will meet on January 10, 2001, at the U.S. Department of Commerce, Herbert C. Hoover Building, Room 4832, 14th Street between Pennsylvania and Constitution Avenues, NW., Washington, DC. The meeting will begin in open session at 9:30 a.m. The Subcommittee provides advice on matters pertinent to policies regarding commercial encryption products.

Open Session:

1. Opening remarks by the Chairman.
2. Presentation of papers or comments by the public.
3. Update on Bureau of Export Administration initiatives.
4. Issue briefings.
5. Open discussion.

Closed Session:

6. Discussion of matters properly classified under Executive Order 12958, dealing with the U.S. export control program and strategic criteria related thereto.

A limited number of seats will be available for the open session. Reservations are not accepted. To the extent time permits, members of the public may present oral statements to the PECSENC. The public may submit written statements at any time before or after the meeting. However, to facilitate distribution of public presentation

materials to PECSENC members, the PECSENC suggests that public presentation materials or comments be forwarded before the meeting to the address listed below:

Ms. Lee Ann Carpenter, OSIES/EA/BXA MS: 3876, U.S. Department of Commerce, 14th St. & Constitution Ave., NW., Washington, DC 20230.

A Notice of Determination to close meetings, or portions of meetings, of the Subcommittee to the public on the basis of 5 U.S.C. 522(c)(1) was approved October 25, 1999, in accordance with the Federal Advisory Committee Act. A copy of the Notice of Determination is available for public inspection and copying in the Central Reference and Records Inspection Facility, Room 6020, U.S. Department of Commerce, Washington, DC. For more information, contact Ms. Lee Ann Carpenter on (202) 482-2583.

Dated: December 19, 2000.

R. Roger Majak,

Assistant Secretary For Export Administration.

[FR Doc. 00-32768 Filed 12-21-00; 8:45 am]

BILLING CODE 3510-JT-M

DEPARTMENT OF COMMERCE

International Trade Administration

Overseas Trade Missions; Private Sector Participants Recruitment and Selection

AGENCY: International Trade Administration, Department of Commerce.

ACTION: Notice.

SUMMARY: The Department of Commerce invites U.S. companies to participate in the below listed overseas trade missions.

SUPPLEMENTARY INFORMATION: For a more complete description of each trade mission, obtain a copy of the mission statement from the Project Officer, Beth Moser for each mission below.

Recruitment and selection of private sector participants for these missions will be conducted according to the Statement of Policy Governing Department of Commerce Overseas Trade Missions dated March 3, 1997. 2nd Annual U.S. Information

Technology Dealmaker, Toronto, Canada, February 8-9, 2001.

Recruitment closes January 5, 2001.

Electrical Power Trade Mission & Seminar, Toronto, Canada, April 2-3, 2001, Recruitment closes February 15, 2001.

CanAm E-Commerce Partnering @
Vancouver, Vancouver, Canada,
February 15–16, 2001, Recruitment
closes January 2, 2001.

FOR FURTHER INFORMATION CONTACT: Ms.
Beth Moser, U.S. Department of
Commerce Tel: 202–482–2736, Fax:
202–219–9207, E-Mail: beth
moser@mail.doc.gov

Dated: December 19, 2000.

Beth Moser,

*International Trade Specialist, U.S.
Commercial Service, U.S. Department of
Commerce.*

[FR Doc. 00–32769 Filed 12–21–00; 8:45 am]

BILLING CODE 3510–FP–P

DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

[Notice 2]

National Fire Codes: Request for Proposals for Revision of Codes and Standards

AGENCY: National Institute of Standards
and Technology, Commerce.

ACTION: Notice.

SUMMARY: The National Fire Protection
Association (NFPA) proposes to revise
some of its fire safety codes and
standards and requests proposals from
the public to amend existing or begin

the process of developing new NFPA
fire safety codes and standards. The
purpose of this request is to increase
public participation in the system used
by NFPA to develop its codes and
standards. The publication of this notice
of request for proposals by the National
Institute of Standards and Technology
(NIST) on behalf of NFPA is being
undertaken as a public service; NIST
does not necessarily endorse, approve,
or recommend any of the standards
referenced in the notice.

DATES: Interested persons may submit
proposals on or behalf the dates listed
with standards.

ADDRESSES: Casey C. Grant, Secretary,
Standards Council, NFPA, 1
Batterymarch Park, Quincy,
Massachusetts 02269–9101.

FOR FURTHER INFORMATION CONTACT:
Casey C. Grant, Secretary, Standards
Council, at above address, (617) 770–
3000.

SUPPLEMENTARY INFORMATION:

Background

The National Fire Protection
Association (NFPA) develops building,
fire, and electrical safety codes and
standards. Federal agencies frequently
use these codes and standards as the
basis for developing Federal regulations
concerning fire safety. Often, the Office
of the Federal Register approves the
incorporation by reference of these

standards under 5 U.S.C. 552(a) and 1
CFR Part 51.

Request for Proposals

Interested persons may submit
proposals, supported by written data,
views, or arguments to Casey C. Grant,
Secretary, Standards Council, NFPA, 1
Batterymarch Park, Quincy,
Massachusetts 02269–9101. Proposals
should be submitted on forms available
from the NFPA Codes and Standards
Administration Office.

Each person must include his or her
name and address, identify the
document and give reasons for the
proposal. Proposals received before or
by 5 pm local time on the closing date
indicated would be acted on by the
Committee. The NFPA will consider
any proposal that it receives on or
before the date listed with the codes or
standard.

At a latter date, each NFPA Technical
Committee will issue a report, which
will include a copy of written proposals
that have been received, and on account
of their disposition of each proposal by
the NFPA Committee as the Report on
Proposals. Each person who has
submitted a written proposal will
receive a copy of the report.

Dated: December 18, 2000.

Karen Brown,
Deputy Director.

NFPA No.	Title	Proposal
		Closing date
NFPA/IAPMO UMC	Uniform Mechanical Code	2/1/2001
NFPA/IAPMO UPC	Uniform Plumbing Code	2/1/2001
NFPA 1–2000	Fire Prevention Code	6/8/2001
NFPA 10–1998	Standard for Portable Fire Extinguishers	1/5/2001
NFPA 11–1998	Standard for Low-Expansion Foam	1/5/2001
NFPA 11A–1999	Standard for Medium- and High-Expansion Foam Systems	1/5/2001
NFPA 12A–1997	Standard on Halon 1301 Fire Extinguishing Systems	1/5/2001
NFPA 17–1998	Standard for Dry Chemical Extinguishing Systems	1/5/2001
NFPA 17A–1998	Standard for Wet Chemical Extinguishing Systems	1/5/2001
NFPA 20–1999	Standard for the Installation of Stationary Pumps for Fire Protection	12/28/2001
NFPA 22–1998	Standard for Water Tanks for Private Fire Protection	7/6/2001
NFPA 30B–1998	Code for the Manufacture and Storage of Aerosol Products	1/5/2001
NFPA 42–1997	Code for the Storage of Pyroxylin Plastic	1/5/2001
NFPA 50A–1999	Standard for Gaseous Hydrogen Systems at Consumer Sites	6/28/2001
NFPA 50B–1999	Standard for Liquefied Hydrogen Systems at Consumer Sites	6/28/2001
NFPA 51B–1999	Standard for Fire Prevention During Welding, Cutting, and Other Hot Work	12/28/2001
NFPA 52–1998	Compressed Natural Gas (CNG) Vehicular Fuel Systems Code	1/5/2001
NFPA 54–1999	National Fuel Gas Code	1/5/2001
NFPA 55–1998	Standard for the Storage, Use, and Handling of Compressed and Liquefied Gases in Portable Cylinders.	7/6/2001
NFPA 57–1999	Liquefied Natural Gas (LNG) Vehicular Fuel Systems Code	1/5/2001
NFPA 61–1999	Standard for the Prevention of Fires and Dust Explosions in Agricultural and Food Prod- ucts Facilities.	1/5/2001
NFPA 69–1997	Standard on Explosion Prevention Systems	1/5/2001
NFPA 70B–1998	Recommended Practice for Electrical Equipment Maintenance	1/5/2001
NFPA 79–1997	Electrical Standard for Industrial Machinery	1/5/2001
NFPA 86–1999	Standard for Ovens and Furnaces	12/28/2001
NFPA 86C–1999	Standard for Industrial Furnaces Using a Special Processing Atmosphere	12/28/2001
NFPA 86D–1999	Standard for Industrial Furnaces Using Vacuum as an Atmosphere	12/28/2001
NFPA 88A–1998	Standard for Parking Structures	1/5/2001

NFPA No.	Title	Proposal
		Closing date
NFPA 90A–1999	Standard for the Installation of Air-Conditioning and Ventilating Systems	1/5/2001
NFPA 90B–1999	Standard for the Installation of Warm Air Heating and Air-Conditioning Systems	1/5/2001
NFPA 97–2000	Standard Glossary of Terms Relating to Chimneys, Vents, and Heat-Producing Appliances.	7/6/2001
NFPA 101–2000	Code for Safety to Life from Fire in Buildings and Structures	3/30/2001
NFPA 130–2000	Standard for Fixed Guideway Transit and Passenger Rail Systems	7/6/2001
NFPA 140–1999	Standard on Motion Picture and Television Production Studio Soundstages and Approved Production Facilities.	7/6/2001
NFPA 170–1999	Standard for Fire Safety Symbols	1/5/2001
NFPA 211–2000	Standard for Chimneys, Fireplaces, Vents, and Solid Fuel-Burning Appliances	7/6/2001
NFPA 225–P*	Standard for Manufactured Home Sites, Communities, and Setups	7/6/2001
NFPA 230–1999	Standard for the Fire Protection of Storage	7/6/2001
NFPA 232–2000	Standard for the Protection of Records	1/5/2001
NFPA 252–1999	Standard Methods of Fire Tests of Door Assemblies	12/28/2001
NFPA 256–1998	Standard Methods of Fire Tests of Roof Coverings	7/6/2001
NFPA 259–1998	Standard Test Method for Potential Heat of Building Materials	7/6/2001
NFPA 260–1998	Standard Methods of Tests and Classification System for Cigarette Ignition Resistance of Components of Upholstered Furniture.	12/28/2001
NFPA 261–1998	Standard Method of Test for Determining Resistance of Mock-Up Upholstered Furniture Material Assemblies to Ignition by Smoldering Cigarettes.	12/28/2001
NFPA 262–1999	Standard Method of Test for Flame Travel and Smoke of Wires and Cables for Use in Air-Handling Spaces.	1/5/2001
NFPA 265–1998	Standard Methods of Fire Tests for Evaluating Room Fire Growth Contribution of Textile Wall Coverings.	1/5/2001
NFPA 272–1999	Standard Method of Test for Heat and Visible Smoke Release Rates for Upholstered Furniture Components or Composites and Mattresses Using an Oxygen Consumption Calorimeter.	7/6/2001
NFPA 285–1998	Standard Method of Test for the Evaluation of Flammability Characteristics of Exterior Non-Load-Bearing Wall Assemblies Containing Combustible Components Using the Intermediate-Scale, Multistory Test Apparatus.	12/28/2001
NFPA 299–1997	Standard for Protection of Life and Property from Wildfire	1/5/2001
NFPA 302–1998	Fire Protection Standard for Pleasure and Commercial Motor Craft	12/28/2001
NFPA 318–2000	Standard for the Protection of Cleanrooms	1/5/2001
NFPA 415–1997	Standard on Airport Terminal Buildings, Fueling Ramp Drainage, and Loading Walkways	1/5/2001
NFPA 432–1997	Code for the Storage of Organic Peroxide Formulations	1/5/2001
NFPA 434–1998	Code for the Storage of Pesticides	1/5/2001
NFPA 480–1998	Standard for the Storage, Handling and Processing of Magnesium Solids and Powders ...	1/5/2001
NFPA 481–2000	Standard for the Production, Processing, Handling, and Storage of Titanium	1/5/2001
NFPA 485–1999	Standard for the Storage, Handling, Processing, and Use of Lithium Metal	1/5/2001
NFPA 490–1998	Code for the Storage of Ammonium Nitrate	1/5/2001
NFPA 497–1997	Recommended Practice for Classification of Flammable Liquids, Gases or Vapors and of Hazardous (Classified) Locations for Electrical Installations in Chemical Process Areas.	7/6/2001
NFPA 499–1997	Recommended Practice for Classification of Combustible Dusts and of Hazardous (Classified) Locations for Electrical Installations in Chemical Processing Plants.	7/6/2001
NFPA 501–2000	Standard on Manufactured Housing	1/5/2001
NFPA 501A–2000	Standard for Fire Safety Criteria for Manufactured Home Installations, Sites, and Communities.	1/5/2001
NFPA 505–1999	Fire Safety Standard for Powered Industrial Trucks Including Type Designations, Areas of Use, Conversions, Maintenance, and Operation.	1/5/2001
NFPA 550–1995	Guide to the Fire Safety Concepts Tree	2/16/2001
NFPA 610–P*	Recommended Practice for Safety of Motorsports Venues	7/6/2001
NFPA 651–1998	Standard for the Machining and Finishing of Aluminum and the Production and Handling of Aluminum Powders.	
NFPA 705–1997	Recommended Practice for a Field Flame Test for Textiles and Films	1/5/2001
NFPA 750–2000	Standard on Water Mist Fire Protection Systems	7/6/2001
NFPA 1001–1997	Standard for Fire Fighter Professional Qualifications	1/5/2001
NFPA 1021–1997	Standard for Fire Officer Professional Qualifications	1/5/2001
NFPA 1122–1997	Code for Model Rocketry	1/5/2001
NFPA 1221–1999	Standard for the Installation, Maintenance, and Use of Emergency Services Communications Systems.	1/5/2001
NFPA 1584–P*	Recommended Practice for a Fire Department Rehabilitation Program	1/5/2001
NFPA 1901–1999	Standard for Automotive Fire Apparatus	12/28/2001
NFPA 1911–1997	Standard for Service Tests of Fire Pump Systems on Fire Apparatus	1/5/2001
NFPA 1914–1997	Standard for Testing Fire Department Aerial Devices	1/5/2001
NFPA 1962–1998	Standard for the Care, Use, and Service Testing of Fire Hose Including Coulines and Nozzles.	3/30/2001
NFPA 1964–1998	Standard for Spray Nozzles (Shutoff and Tip)	3/30/2001

* Proposed NEW drafts are available from NFPA's Website—www.nfpa.org or may be obtained from NFPA's Codes and Standards Administration, 1 Batterymarch Park, Quincy, MA 02269.

[FR Doc. 00-32674 Filed 12-21-00; 8:45 am]
BILLING CODE 3510-13-M

DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

[Notice 1]

National Fire Codes: Request for Comments on NFPA Technical Committee Reports

AGENCY: National Institute of Standards and Technology, Commerce.

ACTION: Notice.

SUMMARY: The National Fire Protection Association (NFPA) revises existing standards and adopts new standards twice a year. At both its November Meeting and its May Meeting, the NFPA acts on recommendations made by its technical committees.

The purpose of this notice is to request comments on the technical reports that will be presented at NFPA's 2001 November Meeting. The publication of this notice by the National Institute of Standards and Technology (NIST) on behalf of NFPA is being undertaken as a public service; NIST does not necessarily endorse, approve, or recommend any of the standards referenced in the notice.

DATES: Thirty-five reports are published in the "2001 November Meeting Report on Proposals" and will be available on January 19, 2001. Comments received on or before March 30, 2001 will be

considered by the respective NFPA Committees before final action is taken on the proposals.

ADDRESSES: The "2001 November Meeting Report on Proposals" is available and downloadable from NFPA's Website—www.nfpa.org or by requesting a copy from the NFPA, Fulfillment Center, 11 Tracy Drive, Avon, MA 02322. Comments on the report should be submitted to Casey C. Grant, Secretary, Standards Council, NFPA, 1 Batterymarch Park, P.O. Box 9101, Quincy, Massachusetts 02269-9101.

FOR FURTHER INFORMATION CONTACT: Casey C. Grant, Secretary, Standards Council, NFPA, 1 Batterymarch Park, Quincy, MA 02269-9101, (617) 770-3000.

SUPPLEMENTARY INFORMATION:

Background

The National Fire Protection Association (NFPA) develops building, fire, and electrical safety codes and standards. Federal agencies frequently use these codes and standards as the basis for developing Federal regulations concerning fire safety. Often, the Office of the **Federal Register** approves the incorporation by reference of these standards under 5 U.S.C. 552(a) and 1 CFR Part 51.

Revisions of existing standards and adoption of new standards are reported by the technical committees at the NFPA's November Meeting or at the May Meeting each year. The NFPA

invites public comments on its "Report on Proposals."

Request for Comments

Interested persons may participate in these revisions by submitting written data, views, or arguments to Casey C. Grant, Secretary, Standards Council, NFPA, 1 Batterymarch Park, Quincy, Massachusetts 02269-9101. Commenters may use the forms provided for comments in the "Report on Proposals." Each person submitting a comment should include his or her name and address, identify the notice, and give reasons for any recommendations. Comments received on or before March 30, 2001 for the "2001 November Meeting Report on Proposals" will be considered by the NFPA before final action is taken on the proposals.

Copies of all written comments received and the disposition of those comments by the NFPA committees will be published as the "2001 November Meeting Report on Comments" by September 21, 2001, prior to the November Meeting.

A copy of the Report on Comments will be sent automatically to each commenter. Action on the reports of the Technical Committees (adoption or rejection) will be taken by NFPA members at the November Meeting, November 13-17, 2001 in Dallas, Texas.

Dated: December 18, 2000.

Karen Brown,
Deputy Director.

2001 November Meeting Report on Proposals

Doc. No.	Title	Action
NFPA 25	Standard for the Inspection, Testing, and Maintenance of Water-Based Fire Protection System	P
NFPA 37	Standard for the Installation and Use of Stationary Combustion Engines and Gas Turbines	C
NFPA 51	Standard for the Design and Installation of Oxygen-Fuel Gas Systems for Welding, Cutting, and Allied Processes.	P
NFPA 68	Guide for Venting of Deflagrations	C
NFPA 76	Recommended Practice for the Protection of Telecommunications Facilities	N
NFPA 99	Standard for Health Care Facilities	P
NFPA 99B	Standard for Hypobaric Facilities	P
NFPA 99C	Standard for Gas and Vacuum Systems	P
NFPA 110	Standard for Emergency and Standby Power Systems	C
NFPA 204	Guide for Smoke and Heat Venting	C
NFPA 266	Standard Method of Test for Fire Characteristics of Upholstered Furniture Exposed to Flaming Ignition Source.	W
NFPA 270	Standard Test Method for Measurement of Smoke Obscuration Using a Conical Radiant Source in a Single Closed Chamber.	C
NFPA 471	Recommended Practice for Responding to Hazardous Materials Incidents	P
NFPA 472	Standard for Professional Competence of Responders to Hazardous Materials Incidents	C
NFPA 473	Standard for Competencies for EMS Personnel Responding to Hazardous Materials Incidents	P
NFPA 560	Standard for the Storage, Handling, and Use of Ethylene Oxide for Sterilization and Fumigation	P
NFPA 902	Fire Reporting Field Incident Guide	W
NFPA 903	Fire Reporting Property Survey Guide	W
NFPA 904	Incident Follow-up Report Guide	W
NFPA 1041	Standard for Fire Service Instructor Professional Qualifications	P
NFPA 1051	Standard for Wildland Fire Fighter Professional Qualifications	C

Doc. No.	Title	Action
NFPA 1061	Standard for Professional Qualifications for Public Safety Telecommunicator	P
NFPA 1192	Standard for Recreational Vehicles	P
NFPA 1194	Standard for Recreational Vehicle Parks and Campgrounds	P
NFPA 1402	Guide to Building Fire Service Training Centers	C
NFPA 1403	Standard on Live Fire Training Evolutions	C
NFPA 1404	Standard for a Fire Department Self-Contained Breathing Apparatus Program	C
NFPA 1451	Standard for a Fire Service Vehicle Operations Training Program	C
NFPA 1500	Standard on Fire Department Occupational Safety and Health Program	C
NFPA 1521	Standard for Fire Department Safety Officer	W
NFPA 1561	Standard on Emergency Services Incident Management System	C
NFPA 1852	Standard on Selection, Care, and Maintenance on Open-Circuit SCBA	N
NFPA 1961	Standard for Fire Hose	C
NFPA 1981	Standard on Open-Circuit Self-Contained Breathing Apparatus for the Fire Service	C
NFPA 1982	Standard on Personal Alert Safety Systems (PASS)	C

(P=Partial revision; W=Withdrawal; R=Reconfirmation; N=New; C=Complete Revision)

[FR Doc. 00-32673 Filed 12-21-00; 8:45 am]

BILLING CODE 3510-13-M

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 121800C]

Gulf of Mexico Fishery Management Council; Public Meetings

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of public meeting.

SUMMARY: The Gulf of Mexico Fishery Management Council will convene public meetings.

DATES: The meetings will be held on January 15-19, 2001.

ADDRESSES: These meetings will be held at the San Luis Hotel, 5222 Seawall Boulevard, Galveston, Texas; telephone: 409-744-1500.

Council address: Gulf of Mexico Fishery Management Council, 3018 U.S. Highway 301 North, Suite 1000, Tampa, FL 33619.

FOR FURTHER INFORMATION CONTACT: Wayne E. Swingle, Executive Director, Gulf of Mexico Fishery Management Council; telephone: (813) 228-2815.

SUPPLEMENTARY INFORMATION:

Monday, January 15, 2001

9 a.m. - 10:30 a.m.—Convene the Artificial Reef Committee to hear a review of the National Artificial Reef Plan.

10:30 a.m. - 12 noon—Convene the Habitat Protection Committee to discuss habitat protection issues related to Brownsville Weir and Reservoir project and Gulf Intercoastal Waterway (near Freeport).

1 p.m. - 5:30 p.m.—Convene the Reef Fish Management Committee to develop

its recommendations to the Council on total allowable catch (TAC) for the reef fish stocks and to review an options paper for grouper management.

Tuesday, January 16, 2001

8 a.m. - 9:30 a.m.—Continue the Reef Fish Management Committee, if necessary.

9:30 a.m. - 12:30 p.m.—Convene the Shrimp Management Committee to develop recommendations to the Council for the extent of the Texas Shrimp Closure for 2001 and the provisions of Amendment 11 which has alternatives for vessel permits and permitting of vessel operators.

1:30 p.m. - 4 p.m.—Convene the Mackerel Management Committee to hear a stock assessment report on wahoo and to develop recommendations to the Council on the provisions of the Dolphin/Wahoo Fishery Management Plan (FMP).

4 p.m. - 5:30 p.m.—Convene the Law Enforcement Committee to review a Strategic Law Enforcement Plan for the Gulf.

Wednesday, January 17, 2001

8:30 a.m.—Convene Council.

8:45 a.m. - 12 noon—Receive public testimony on the Texas Shrimp Closure for 2001, a proposed Dolphin/Wahoo FMP, a proposed amendment to the Shrimp FMP, and proposed regulatory actions on setting TAC and restrictive management measures for greater amberjack and red grouper. The Council will also consider adopting a 5-year restoration scenario for rebuilding of the overfished red snapper stock. The TAC and management measures would remain constant over this 5-year period and then be adjusted based on new stock assessment information in 2005.

Note: Persons who will testify must turn in a registration card before the start of the testimony period on Wednesday.

1:30 p.m. - 5 p.m.—Continue public testimony if needed.

5 p.m. - 5:30 p.m.—Discuss adoption of a possible Council logo.

11:30 a.m. - 12 noon—Receive a report of the Artificial Reef Committee.

Thursday, January 18, 2001

8:30 a.m. - 11:30 a.m.—Receive a report of the Reef Fish Management Committee.

11:30 a.m. - 12 noon—Receive a report of the Artificial Reef Committee.

1:30 p.m. - 3:30 p.m.—Receive a report of the Shrimp Management Committees.

3:30 p.m. - 5:30 p.m.—Receive a report of the Mackerel Management Committee Report.

Friday, January 19, 2001

8:30 a.m. - 9 a.m.—Receive a report of the Habitat Protection Committee.

9 a.m. - 10 a.m.—Receive a report of the Law Enforcement Committee Report.

10 a.m. - 10:15 a.m.—Receive the South Atlantic Fishery Management Council Liaison report.

10:15 a.m. - 10:30 a.m.—Receive enforcement reports.

10:30 a.m. - 10:45 a.m.—Receive the NMFS Regional Administrator's Report.

10:45 a.m. - 11 a.m.—Receive Director's Reports.

11 a.m.—Other Business

Although non-emergency issues not contained in this agenda may come before this Council for discussion, in accordance with the Magnuson-Stevens Fishery Conservation and Management Act, those issues may not be the subject of formal Council action during this meeting. Action will be restricted to those issues specifically listed in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the Council's intent to take final action to address the emergency. A copy of the

Committee schedule and agenda can be obtained by calling (813) 228-2815.

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Anne Alford at the Council (see **ADDRESSES**) by January 8, 2001.

Dated: December 18, 2000.

Richard W. Surdi,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 00-32726 Filed 12-21-00; 8:45 am]

BILLING CODE: 3510-22-S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Notice of Availability for License and Intent To Grant an Exclusive Patent License

AGENCY: Office of Oceanic and Atmospheric Research, NOAA, DOC.

ACTION: Notice of availability for license and intent to grant an exclusive patent license.

SUMMARY: The Environmental Technology Laboratory, Oceanic and Atmospheric Research Laboratories, National Oceanic and Atmospheric Administration, Department of Commerce, intends to grant the Department of Fisheries and Oceans of the Canadian Government, an exclusive license to its undivided interest in U.S. Patent 4,760,743 entitled "Acoustic Scintillation Liquid Flow Measurement" which is jointly owned by the U.S. Department of Commerce and the Canadian Patents and Development Limited. The counterpart Canadian patent 1,254,649 is owned by the Canadian Government.

DATES: The proposed license may be granted unless written evidence and argument is received within 60 days from the publication of this notice, establishing that the grant of the license would not be consistent with 35 U.S.C. 209 and 37 CFR 404.7.

ADDRESSES: Any comments about or objections to the proposed license shall be mailed to John H. Raubitschek, Patent Counsel, Department of Commerce, Room 4613, Washington, DC 20230.

FOR FURTHER INFORMATION CONTACT: If there are any questions, Mr. John H. Raubitschek may be contacted at 202-482-8010.

Dated: December 15, 2000.

David L. Evans,

Assistant Administrator, Office of Oceanic and Atmospheric Research.

[FR Doc. 00-32728 Filed 12-21-00; 8:45 am]

BILLING CODE 3510-KD-M

DEPARTMENT OF DEFENSE

Department of the Air Force

Department of Defense Commercial Air Carrier Quality and Safety Review

AGENCY: Department of the Air Force, DoD.

ACTION: Notice, correction.

SUMMARY: The Air Force published a document in the **Federal Register** September 5, 2000, concerning request for comments to assist the overall evaluation of commercial aircraft to provide quality, safe, and reliable airlift service when procured by the Department of Defense. The document contained incorrect information for "Average Burden per Respondent."

FOR FURTHER INFORMATION CONTACT: Mr. Larry Elliott, HQ (AMC/DOB) 402 Scott Drive, Unit 3A1, Scott AFB, IL 62225-5302.

Correction

In the **Federal Register** of September 5, 2000, in FR Doc. 00-22573, on page 53706, correct the Average Burden per Respondent to read:

Average Burden per Respondent: 20 hours.

Dated: December 12, 2000.

Janet A. Long,

Air Force Federal Register Liaison Officer.

[FR Doc. 00-32640 Filed 12-21-00; 8:45 am]

BILLING CODE 5001-05-P

DEPARTMENT OF DEFENSE

Department of the Army

Reserve Officers' Training Corps (ROTC) Program Subcommittee

AGENCY: U.S. Army Cadet Command, U.S. Army DoD.

ACTION: Notice of meeting.

SUMMARY: In accordance with Section 10(a)(2) of the Federal Advisory Committee Act (5 U.S.C., App. 2), announcement is made of the following Committee meeting:

Name of Committee: Reserve Officers' Training Corps (ROTC) Program Subcommittee.

Dates of Meeting: February 4-7, 2001.

Place: Quality Inn, Hampton, Virginia.

Time: 0800-1700 hours, February 5-6, 2001; and 0800-1200 hours February 7, 2001.

Proposed Agenda: Review and discuss status of Army ROTC since the July 2000 meeting held in Tacoma, Washington.

FOR FURTHER INFORMATION CONTACT:

Commander, HQ U.S. Army Cadet Command, ATTN: ATCC-TT (MAJ Hewitt), Fort Monroe, VA 23430. Telephone number is (757) 788-5456.

SUPPLEMENTARY INFORMATION: This meeting is open to the public. Any interested person may attend, appear before, or file statements with the committee.

Gregory D. Showalter,

Army Federal Register Liaison Officer.

[FR Doc. 00-32631 Filed 12-21-00; 8:45 am]

BILLING CODE 3710-08-M

DEPARTMENT OF DEFENSE

Department of the Army; Corps of Engineers

Intent To Prepare a Draft Environmental Impact Statement (DEIS) for an Emergency Outlet From Devils Lake, ND, to the Sheyenne River

AGENCY: U.S. Army Corps of Engineers, DoD.

ACTION: Notice of Intent (Revised).

SUMMARY: Devils Lake is a terminal lake located in northeastern North Dakota. Devils Lake has a long history of a wide range of fluctuating lake levels. Since 1993, the lake has risen about 25 feet. Rising lake levels have resulted in damages to homes, businesses, infrastructure, transportation systems, and land uses. Significant expenditures of Federal, State, and local funds have been required to relocate structures and to raise and strengthen roads and levees. While these efforts will provide immediate protection, there is great concern that the lake could continue to rise. The Devils Lake basin is a subbasin of the Hudson Bay drainage system. Although Devils Lake has not contributed to the Hudson Bay drainage for many centuries, there is a potential for the lake to rise to its natural outlet elevation if the recent climate patterns persist. There is a potential for substantial damages to occur along the Sheyenne River, depending on the magnitude of the overflow event.

Purpose and Need. The purpose of the proposed action is to reduce the flood damages related to the rising lake levels in the flood-prone areas around Devils Lake and to reduce the potential for a natural overflow event.

Proposed Action. The proposed action is the construction of an outlet from Devils Lake, North Dakota, to the Sheyenne River.

FOR FURTHER INFORMATION CONTACT:

Questions concerning the DEIS can be directed to: Colonel Kenneth S. Kasprisin, District Engineer, St. Paul District, Corps of Engineers, ATTN: Mr. Robert Whiting, 190 Fifth Street East, St. Paul, Minnesota 55101-1638, or phone (651) 290-5264.

SUPPLEMENTARY INFORMATION:

1. The 1997 Emergency Supplemental Appropriations Act provided up to \$5 million under the Flood Control and Coastal Emergency account to conduct preconstruction engineering and design (PED) and prepare an associated Environmental Impact Statement (EIS) for an emergency outlet at Devils Lake. A Notice of Intent to prepare an EIS for an outlet from Devils Lake to the Sheyenne River under Public Law 105-18 was published in the **Federal Register** on 21 October 1997. That study was not completed.

2. The Energy and Water Development Appropriations Acts of 1998, 1999, and 2000 included funds for construction of the Devils Lake project subject to a determination of economic justification, compliance with the National Environmental Policy Act (NEPA) of 1969, compliance with the Boundary Waters Treaty Act of 1909, and technical soundness. No funds were provided to the Corps under these authorities.

3. An amount of \$2 million was provided from a supplemental appropriation in Fiscal Year 2000, and another \$4 million was included in the Fiscal Year 2001 appropriations. These funds are for preconstruction engineering and design of an emergency outlet from Devils Lake, North Dakota, to the Sheyenne River. The Corps is issuing a revised Notice of Intent because of the changed authority and funding.

4. *Proposed Action.* The proposed action in the authorizing legislation consists of an outlet to the Sheyenne River. Many potential outlet routes and concepts have been evaluated in prior studies. The route that has the greatest potential for being implementable is the Peterson Coulee route. Therefore, it is likely that, following an initial screening, this will be the outlet alternative that will be evaluated in detail. Further consideration would be needed to determine the recommended outlet operation plan. The evaluation would address an array of operating plans ranging from a discharge of 300 cubic feet per second (cfs) constrained by downstream channel capacity and water quality standards, to a 480 cfs unconstrained discharge. Outlet operation would be limited to 7 months

of the year, from May through November.

5. *Alternatives to be Investigated.* The Corps will examine the environmental impacts of the alternatives in an Environmental Impact Statement (EIS) in accordance with the National Environmental Policy Act (NEPA). The EIS will identify and evaluate alternatives to the proposed action, and will evaluate in detail only those alternatives that meet the purpose and need identified previously. Alternatives include the following:

a. *Future Without the Proposed Project.* The measures identified with this alternative are the base condition upon which other alternatives are to be compared for impact assessment under NEPA. This alternative assumes that the types of emergency measures currently being pursued in the project area would continue to be implemented as necessary due to rising lake levels. These emergency measures include such actions as raising the levees protecting the City of Devils Lake and relocating homes if the lake level continues to rise. If technically and economically feasible, emergency measures may also include building temporary levees, raising selected roads and railroads (within limits of reasonable safety acceptance), and protecting or relocating utilities. A continuation of the current level of upper basin storage and measures at the location of a natural overflow to minimize erosion will also be considered as potential features of the future without the proposed project. For the portion of the cost effectiveness evaluation using a scenario approach, it will be assumed that the current wet cycle will continue, as evidenced by U.S. Geological Survey and University of North Dakota studies, to the point of naturally overflowing into the Sheyenne River. Proposed actions by the State of North Dakota, such as an overflow to Stump Lake and a temporary outlet to the Sheyenne River along the Twin Lakes route, will not be assumed to be included in the future without conditions alternative at this time. If either or both are implemented, the evaluation of alternatives will be reviewed to determine what measures are needed to complete NEPA with this changed base condition.

b. *Upper Basin Management.* This alternative would examine taking further measures in the upper basin to reduce inflow into the lake, such as providing storage through retention structures, wetland restoration, or land use change.

c. *Expanded Infrastructure Measures.* Currently, roads are serving as barriers

to the rising and expanding waters of Devils Lake. These roads are acting as dams; however, they were not constructed to function as dams. This presents the possibility of safety concerns for road users and people living in areas protected by the roads. This alternative will examine taking additional measures beyond those described in the future without the proposed action alternative to ensure a safe level of flood protection within the basin.

d. *Combinations and Sensitivity Analysis.* In addition to evaluation of the above alternatives independently, several combinations of these alternatives will also be addressed. To better understand the sensitivity of assumptions used for the future without a proposed project condition, the selected alternative will be evaluated in comparison to at least three other base conditions. The other three scenarios are as follows:

(1) No additional Emergency Measures will be done in the Devils Lake basin.

(2) A more moderate scenario for future lake stage (maximum elevation 1455).

(3) An even more moderate scenario for future lake stage (maximum elevation 1450).

6. The DEIS will discuss the proposed action and alternatives. There will be an identification and evaluation of alternatives, additional supplemental scoping, a discussion of the direct impacts of the proposed action, and a general discussion of the need for monitoring project operation to determine impacts and mitigation needs.

7. Significant issues and resources to be identified in the DEIS were determined through coordination and scoping activities with responsible Federal, State, Canadian, and local agencies; the general public; interested private organizations and parties; and affected Native Americans during the previous scoping process. This scoping was conducted in conjunction with the previous Devils Lake basin studies. Significant issues identified through previous scoping activities for discussion in the DEIS are as follows:

a. Natural resources including: Aquatic, wildlife, vegetation, wetlands, and riparian areas;

b. Cultural resources;

c. Water quality and quantity, groundwater, erosion, sedimentation, and induced flooding;

d. Federally and State listed threatened or endangered plant or animal species;

e. Social and economic resources, soils, and downstream water users;
f. Downstream intrastate, interstate, and international resources; and
g. Native American and Tribal Trust resources and responsibilities.

8. Supplemental scoping/public involvement will be used to help identify any additional concerns and issues. Anyone who has an interest in participating in the development of the DEIS is invited to contact the St. Paul District, Corps of Engineers. A notice of any meetings will be provided to interested parties and to local news media.

9. Measures to address the project purpose and need are considered to be major in scope. Project features have the potential to result in significant impacts. The Corps of Engineers' environmental review will be conducted according to the requirements of the National Environmental Policy Act of 1969, National Historic Preservation Act of 1966, Council on Environmental Quality Regulations, Endangered Species Act of 1973, Section 404 of the Clean Water Act, and applicable laws and regulations.

10. It is anticipated that the DEIS will be available to the public in February 2002. The EIS will be supplemented as appropriate.

Gregory D. Showalter,

Army Federal Register Liaison Officer.

[FR Doc. 00-32629 Filed 12-21-00; 8:45 am]

BILLING CODE 3710-CY-U

DEPARTMENT OF DEFENSE

Department of the Army

Corps of Engineers Availability of Exclusive or Partially Exclusive Licenses

AGENCY: U.S. Army Corps of Engineers, DoD.

ACTION: Notice.

SUMMARY: The Department of the Army, U.S. Army Corps of Engineers, announces the general availability of exclusive, or partially exclusive licenses under the following pending patents. Any license granted shall comply with 35 U.S.C. 209 and 37 CFR Part 404.

Serial Number: 09/229,161.

Filing Date: 1/13/99.

Title: Method for Attaching Fabric and Floor Covering Materials to Concrete.

Serial Number: 09/397,071.

Filing Date: 9/16/99.

Title: Groundwater Flow Measuring System.

Serial Number: 09/408,911.

Filing Date: 9/30/99.

Title: Retrievable Filter Element for Subsurface Drainage.

Serial Number: 09/418,367.

Filing Date: 10/14/99.

Title: A Method for Measuring Depths of a Waterway and for Determining Vertical Positions of a Waterborne Vessel.

Serial Number: 09/418,481.

Filing Date: 10/15/99.

Title: Method of CEL Hybrid Modeling for Simulation of Ecosystem-Level Processes in Aquatic Environments.

Serial Number: 09/418,482.

Filing Date: 10/15/99.

Title: Method and System Capable of Performing a Substantially Continuous Uptake During a Trawling Operation.

Serial Number: 09/432,213.

Filing Date: 11/3/99.

Title: A Wearable Computer Configured for Geophysical Radar Profiling Applications.

Serial Number: 09/551,860.

Filing Date: 4/18/00.

Title: Instrument Channel Approach.

Serial Number: 09/553,613.

Filing Date: 4/20/2000.

Title: Method and Apparatus for Measuring and Assessing Corrosive Conditions of a Surface by a Remotely Controlled Robotic Vehicle.

Serial Number: 09/564,030.

Filing Date: 5/4/2000.

Title: Method and Apparatus for Installing a Small-scale Groundwater Sampling Well.

Serial Number: 09/572,942.

Filing Date: 5/18/2000.

Title: Method of Manufacturing Cement Board Incorporating Recycled Carpet Fiber and Cement Board Made in Accordance Therewith.

Serial Number: 09/628,940.

Filing Date: 7/28/00.

Title: Bag Dispenser.

Serial Number: 09/628,941.

Filing Date: 7/28/00.

Title: Detection of Sub-Surface Failures in Barriers

DATES: Applications for an exclusive or partially exclusive license may be submitted at any time from the date of this notice. However, no exclusive or partially exclusive license shall be granted until 90 days from the date of this notice.

ADDRESSES: Humphreys Engineer Center Support Activity, Office of Counsel, 7701 Telegraph Road, Alexandria, Virginia 22315-3860.

FOR FURTHER INFORMATION CONTACT: Patricia L. Howland (703) 428-6672.

SUPPLEMENTARY INFORMATION:

Title: Method for Attaching Fabric and Floor Covering Materials to

Concrete. A method of bonding a variety of moisture-sensitive materials, such as vinyl, wood, pressed boards, and textile materials to concrete, utilizing a steel foil or plate layer as an effective vapor barrier, that protects the adhesive beneath the floor covering from the moisture which moves through the concrete, preventing the adhesive bonding between the covering material, such as carpeting, and the concrete from failing, preventing permeation of moisture from the concrete to the adhesive bonding area, protecting the concrete and the covering material from premature weathering and providing a surface for paint or spray-on coatings.

Title: Groundwater Flow Measuring System. An apparatus and method of measuring and monitoring groundwater flow at extremely low seepage velocities (0.1-1.0 ft/day). The use of temperature sensors with a linear temperature response, as opposed to the highly nonlinear temperature response provided by thermistors, employs a groundwater monitoring probe comprising a central electric heater and three or more temperature sensors surrounding the heater, which are immersed in the groundwater in a slotted, perforated, or screened section of a casing inserted in a monitoring well, and which are electrically connected to electronic measuring, computing, and recording means at the surface.

Title: Retrievable Filter Element for Subsurface Drainage. The filter elements and process for constructing leach fields. The filter elements are assembled by placing rubber or plastic scrap pieces, in the form of chips, in net sacks. The net sacks containing the aggregate are attached to pieces of fabric filter cloth, which may be wrapped around the net sacks or draped around adjacent filter elements so that the soil surrounding the net sacks cannot infiltrate into the enclosed aggregate chips, but water draining into the aggregate chips can escape through the filter cloth into the surrounding soil.

Title: A Method for Measuring Depths of a Waterway and for Determining Vertical Positions of a Waterborne Vessel. A method for determining, on a continuous basis, the clearance between the bottom of a waterborne vessel and the bottom of a waterway.

Title: Method of CEL Hybrid Modeling for Simulation of Ecosystem-Level Processes in Aquatic Environments. A method for coupling Eulerian and Lagrangian reference frames so higher tropic levels of an aquatic ecosystem, such as fish and shellfish, can be systematically and realistically simulated, allowing for the

analysis of higher tropic level processes with minimal distortion and loss of information by coupling two frames of reference and exploiting the advantages associated with each.

Title: Method and System Capable of Performing a Substantially Continuous Uptake During a Trawling Operation. A trawler method and system achieving an increased consumption ratio of catch-to-bycatch during the trawling operation, reducing the mortality of the bycatch in commercial trawling, and also minimizing loss of the target species.

Title: A Wearable Computer Configured for Geophysical Radar Profiling Applications. A portable, lightweight system, fully integrated for using penetrating ground radar for taking simplified field geophysical measurements and can be operated from the body of an operator while the operator is moving. The system operates for extended periods of time using lightweight portable rechargeable and replaceable batteries and facilitates continuous, glare-free viewing of computer screens associated with the scanning system. The computer-controlled radar system boards are easily changeable for a wide variety of different environments. Real-time viewing of radar data and integration with other real-time data input sources create an integrated data stream with accurate time correlation between all data inputs.

Title: Instrument Channel Approach. A system to determine the water depth in a channel or harbor below a low water reference permitting the navigation of a channel or harbor having a reference GPS signal receiving station on land which sends information to a ship with its GPS signal receiving system.

Title: Method and Apparatus for Measuring and Assessing Corrosive Conditions of a Surface by a Remotely Controlled Robotic Vehicle. A remotely controlled robotic vehicle is used for inspecting the interior of ferrous structures such as liquid storage tanks without removing the stored liquid. The robotic vehicle cleans the surface of debris and corrosive deposits prior to inspection, measures and assesses wall integrity and thickness, and communicates the results to a computer which continuously ascertains the position of the robotic vehicle. The robotic vehicle can navigate in various orientations, including vertical and inverted orientations throughout the interior of a substantially cylindrical tank.

Title: Method and Apparatus for Installing a Small-scale Groundwater Sampling Well. A method and

apparatus for installing a small-scale groundwater sampling device which is easy to construct and inexpensive to manufacture. The device can be used by the conventional push-in equipment associated with a civil engineering cone penetrometer. The conventional penetrometer can install a well that can be used for continuous monitoring of groundwater quality using two penetrometer operators with only one or two hours of work and uses the same design that the U.S. EPA requires for a full-scale monitoring well. The installation of the well is done by pushing and not drilling and does not generate any well cuttings which typically have to be tested prior to disposal to determine if the soil is contaminated.

Title: Method of Manufacturing Cement Board Incorporating Recycled Carpet Fiber and Cement. A method of manufacturing a smooth surface cement board incorporating recycled carpet fiber which produces a strong cement board even with a fluid mortar. Air-filled voids or "bugholes" are eliminated. The use of tangled fibers produces a cement board in which the fiber has high pull-out resistance. The mixed fiber and mortar can be placed as a discrete layer thereby making it possible to make a cement board that has two exterior layers containing fiber and a central layer containing only mortar.

Title: Bag Dispenser. Plastic, paper, aluminum foil, or aluminum foil laminated with plastic bags are dispensed, one at a time, from a bag dispenser. Bags are either provided in rolls connected top-to-top and bottom-to-bottom, nested with one bag inside the next adjacent bag, or are nested and attached to a perforated central tab that passes through the bottom seam of each bag, which may be placed in a funnel-like dispenser that holds the nested bags in an upright position.

Title: Detection of Sub-Surface Failures in Barriers. An early warning method to remotely and continually monitor the structural integrity of a barrier such as levees and dams. Failure mechanisms due to the existence of water or moisture content within the structure and structural irregularities due to changes in moisture content such as boils are detected in their early stages thus allowing remedial measures.

Richard L. Frenette,
Counsel.

[FR Doc. 00-32630 Filed 12-21-00; 8:45 am]

BILLING CODE 3710-92-U

DEPARTMENT OF EDUCATION

Student Assistance General Provisions, Federal Perkins Loan, Federal Work-Study, Federal Supplemental Educational Opportunity Grant, Federal Family Education Loan, William D. Ford Federal Direct Loan, Federal Pell Grant, and Leveraging Educational Assistance Partnership Programs

AGENCY: Department of Education.

ACTION: Notice of deadline date.

SUMMARY: We give notice that institutions participating in the student financial assistance programs authorized by title IV of the Higher Education Act of 1965, as amended (Title IV, HEA programs), must meet the updated minimum technical hardware and software specifications described in this notice in order to participate in the designated electronic processes that the Department uses in the administration of those programs.

DATES: The provisions in this notice are effective January 1, 2002.

SUPPLEMENTARY INFORMATION: The Student Assistance General Provisions regulations in 34 CFR 668.16(o) provide that the Secretary considers an institution to have administrative capability if it participates in electronic processes that the Secretary identifies in a notice published in the **Federal Register** and provides at no substantial charge to the institution. On September 19, 1997 (62 FR 49414), we published a notice in the **Federal Register** that provided the minimum hardware and software technical specifications that an institution had to have in order to participate in those electronic processes. Because of advances in technology it is necessary to update those minimum technical specifications. Beginning January 1, 2002, for the 2002-2003 processing year, institutions must meet the updated minimum hardware and software requirements that appear in the technical specifications table provided under the next heading in order to continue to participate in those electronic processes. Most institutions already have hardware and software that satisfy the updated specifications. We believe that those institutions that have to upgrade hardware or software to meet these standards will be making an investment that will improve their institutional processes at minimal cost.

Technical Specifications

The technical specifications table that follows provides the current and future minimum hardware and software requirements. The table includes two

columns of specifications; the left column provides the current specifications, the right column provides the specifications that must be satisfied beginning January 1, 2002. We recommend that participating institutions prepare now to upgrade their equipment and software in time to meet the January 1, 2002, requirements. When reviewing these specifications,

institutions should be aware that capacity requirements (processor speed, available memory, hard drive storage, etc.) are greatly affected by specific factors at each institution, including which EDEExpress and other Departmental functions the institution uses, the number of records processed, and institutional database interfaces.

We plan to continue to upgrade and enhance our Title IV, HEA program delivery system. Therefore, we recommend that institutions include in their automated data processing budgets, on a regular basis, plans for appropriate hardware and software upgrades and enhancements.

TECHNICAL SPECIFICATIONS

	Current Minimum Configuration (Depending Upon Volume and Usage)	Minimum Configuration Required by January 1, 2002
Equipment	IBM or fully IBM-compatible PC	IBM or fully IBM-compatible PC
	200MHz Pentium Processor or comparable	800MHz Pentium Processor or comparable
	64MB RAM	128 MB RAM or more
	4.0 GB SCSI Hard Drive	20 GB hard drive or more
	56K Analog Modem	56K modem (that meets or is upgradable to V.90 standard)
	3.5"/1.44 MB Diskette Drive	3.5"/1.44 MB Diskette Drive
	Super Video Graphics Adapter (SVGA) Monitor	Monitor and video card capable of Super Video Graphics Adapter (SVGA) (800x600) resolution (small fonts only) or higher*
	Windows 95 Keyboard	Windows 95 Keyboard with Microsoft compatible mouse
	Laser printer capable of printing on standard paper (8½" x 11")	Laser printer capable of printing on standard paper (8½" x 11")
	12x CD-ROM Drive with sound board	24x CD-ROM Drive or higher with sound board
Software	32 bit operating system (Windows 95 or Windows NT 4.x)	32 bit operating system (Microsoft Windows 98, Microsoft Windows NT 4.0, or Microsoft Windows 2000)
	Internet Service Provider (ISP)	Internet Service Provider (ISP) that supports 56K modem connection or higher
	Netscape Navigator 3.0 or 3.01 (domestic) or web browser	<u>Browser Requirements</u> • Internet Explorer v4.01 Service Pack 2 or higher, or • Netscape Navigator v4.73 or higher
		Supported Networks: Windows NT or Novell Netware
Phone Line	Dedicated phone line	Dedicated phone line
Diskettes	3.5" high-density double-sided diskettes	3.5" high-density double-sided diskettes

* EDEExpress is designed in SVGA. You may use a higher resolution than SVGA at your own discretion without adverse impact on EDEExpress.

Applicable Regulations

The regulations applicable to this notice are the Student Assistance General Provisions, 34 CFR part 668.

FOR FURTHER INFORMATION CONTACT: For questions relating to these requirements, contact the Customer Service Call Center at 1-800-433-7327. For questions relating to EDEExpress software, contact the Central Processing System (CPS) Customer Service at 1-800-330-5947.

If you use a telecommunications device for the deaf (TDD), you may call the Federal Information Relay Service at 1-800-877-8339.

Individuals with disabilities may obtain this document in an alternative format (e.g., Braille, large print, audiotape, or computer diskette) on request to Katie Mincey, Director of Alternate Format Center, U.S. Department of Education, 400 Maryland Avenue, SW., (Switzer Bldg., Room 1000), Washington, DC 20202-4560. Telephone: (202) 260-9895.

Electronic Access to This Document

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Note: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available on GPO Access at: <http://www.access.gpo.gov/nara/index.html>

Program Authority: 20 U.S.C. 1070a, 1070b-1070b-4, 1070c-1070c-4, 1071-1087-2, 1087a-1087j, 1087aa-1087ii, 1094, and 1099c; 42 U.S.C. 2751-2756b.

(Catalog of Federal Domestic Assistance numbers: 84.007 Federal Supplemental Educational Opportunity Grant (FSEOG) Program; 84.032 Federal Family Education Loan (FFEL) Programs; 84.033 Federal Work-Study (FWS) Program; 84.038 Federal Perkins (Perkins) Loans; 84.063 Federal Pell Grant (Pell) Program; 84.069 Leveraging Educational Assistance Partnership (LEAP) Programs; and 84.268 William D. Ford Federal Direct Loan (Direct Loan) Programs)

Dated: December 19, 2000.

Greg Woods,

Chief Operating Officer, Student Financial Assistance.

[FR Doc. 00-32705 Filed 12-21-00; 8:45 am]

BILLING CODE 4000-01-P

DEPARTMENT OF ENERGY

Environmental Management Site-Specific Advisory Board, Paducah

AGENCY: Department of Energy (DOE).

ACTION: Notice of open meeting.

SUMMARY: This notice announces a meeting of the Environmental Management Site-Specific Advisory Board (EM SSAB), Paducah. The Federal Advisory Committee Act (Pub. L. No. 92-463, 86 Stat. 770) requires that public notice of these meetings be announced in the **Federal Register**.

DATES: Thursday, January 18, 2001, 5:30 p.m.-9 p.m.

ADDRESSES: Paducah Information Age Park Resource Center, 2000 McCracken Boulevard, Paducah, Kentucky.

FOR FURTHER INFORMATION CONTACT: John D. Sheppard, Deputy Designated Federal Officer, Department of Energy Paducah Site Office, Post Office Box 1410, MS-103, Paducah, Kentucky 42001, (270) 441-6804.

SUPPLEMENTARY INFORMATION:

Purpose of the Board: The purpose of the Board is to make recommendations to DOE and its regulators in the areas of environmental restoration and waste management activities.

Tentative Agenda

5:30 p.m.

Informal Discussion

6:00 p.m.

Call to Order

6:10 p.m.

Approve Minutes

6:20 p.m.

Presentations

Board Response

Public Comments

8:00 p.m.

Subcommittee Reports

Board Response

Public Comments

8:30 p.m.

Administrative Issues

9:00 p.m.

Adjourn

Copies of the final agenda will be available at the meeting.

Public Participation: The meeting is open to the public. Written statements may be filed with the Committee either before or after the meeting. Individuals who wish to make oral statements

pertaining to agenda items should contact John D. Sheppard at the address or telephone number listed above. Requests must be received 5 days prior to the meeting and reasonable provision will be made to include the presentation in the agenda. The Designated Federal Officer is empowered to conduct the meeting in a fashion that will facilitate the orderly conduct of business. Each individual wishing to make public comment will be provided a maximum of five minutes to present their comments as the first item of the meeting agenda.

Minutes: The minutes of this meeting will be available for public review and copying at the Freedom of Information Public Reading Room, 1E-190, Forrestal Building, 1000 Independence Avenue, SW., Washington, DC 20585 between 9 a.m. and 4 p.m., Monday-Friday, except Federal holidays. Minutes will also be available at the Department of Energy's Environmental Information Center and Reading Room at 175 Freedom Boulevard, Highway 60, Kevill, Kentucky between 8 a.m. and 5 p.m. on Monday thru Friday or by writing to John D. Sheppard, Department of Energy Paducah Site Office, P.O. Box 1410, MS-103, Paducah, Kentucky 42001 or by calling him at (270) 441-6804.

Issued at Washington, DC on December 18, 2000.

Rachel M. Samuel,

Deputy Advisory Committee Management Officer.

[FR Doc. 00-32680 Filed 12-21-00; 8:45 am]

BILLING CODE 6450-01-P

DEPARTMENT OF ENERGY

Environmental Management Site-Specific Advisory Board, Fernald

AGENCY: Department of Energy.

ACTION: Notice of open meeting.

SUMMARY: This notice announces a meeting of the Environmental Management Site-Specific Advisory Board (EM SSAB), Fernald. The Federal Advisory Committee Act (Pub. L. No. 92-463, 86 Stat. 770) requires that public notice of these meetings be announced in the **Federal Register**.

DATES: Saturday, January 13, 2001, 8:30 p.m.-12:30 p.m.

ADDRESSES: Fernald Environmental Management Project, Site Services Building Conference Room, 7400 Willey Road, Hamilton, OH 45219.

FOR FURTHER INFORMATION CONTACT: Victoria Spriggs, Phoenix Environmental, 6186 Old Franconia Road, Alexandria, VA 22310, at (703)

971-0058 or e-mail:
vspriggs@theperspectivesgroup.com

SUPPLEMENTARY INFORMATION:

Purpose of the Board: The purpose of the Board is to make recommendations to DOE in the areas of environmental restoration, waste management, and related activities.

Tentative Agenda:

8:30 a.m. Call to Order
8:30–8:45 a.m. Chair's Remarks and Ex-Officio Announcements
8:45–9:30 a.m. Upcoming Chairs Meeting
9:30–10:15 a.m. Questions and Answers on New Contract and Rebaseline
10:30–11:00 a.m. WRAP Update and Discussion
11:00–11:30 a.m. Silos Update and Discussion
11:30–11:45 a.m. Stewardship Plans for 2001
11:45–12:15 p.m. New Member Candidates
12:15–12:30 p.m. Public Comment Session
12:30 p.m. Adjourn

Public Participation: The meeting is open to the public. Written statements may be filed with the Board either before or after the meeting. Individuals who wish to make oral statements pertaining to agenda items should contact Board chair at the address or telephone number listed below. Requests must be received five days prior to the meeting and reasonable provision will be made to include the presentation in the agenda. The Deputy Designated Federal Officer, Gary Stegner, Public Affairs Office, Ohio Field Office, U.S. Department of Energy, is empowered to conduct the meeting in a fashion that will facilitate the orderly conduct of business. Each individual wishing to make public comment will be provided a maximum of five minutes to present their comments.

Minutes: Minutes of this meeting will be available for public review and copying at the Freedom of Information Public Reading Room, 1E-190, Forrestal Building, 1000 Independence Avenue, SW., Washington, DC, 20585 between 9:00 a.m. and 4:00 p.m., Monday-Friday, except Federal holidays. Minutes will also be available by writing to the Fernald Citizens' Advisory Board, c/o Phoenix Environmental Corporation, MS-76, Post Office Box 538704, Cincinnati, OH 43253-8704, or by calling the Advisory Board at (513) 648-6478.

Issued at Washington, DC on December 18, 2000.

Rachel M. Samuel,

Deputy Advisory Committee Management Officer.

[FR Doc. 00-32681 Filed 12-21-00; 8:45 am]

BILLING CODE 6450-01-P

DEPARTMENT OF ENERGY

Environmental Management Site-Specific Advisory Board, Oak Ridge Reservation

AGENCY: Department of Energy.

ACTION: Notice of open meeting.

SUMMARY: This notice announces a meeting of the Environmental Management Site-Specific Advisory Board (EM SSAB) Oak Ridge. The Federal Advisory Committee Act (Pub. L. No. 92-463, 86 Stat. 770) requires that public notice of these meetings be announced in the **Federal Register**.

DATES: Wednesday, January 10, 2001 6 p.m.–9:30 p.m.

ADDRESSES: Garden Plaza Hotel, 215 South Illinois Avenue, Oak Ridge, TN.

FOR FURTHER INFORMATION CONTACT: Pat Halsey, Federal Coordinator, Department of Energy Oak Ridge Operations Office, P.O. Box 2001, EM-922, Oak Ridge, TN 37831. Phone (865) 576-4025; Fax (865) 576-9121 or e-mail: halseypj@oro.doe.gov.

SUPPLEMENTARY INFORMATION: Purpose of the Board: The purpose of the Board is to make recommendations to DOE and its regulators in the areas of environmental restoration, waste management, and related activities.

Tentative Agenda:

1. A presentation on Upper East Fork Poplar Creek will be provided by Mildred Ferre, DOE/Oak Ridge Operations.

Public Participation: The meeting is open to the public. Written statements may be filed with the Committee either before or after the meeting. Individuals who wish to make oral statements pertaining to agenda items should contact Pat Halsey at the address or telephone number listed above. Requests must be received five days prior to the meeting and reasonable provision will be made to include the presentation in the agenda. The Deputy Designated Federal Officer is empowered to conduct the meeting in a fashion that will facilitate the orderly conduct of business. Each individual wishing to make public comment will be provided a maximum of five minutes to present their comments at the end of the meeting.

Minutes: Minutes of this meeting will be available for public review and copying at the Department of Energy's Information Resource Center at 105 Broadway, Oak Ridge, TN between 7:30 a.m. and 5:30 p.m. Monday through Friday, or by writing to Pat Halsey, Department of Energy Oak Ridge Operations Office, P.O. Box 2001, EM-922, Oak Ridge, TN 37831, or by calling her at (865) 576-4025.

Issued at Washington, DC on December 18, 2000.

Rachel M. Samuel,

Deputy Advisory Committee Management Officer.

[FR Doc. 00-32682 Filed 12-21-00; 8:45 am]

BILLING CODE 6450-01-P

DEPARTMENT OF ENERGY

Environmental Management Site-Specific Advisory Board, Savannah River

AGENCY: Department of Energy.

ACTION: Notice of open meeting.

SUMMARY: This notice announces a meeting of the Environmental Management Site-Specific Advisory Board (EM SSAB), Savannah River. The Federal Advisory Committee Act (Pub. L. No. 92-463, 86 Stat. 770) requires that public notice of these meetings be announced in the **Federal Register**.

DATES: Monday, January 22, 2001, 6:30 p.m.–9 p.m., Tuesday, January 23, 2001, 8:30 a.m.–4 p.m.

ADDRESSES: Hilton Oceanfront Hotel-Palmetto Dunes, 23 Ocean Lane, Hilton Head Island, SC 29928.

FOR FURTHER INFORMATION CONTACT: Gerri Flemming, Science Technology & Management Division, Department of Energy Savannah River Operations Office, P.O. Box A, Aiken, SC, 29802; Phone: (803) 725-1958.

SUPPLEMENTARY INFORMATION: Purpose of the Board: The purpose of the Board is to make recommendations to DOE and its regulators in the areas of environmental restoration, waste management, and related activities.

Tentative Agenda:

Monday, January 22, 2001

6:00 p.m.–6:30 p.m. Public comment session

6:30 p.m.–8:00 p.m. Committee meetings

Tuesday, January 23, 2001

8:30 a.m.–9:30 a.m. Approval of minutes; Agency updates; Recognition for Outgoing Board

Members; Public Comment Session;
Facilitator Update

9:30 a.m.–11:00 a.m. Waste Management
Committee Report

11:00 a.m.–12:00 p.m. Nuclear Materials
Committee Report, Public
Comments

1:00 p.m.–1:30 p.m. Savannah River
History Project

1:30 p.m.–2:15 p.m. Packaging and
Transportation

2:15 p.m.–3:00 p.m. Environmental
Remediation Committee

3:00 p.m.–4:00 p.m. Administrative
Committee Report; 2001
Subcommittee Chair and
Membership Elections; Public
comments

If needed, time will be allotted after
public comments for items added to the
agenda, and administrative details. A
final agenda will be available at the
meeting, Monday, January 22.

Public Participation: The meeting is
open to the public. Written statements
may be filed with the Board either
before or after the meeting. Individuals
who wish to make the oral statements
pertaining to agenda items should
contact Gerri Flemming's office at the
address or telephone listed above.
Requests must be received five days
prior to the meeting and reasonable
provision will be made to include the
presentation in the agenda. The Deputy
Designated Federal Officer is
empowered to conduct the meeting in a
fashion that will facilitate the orderly
conduct of business. Each individual
wishing to make public comment will
be provided equal time to present their
comments.

Minutes: The minutes of this meeting
will be available for public review and
copying at the Freedom of Information
Public Reading Room, 1E–190, Forrestal
Building, 1000 Independence Avenue,
SW., Washington, DC, 20585 between 9
a.m. and 4 p.m., Monday through
Friday, except Federal holidays.
Minutes will also be available by
writing to Gerri Fleming, Department of
Energy Savannah River Operations
Office, PO Box A, Aiken, SC 29802, or
by calling her at (803) 725–1958.

Issued at Washington, DC, on December 18,
2000.

Rachel M. Samuel,

*Deputy Advisory Committee Management
Officer.*

[FR Doc. 00–32684 Filed 12–21–00; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Worker Advocacy Advisory Committee Meeting

AGENCY: Department of Energy.

ACTION: Notice of open meeting.

SUMMARY: This notice announces a
meeting of the Worker Advocacy
Advisory Committee Meeting. The
Federal Advisory Committee Act (Pub.
L. No. 92–463, 86 Stat. 770), requires
that public notice of the meetings be
announced in the **Federal Register**.

DATE: Thursday, January 11, 2001, 9 am
to 4:30 pm.

ADDRESSES: L'Enfant Plaza Hotel, 480
L'Enfant Plaza, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Judy
Keating, Executive Administrator,
Worker Advocacy Advisory Committee,
U.S. Department of Energy, EH–8, 1000
Independence Avenue, S.W.,
Washington, DC 20585, Telephone
Number 202–586–7551, E-mail:
Judy.Keating@eh.doe.gov.

SUPPLEMENTARY INFORMATION: Purpose of
the Meeting: To provide advice to the
Director of the Office of Worker
Advocacy of the Department of Energy
on plans, priorities, and strategies for in
providing assistance to workers who
have been diagnosed with work-related
illnesses.

Tentative Agenda:
Welcome and Introduction
Opening Remarks
Role of the Advisory Committee
Status of the Energy Employees
Occupational Illness Compensation
Act of 2000
Status and direction of DOE worker
advocacy efforts
Relationships with other federal
agencies
Public comment
Next Steps/Path Forward

Public Participation: The meeting is
open to the public on a first-come, first-
serve basis because of limited seating.
Written statements may be filed with
the committee before or after the
meeting. Members of the public who
wish to make oral statements pertaining
to agenda items should contact Judy
Keating at the address or telephone
listed above. Requests to make oral
statements must be made and received
five days prior to the meeting;
reasonable provision will be made to
include the statement in the agenda.
The Chair of the committee is
empowered to conduct the meeting in a
fashion that will facilitate the orderly
conduct of business.

Minutes: The minutes of this meeting
will be available for public review and

copying at the Freedom of Information
Reading Room, 1E–190, Forrestal
Building, 1000 Independence Avenue,
SW., Washington, DC, between 9 a.m.
and 4 p.m., Monday through Friday,
except holidays.

Issued in Washington, DC, on December
18, 2000.

Rachel M. Samuel,

*Deputy Advisory Committee Management
Officer.*

[FR Doc. 00–32683 Filed 12–21–00; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

[Docket Nos. FE C&E 00–33, 00–34, 00–35,
00–36, 00–37, 00–38, 00–39, 00–40, 00–41
and 00–42; Certification Notice–194]

**Office of Fossil Energy; Notice of
Filings of Coal Capability of LSP-Pike
Energy, Covert Generating Company,
Sithe Mystic Development Company,
Sithe Fore River Development
Company, Cogentrix Lawrence County
Power, Caledonia Generating, Santa
Rosa Energy, Calpine Construction
Finance Co., GenPower Keo, and
Reliant Energy Hunterstown**

AGENCY: Office of Fossil Energy,
Department of Energy.

ACTION: Notice of filing.

SUMMARY: LSP-Pike Energy, LLC, Covert
Generating Company, LLC, Sithe Mystic
Development Company, LLC, Sithe Fore
River Development Company, LLC,
Cogentrix Lawrence County Power, LLC,
Caledonia Generating, LLC, Santa Rosa
Energy LLC, Calpine Construction
Finance Company, GenPower Keo, LLC
and Reliant Energy Hunterstown, LLC,
have submitted coal capability self-
certifications pursuant to section 201 of
the Powerplant and Industrial Fuel Use
Act of 1978, as amended.

ADDRESSES: Copies of self-certification
filings are available for public
inspection, upon request, in the Office
of Coal & Power Im/Ex (FE–27), Fossil
Energy, Room 4G–025, FE–27, Forrestal
Building, 1000 Independence Avenue,
SW., Washington, DC 20585.

FOR FURTHER INFORMATION CONTACT:
Ellen Russell (Program Office) 202–586–
9624.

SUPPLEMENTARY INFORMATION: Title II of
the Powerplant and Industrial Fuel Use
Act of 1978 (FUA), as amended (42
U.S.C. 8301 *et seq.*), provides that no
new baseload electric powerplant may
be constructed or operated without the
capability to use coal or another fuel as
a primary energy source. In order to
meet the requirement of coal capability,
the owner or operator of such facilities

proposing to use natural gas or petroleum as its primary energy source shall certify, pursuant to FUA section 201(d), to the Secretary of Energy prior to construction, or prior to operation as a baseload powerplant, that such powerplant has the capability to use coal or another alternate fuel. Such certification establishes compliance with section 201(a) as of the date filed with the Department of Energy. The Secretary is required to publish a notice in the **Federal Register** that a certification has been filed. The following owners/operators of the proposed new baseload powerplants have filed self-certifications in accordance with section 201(d).

Owner: LSP-Pike Energy, LLC (C&E 00-33).

Operator: LSP-Pike Energy, LLC.

Location: Summit, MS.

Plant Configuration: Combined cycle.

Capacity: 1,100 megawatts (MW).

Fuel: Natural gas.

Purchasing Entities: Wholesale power markets.

In-Service Date: Spring of 2003.

Owner: Covert Generating Company, LLC (C&E 00-34).

Operator: Covert Generating Company, LLC.

Location: Van Buren County, MI.

Plant Configuration: Combined cycle.

Capacity: 1,200 MW.

Fuel: Natural gas.

Purchasing Entities: Wholesale power markets.

In-Service Date: First or second quarter of 2003.

Owner: Sithe Mystic Development, LLC (C&E 00-35).

Operator: Sithe Boston Power Services, LLC.

Location: Everett, Massachusetts.

Plant Configuration: Combined cycle.

Capacity: 1,550 MW.

Fuel: Natural gas.

Purchasing Entities: Wholesale power markets.

In-Service Date: April 2002.

Owner: Sithe Fore River Development, LLC (C&E 00-36).

Operator: Sithe Boston Power Services, LLC.

Location: Weymouth, Massachusetts.

Plant Configuration: Combined cycle.

Capacity: 775 MW.

Fuel: Natural gas.

Purchasing Entities: Wholesale power markets.

In-Service Date: June 2002.

Owner: Cogentrix Lawrence County Power, LLC (C&E 00-37).

Operator: Cogentrix Energy, Inc.

Location: Lawrence County, IN.

Plant Configuration: Combined cycle.

Capacity: 820 MW.

Fuel: Natural gas.

Purchasing Entities: Power Marketer.

In-Service Date: June 1, 2003.

Owner: Caledonia Generating, LLC (C&E 00-38).

Operator: Cogentrix Energy, Inc.

Location: Caledonia, MS.

Plant Configuration: Combined cycle.

Capacity: 800 MW.

Fuel: Natural gas.

Purchasing Entities: Power Markets.

In-Service Date: June 1, 2003.

Owner: Santa Rosa Energy LLC (C&E 00-39).

Operator: Calpine Eastern Corporation.

Location: Pace, FL.

Plant Configuration: Combined cycle.

Capacity: 242 MW.

Fuel: Natural gas.

Purchasing Entities: Wholesale power markets.

In-Service Date: June 2002.

Owner: Calpine Construction Finance Company, L.P. (C&E 00-40).

Operator: Calpine Eastern Corporation.

Location: Reading, PA.

Plant Configuration: Combined cycle.

Capacity: 562.9 MW.

Fuel: Natural gas.

Purchasing Entities: Wholesale power markets.

In-Service Date: May 2002.

Owner: GenPower Keo, LLC (C&E 00-41).

Operator: General Electric International, Inc.

Location: Keo, AR.

Plant Configuration: Combined cycle.

Capacity: 640 MW.

Fuel: Natural gas.

Purchasing Entities: Wholesale power markets.

In-Service Date: May 2003.

Owner: Reliant Energy Hunterstown, LLC (C&E 00-42).

Operator: Reliant Energy Hunterstown, LLC.

Location: Adams County, PA.

Plant Configuration: Combined cycle.

Capacity: 800 MW.

Fuel: Natural gas.

Purchasing Entities: Regional power pool.

In-Service Date: June 1, 2003.

Issued in Washington, DC, on December 18, 2000.

Anthony J. Como,

Deputy Director, Electric Power Regulation, Office of Coal & Power Im/Ex, Office of Coal & Power Systems, Office of Fossil Energy.

[FR Doc. 00-32679 Filed 12-21-00; 8:45 am]

BILLING CODE 6450-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER01-677-000]

American Transmission Company LLC; Notice of Filing

December 18, 2000.

Take notice that on December 15, 2000, American Transmission Company LLC (ATCLLC) tendered for filing Open Access Transmission rates under Section 205.

ATCLLC request an effective date of January 1, 2001.

Any person desiring to be heard or to protest such filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). All such motions and protests should be filed on or before December 27, 2000. Protests will be considered by the Commission to determine the appropriate action to be taken, but will not serve to make protestants parties to the proceedings. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection. This filing may also be viewed on the Internet at <http://www.ferc.fed.us/online/rims.htm> (call 202-208-2222 for assistance). Comments and protests may be filed electronically via the internet in lieu of paper. See, 18 CFR 385.20012(a)(1)(iii) and the instructions on the Commission's web site at <http://www.ferc.fed.us/efi/doorbell.htm>.

David P. Boergers,

Secretary.

[FR Doc. 00-32700 Filed 12-21-00; 8:45 am]

BILLING CODE 6717-01-M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2069-003 Arizona]

Arizona Public Service Company; Errata Notice; Notice of Site Visit and Technical Conference

December 8, 18, 2000.

Anyone who wishes to attend the January 9, 2001, project site visit should contact Mr. Larry Johnson of Arizona Public Service Company at 480-350-3131 by 4:00 p.m. on Friday, January 5, 2001, rather than by 4:00 p.m. on

Monday, January 8, 2001, as stated in the above-referenced notice published in the **Federal Register** on December 14, 2000, at 65 FR 78152.

David P. Boergers,
Secretary.

[FR Doc. 00-32699 Filed 12-21-00; 8:45 am]

BILLING CODE 6717-01-M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP01-48-000]

Columbia Gas Transmission Corporation; Notice of Request Under Blanket Authorization

December 18, 2000.

Take notice that on December 7, 2000, Columbia Gas Transmission Corporation (Columbia), 12801 Fair Lakes Parkway, Fairfax, Virginia 22030-0146, filed a request with the Commission in Docket No. CP01-48-000, pursuant to Section 157.205 and 157.208 of the Commission's Regulations under the Natural Gas Act (NGA) for authorization to increase the maximum allowable operating pressure (MAOP) of a portion of its existing transmission pipeline designated as PM-3 located in Letcher County, Kentucky, authorized in blanket certificate issued in Docket No. CP83-76-000, all as more fully set forth in the request on file with the Commission and open to public inspection. This filing may be viewed on the web at <http://www.ferc.fed.us/online/rims.htm> (call 202-208-2222 for assistance).

Columbia proposes to increase the current MAOP of a portion of its Line PM-3 from 180 psig to a MAOP of 250 psig and to operate that portion of the pipeline at the higher pressure. The portion of the pipeline to be uprated consists of 12.7 miles beginning at a point near Measuring Station No. 16641 and ending at a point near Runners Branch. Columbia states the uprate is requested in order for Columbia to maximize operating efficiency of its facilities and to minimize the interruption of receipt of gas from local producers.

Any questions regarding the application may be directed to:

Victoria J. Hamilton, Certificates, Columbia Gas Transmission Corporation, 1700 MacCorkle Avenue, SE., Post Office Box 1273, Charleston, WV 25325-1273, (304) 357-2297, Telecopier: (304) 357-2926

Fredric J. George, Attorney, Columbia Gas Transmission Corporation, 1700 MacCorkle Avenue, SE., Post Office Box 1273, Charleston, WV 25325-1273 (304) 357-2359, Telecopier: (304) 357-3206

Sharon J. Royka, Regulatory Affairs Manager, Columbia Gas Transmission Corporation, 10 G Street, NE., Suite 580, Washington, DC 20002, (202) 216-9766, Telecopier: (202) 216-9785.

Any person or the Commission's staff may, within 45 days after the Commission has issued this notice, file pursuant to Rule 214 of the Commission's Procedural Rules (18 CFR 385.214) a motion to intervene or notice of intervention and pursuant to Section 157.205 of the Regulations under the NGA (18 CFR 157.205) a protest to the request. If no protest is filed within the allowed time, 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 NGA. Comments and protests may be filed electronically via the internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's web site at <http://www.ferc.fed.us/efi/doorbell.htm>.

David P. Boergers,
Secretary.

[FR Doc. 00-32688 Filed 12-21-00; 8:45 am]

BILLING CODE 6717-01-M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket Nos. RP00-604-002; RP00-605-001]

Columbia Gas Transmission Corporation; Columbia Gulf Transmission Company; Notice of Compliance Filing

December 18, 2000.

Take notice that on November 27, 2000, Columbia Gas Transmission Corporation (Columbia Gas) and Columbia Gulf Transmission Company (Columbia Gulf) tendered its compliance filing with the Commission's Order on Filings to Establish Imbalance Netting and Trading Pursuant to Order Nos. 587-G and 587-L [93 FERC ¶ 61,093 (2000)] issued on October 27, 2000 (October 27 Order).

Columbia Gas and Columbia Gulf states that the purpose of this filing is to comply with the requirements of the October 27 Order.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C.

20426, in accordance with Section 385.211 of the Commission's Rules and Regulations. All such protests must be filed on or before December 26, 2000. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceedings. Copies of this filing are on file with the Commission and are available for public inspection in the Public Reference Room. This filing may be viewed on the web at <http://www.ferc.fed.us/online/rims.htm> (call 202-208-2222 for assistance). Comments and protests may be filed electronically via the internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's web site at <http://www.ferc.fed.us/efi/doorbell.htm>.

David P. Boergers,
Secretary.

[FR Doc. 00-32690 Filed 12-21-00; 8:45 am]

BILLING CODE 6717-01-M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP01-185-000]

Eastern Shore Natural Gas Company; Notice of Proposed Changes in FERC Gas Tariff

December 18, 2000.

Take notice that on December 11, 2000, Eastern Shore Natural Gas Company (ESNG) tendered for filing as part of its FERC Gas Tariff, Second Revised Volume No. 1, certain revised tariff sheets in the above captioned docket, bear a proposed effective date of January 1, 2001.

ESNG states that the purpose of this instant filing is to track rate changes attributable to storage services purchased from Columbia Gas Transmission Corporation (Columbia) under its Rate Schedule CFSS. The costs of the above referenced storage services comprise the rates and charges payable under ESNG's Rate Schedule CFSS. This tracking filing is being made pursuant to Section 3 of ESNG's Rate Schedule CFSS.

ESNG states that copies of the filing have been served upon its jurisdictional customers and interested State Commissions.

Any person desiring to be heard or to protest said filing should file a motion to intervene or a protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Sections

385.214 or 385.211 of the Commission's Rules and Regulations. All such motions or protests must be filed in accordance with Section 154.210 of the Commission's Regulations. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceedings. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection in the Public Reference Room. This filing may be viewed on the web at <http://www.ferc.fed.us/online/rims.htm> (call 202-208-222 for assistance). Comments and protests may be filed electronically via the internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's web site at <http://www.ferc.fed.us/efi/doorbell.htm>.

David P. Boergers,

Secretary.

[FR Doc. 00-32692 Filed 12-21-00; 8:45 am]

BILLING CODE 6717-01-M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP01-12-000]

El Paso Natural Gas Company; Notice of Site Visit

December 18, 2000.

On January 4, 2001, the staff of the Office of Energy Projects (OEP) will conduct a site visit of El Paso Natural Gas Company's (El Paso's) proposed Line No. 2039 Pipeline Relocation Project in Maricopa County, Arizona. The site visit will start at 9:00 am at Eures Dining located at the intersection of South 43th Avenue and West Buckeye Road. Representatives of El Paso will accompany the staff.

All interested parties may attend, although those planning to attend must provide their own transportation.

For further, information, please contact the Commission's Office of External Affairs at (202) 208-1088.

David P. Boergers,

Secretary.

[FR Doc. 00-32698 Filed 12-21-00; 8:45 am]

BILLING CODE 6717-01-M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP99-474-002]

Natural Gas Pipeline Company of America; Notice of Compliance Filing

December 18, 2000.

Take notice that on September 29, 2000, Natural Gas Pipeline Company of America (Natural) tendered its compliance filing with the Commission's Order on Accepting Tariff Sheets Subject to Conditions in Docket No. RP99-474-000] [88 FERC ¶ 61,312 (1999)] issued on September 30, 1999 (September 30 Order).

Natural states that the purpose of this filing is to comply with one of the requirements of the September 30 Order, which required Natural to file a report detailing the discounts its shippers received for Balancing Service Charged and whether those shippers were affiliated with Natural.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426 in accordance with Section 385.211 of the Commission's Rules and Regulations. All such protests must be filed on or before December 26, 2000. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceedings. Copies of this filing are on file with the Commission and are available for public inspection in the Public Reference Room. This filing may be viewed on the web at <http://www.ferc.fed.us/online/rims.htm> (call 202-208-2222 for assistance). Comments and protests may be filed electronically via the internet in lieu of paper. See, 8 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's web site at <http://www.ferc.fed.us/efi/doorbell.htm>.

David P. Boergers,

Secretary.

[FR Doc. 00-32695 Filed 12-21-00; 8:45 am]

BILLING CODE 6717-01-M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EC01-44-000]

The New Power Company; Notice of Filing

December 18, 2000.

Take notice that on December 12, 2000, The New Power Company (New Power), on behalf of itself and its parent companies, TNPC Holdings, Inc. (TNPC Holdings) and TNPC, Inc. (TNPC), filed an application pursuant to Section 203 of the Federal Power Act requesting all necessary authorizations for a name change of its parent TNPC, which name change will be accomplished by means of a short-form merger of TNPC with a newly-created wholly-owned subsidiary, New Power Holdings, Inc.

Any person desiring to be heard or to protest such filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). All such motions and protests should be filed on or before January 2, 2000. Protests will be considered by the Commission to determine the appropriate action to be taken, but will not serve to make protestants parties to the proceedings. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection. This filing may also be viewed on the Internet at <http://www.ferc.fed.us/online/rims.htm> (call 202-208-2222 for assistance). Comments and protests may be filed electronically via the internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's web site at <http://www.ferc.fed.us/efi/doorbell.htm>.

David P. Boergers,

Secretary.

[FR Doc. 00-32701 Filed 12-21-00; 8:45 am]

BILLING CODE 6717-01-M

DEPARTMENT OF ENERGY**Federal Energy Regulatory Commission****[Docket No. RP01-189-000]****Northern Nevada Industrial Gas Users, Complainants, v. Northwest Pipeline Corporation Respondent; Notice of Filing**

December 15, 2000.

Take notice that on December 15, 2000, Eagle-Pilcher Minerals, Inc., Harrah's Reno Casino, Nevada Cement Company, Newmont Mining Corporation, Premier Chemicals, RR Donnelly & Sons Company, Sparks Nugget, Inc. and Winnemucca Farms, Inc. (jointly "Northern Nevada Industrial Users" or "NNIGU shippers") filed a complaint under Section 5 of the Natural Gas Act requesting that Northwest Pipeline Corporation ("Northwest") be directed to cease and desist violating the procedures for Must-Flow Operational Flow Orders set forth in section 14.15 of its FERC Gas Tariff.

NNIGU shippers allege that Northwest has violated section 14.15 by directing them to flow volumes southward on its system to create capacity by displacement for northward service on behalf of other shippers, notwithstanding the extremely high costs to NNIGU shippers under current market conditions of doing so. By denying their requests for exemption from the Must-Flow orders, Northwest has, they allege, ignored the Commission's rejection of the view that, to comply with section 14.15, shippers may be required to acquire "gas at any price." NNIGU shippers request disposition of this issue on a "Fast Track" basis under 18 CFR 385.206(h).

NNIGU shippers also allege that section 14.15 is unjust, unreasonable, and unduly discriminatory to the extent that it requires certain shippers to flow gas to create capacity for other shippers. They request amendment of section 14.15 accordingly. NNIGU shippers further request that Northwest be directed to compensate them for losses they have incurred as a result of its tariff violations.

Any person desiring to be heard or to protest this filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). All such motions or protests must be filed on or before December 27, 2000. 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. This filing may also be viewed on the Internet at <http://www.ferc.fed.us/online/rims.htm> (call 202-208-2222) for assistance. Answers to the complaint shall also be due on or before December 27, 2000. Comments and protests may be filed electronically via the internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's web site at <http://www.ferc.fed.us/efi/doorbell.htm>.

David P. Boergers,
Secretary.

[FR Doc. 00-32647 Filed 12-21-00; 8:45 am]

BILLING CODE 6717-01-M**DEPARTMENT OF ENERGY****Federal Energy Regulatory Commission****[Docket No. CP01-49-000]****Northwest Pipeline Corporation; Notice of Application**

December 18, 2000.

Take notice that on December 8, 2000, Northwest Pipeline Corporation (Northwest), 295 Chipeta Way, Salt Lake City, Utah, 84158, filed in Docket No. CP01-49-000, an application, pursuant to Section 7(c) of the Natural Gas Act and Part 157 of the Federal Energy Regulatory Commission's Regulations for a certificate of public convenience and necessity authorizing Northwest to construct and operate certain facilities in Snohomish County, Washington, all as more fully set forth in the application which is on file with the Commission and open to public inspection. This filing may be viewed on the web at <http://www.ferc.fed.us/online/rims.htm>. (Call 202-108-2222 for assistance.)

Specifically, Northwest proposes to construct and operate: (1) approximately 9 miles of 20-inch diameter delivery lateral pipeline in Snohomish County (Everett Delta Lateral), extending from an interconnect with Northwest's existing mainline and mainline loop north of the City of Lake Stevens to the proposed Northwest Power Company, LLC (NPC) power plant near Everett, Washington; and (2) two delivery meter stations at the terminus of the lateral, the Everett Delta Meter Station for deliveries to NPC and the Preston Point Meter Station for deliveries to the

distribution system of Puget Sound Energy, Inc. (PSE).

Northwest states that the Everett Delta Lateral will have a design capacity of approximately 133,000 Dth per day. Further, Northwest avers that the proposed facilities will be used to deliver natural gas to NPC to fuel its planned Everett Delta Power Plant and to PSE to accommodate increased demand for natural gas in its local distribution area.

Northwest estimates the cost of the proposed facilities at approximately \$17.2 million and states that all costs will be reimbursed by NPC and PSE pursuant to the delivery facilities reimbursement provisions of Northwest's FERC Gas Tariff. Northwest requests that the FERC issue a preliminary determination on non-environmental aspects of its requested authorizations by June 30, 2001 and issue a final certificate order herein no later than the end of year 2001, to allow adequate time for construction of the proposed delivery facilities before August 15, 2002, the date NPC estimates it will require test gas for its new power generating plant.

Any questions regarding this application should be directed to Gary Kotter, Manager, Certificates, at (801) 584-7117, Northwest Pipeline Corporation, P.O. Box 58900, Salt Lake City, Utah 84158.

There are two ways to become involved in the Commission's review of this project. First, any person wishing to obtain legal status by becoming a party of the proceedings for this project should, on or before January 8, 2001, file with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, a motion to intervene in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214) and the regulations under the Natural Gas Act (18 CFR 157.10). A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies of all documents filed by the applicant and by all other parties. A party must submit 14 copies of filings made with the Commission and must mail a copy to the applicant and to every other party in the proceeding. Only parties to the proceeding can ask for court review of Commission orders in the proceeding.

Persons who wish to comment only on the environmental review of this project should submit an original and two copies of their comments to the Secretary of the Commission. Environmental comments will be placed

on the Commission's environmental mailing list, will receive copies of environmental documents, and will be able to participate in meetings associated with the Commission's environmental review process. Comments will not be required to serve copies of filed documents on all other parties. However, Commenters will not receive copies of all documents filed by other parties or issued by the Commission, and will not have the right to seek rehearing or appeal the Commission's final order to a Federal court.

The Commission may issue a preliminary determination on non-environmental issues prior to the completion of its review of the environmental aspects of the project. This preliminary determination typically considers such issues as the need for the project and its economic effect on existing customers of the applicant, on other pipelines in the area, and on landowners and communities. For example, the Commission considers the extent to which the applicant may need to exercise eminent domain to obtain rights-of-way for the proposed project and balances that against the non-environmental benefits to be provided by the project. Therefore, if a person has comments on community and landowner impacts from this proposal, it is important to file comments or to intervene as early in the proceedings as possible.

Comments and protests may be filed electronically via the internet in lieu of paper. See 18 CFR 385.2001(a)(1)(iii) and the Commission's website at <http://www.ferc.fed.us/efi/doorbell.htm>.

If the Commission decides to set the application for a formal hearing before an Administrative Law Judge, the Commission will issue another notice describing that process. At the end of the Commission's review process, a final Commission order approving or denying a certificate will be used.

David P. Boergers,

Secretary.

[FR Doc. 00-32687 Filed 12-21-00; 8:45 am]

BILLING CODE 6717-01-M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP01-33-002]

Questar Pipeline Company; Notice of Compliance Filing

December 18, 2000.

Take notice that on December 7, 2000, pursuant to 18 CFR 154.7, Questar Pipeline Company (Questar) tendered its answer to protest.

Questar states that the purpose of this filing is to comply with Ordering Paragraph (C) of the Commission's Order on Filings to Establish Imbalance Netting and Trading Pursuant to Order Nos. 587-G and 587-L issued November 9, 2000, in Docket Nos. RM96-1-014, *et al.*, which directed Questar to file an answer to the joint protest of the protestors in Docket No. RP01-33-000.

Questar states that a copy of this answer has been served upon each person designated of the official service list compiled by the Secretary in this proceeding.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Section 385.211 of the Commission's Rules and Regulations. All such protests must be filed on or before December 26, 2000. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceedings. Copies of this filing are on file with the Commission and are available for public inspection in the Public Reference Room. This filing may be viewed on the web at <http://www.ferc.fed.us/online/rims.htm> (call 202-208-2222 for assistance). Comments and protests may be filed electronically via the internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's web site at <http://www.ferc.fed.us/efi/doorbell.htm>.

David P. Boergers,

Secretary.

[FR Doc. 00-32691 Filed 12-21-00; 8:45 am]

BILLING CODE 6717-01-M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP01-12-001]

Reliant Energy Gas Transmission Company; Notice of Compliance Filing

December 18, 2000.

Take notice that on November 27, 2000, Reliant Energy Gas Transmission Company (Reliant) tendered its compliance filing with the Commission's Order on Filings to Establish Imbalance Netting and Trading Pursuant to Order Nos. 587-G and 587-L [93 F.E.R.C. ¶ 61,093 (2000)] issued on October 27, 2000 (October 27 Order).

Reliant states that the purpose of this filing is to comply with the requirements of the October 27 Order.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Section 385.211 of the Commission's Rules and Regulations. All such protests must be filed on or before December 26, 2000. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceedings. Copies of this filing are on file with the Commission and are available for public inspection in the Public Reference Room. This filing may be viewed on the web at <http://www.ferc.fed.us/online/rims.htm> (call 202-208-2222 for assistance). Comments and protests may be filed electronically via the internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's web site at <http://www.ferc.fed.us/efi/doorbell.htm>.

David P. Boergers,

Secretary.

[FR Doc. 00-32694 Filed 12-21-00; 8:45 am]

BILLING CODE 6717-01-M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP01-55-001]

WestGas InterState, Inc.; Notice of Compliance Filing

December 18, 2000.

Take notice that on December 11, 2000, WestGas InterState, Inc. (WGI) tendered for filing as part of its FERC Gas Tariff, First Revised Volume No. 1,

the following tariff sheets, with an effective date of November 1, 2000:

Second Revised Sheet No. 47

Original Sheet No. 47A

Original Sheet No. 47B

WGI states that the purpose of the filing to provide for netting and trading of imbalances, in compliance with the Commission's "Order on Filings to Establish Imbalance Netting and Trading Pursuant to Order Nos. 587-G and 587-L," issued in Docket Nos. RM96-1-014, *et al.*, on November 9, 2000. *Standard for Business Practices of Interstate Natural Gas Pipelines*, 93 FERC ¶61,150 (2000).

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Section 385.211 of the Commission's Rules and Regulations. All such protests must be filed on or before December 26, 2000. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceedings. Copies of this filing are on file with the Commission and are available for public inspection in the Public Reference Room. This filing may be viewed on the web at <http://www.ferc.fed.us/online/rims.htm> (call 202-208-2222 for assistance). Comments and protests may be filed electronically via the internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's web site at <http://www.ferc.fed.us/efi/doorbell.htm>.

David P. Boergers,

Secretary.

[FR Doc. 00-32693 Filed 12-21-00; 8:45 am]

BILLING CODE 6717-01-M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP00-394-001]

Williams Gas Pipelines Central, Inc.; Notice of Petition To Amend

December 18, 2000.

Take notice that on December 11, 2000, Williams Gas Pipelines Central, Inc. (Williams), P.O. Box 20008, Owensboro, Kentucky 42304, filed in Docket No. CP00-394-001 a petition pursuant to Section 7(b) of the Natural Gas Act to amend its application filed June 21, 2000, for permission and approval to abandon certain pipeline facilities located in Kansas, all as more fully set forth in the application on file

with the Commission and open to public inspection. This filing may be viewed on the web at <http://www.ferc.fed.us/online/htm> (call 202-208-2222 for assistance).

In Docket No. CP00-394-000 Williams proposed to abandon approximately 64.3 miles of the Pampa 20-inch pipeline (Line G) and appurtenant facilities located in Butler, Chase and Lyon Counties, Kansas. Williams proposed to abandon the facilities by sale for subsequent reclaim for salvage and abandonment in place. It was explained that the proposed abandonment is part of Williams' ongoing effort to eliminate old, high maintenance pipelines.

In Docket No. CP00-394-001 Williams proposes to modify its original proposal by increasing the length of pipeline to be abandoned in place to 50.2 miles and to decrease the length of pipeline to be abandoned by sale for reclaim to 14.1 miles. Williams states that of the 14.1 miles to be removed, it still plans to abandon in place segments of the pipeline located under roads and where it traverses other sensitive environmental areas such as streams and wetlands, and to abandon by removal all above-ground facilities, such as pig traps, value, etc.

It is explained that the total length of the Pampa Line to be abandoned would remain the same 64.3 miles as proposed in the original application. William states that the reason for the change is that following receipt of landowner comments and further evaluation of environmental and land use impacts, it has determined that the proposed modification would minimize these impacts while accommodating landowner preferences. Williams estimates the costs associated with the abandonment at \$173,000 and estimates the sale price of the segment to be reclaimed at \$256,781. Williams proposes to commence the abandonment on April 1, 2001 and estimates completion by June 30, 2001.

Any questions regarding the application should be directed to David N. Roberts, Manager, Tariffs & Regulatory Analysis, at (270) 688-6712, P.O. Box 20008, Owensboro, Kentucky 42304.

Any person desiring to be heard or to make any protests with reference to said application should on or before January 8, 2001, file with the Federal Energy Regulatory Commission, 888 First 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 385.214 or 385.211) 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. Comments and protests may be filed electronically in lieu of paper. See 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's website at <http://ferc.fed.us/efi/doorbell.htm>.

Take further notice that, pursuant to the authority contained in and subject to the 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 application 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 Williams to appear or be represented at the hearing.

David P. Boergers,

Secretary.

[FR Doc. 00-32689 Filed 12-21-00; 8:45 am]

BILLING CODE 6717-01-M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP01-47-000]

Williston Basin Interstate Pipeline Company; Notice of Application

December 18, 2000.

Take notice that on December 7, 2000, Williston Basin Interstate Pipeline Company (Williston Basin), 1250 West Century Avenue, Bismarck, North Dakota 58503, filed in Docket No. CP01-47-000 an application pursuant to Section 7(c) of the Natural Gas Act (NGA) requesting a certificate of public convenience and necessity authorizing Williston Basin to install additional facilities at an existing compressor station located in Fallon County,

Montana, all as more fully set forth in the application on file with the Commission and open to public inspection.¹ This filing may be viewed on the web at <http://www.ferc.fed.us/online/htm> (call 202-208-2222 for assistance).

Williston Basin proposes to construct and operate approximately 300 feet of 12-inch piping and 3 12-inch valves adjacent to its existing Little Beaver Compressor Station in Fallon County, Montana. Williston Basin explains that the reason for the proposed construction of facilities is to increase the operational flexibility of the compressor station. It is asserted that the existing horsepower at the compressor station will not change.

It is further asserted that the proposal is intended to allow Williston Basin to compress increased production of gas from south of the compressor station and transport the gas to storage fields or to markets located north of the compressor station. It is stated that the proposal will also provide additional system security by decreasing Williston Basin's reliance on other compression facilities during critical flow periods and during planned and unplanned maintenance. Williston Basin estimates the cost of installing the proposed piping and valves at \$77,000. It is asserted that the proposal will have system benefits for Williston Basin and will have no detrimental effect on its existing customers.

Any questions regarding the application should be directed to Keith A. Tiggelaar, Manager-Regulatory Affairs, at Williston Basin Interstate Pipeline Company, P.O. Box 5601, Bismarck, North Dakota 58506-5601, or by telephone at (701) 530-1561.

Any person desiring to be heard or to make any protest with reference to said application should on or before December 28, 2000, file with the Federal Energy Regulatory Commission, 888 First 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 385.214 or 385.211) 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. Comments and protests may be filed electronically in lieu of paper. See 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's website at <http://ferc.fed.us/efi/doorbell.htm>.

Take further notice that, pursuant to the authority contained in and subject to the jurisdiction conferred upon the Federal Energy Regulatory Commission by Sections 7 and 15 of the NGA 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 application 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 Williston Basin to appear or be represented at the hearing.

David P. Boergers,

Secretary.

[FR Doc. 00-32686 Filed 12-21-00; 8:45 am]

BILLING CODE 6717-01-M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Application for Transfer of License and Soliciting Comments, Motions to Intervene, and Protests

December 18, 2000.

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

- a. *Application Type:* Transfer of License
- b. *Project No.:* 2487-010
- c. *Date Filed:* December 11, 2000
- d. *Applicants:* John M. Skorupski and Hydro Power, Inc.
- e. *Name of Project:* Hoosick Falls
- f. *Location:* The project is located on Hoosick River in Rensselaer County, New York. The project does not occupy federal or tribal lands.
- g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. §§ 791(a)-825(r)
- h. *Applicant Contact:* Paul V. Nolan, Esquire, 5515 North 17th Street, Arlington, Virginia 22205, Phone: (703) 534-5509; Fax: (703) 538-5257, E-Mail: PVNPVN@AOL.COM

i. *FERC Contact:* Any questions on this notice should be addressed to Tom Papsidero at (202) 219-2715.

j. *Deadline for filing comments and or motions:* January 19, 2001.

All documents (original and eight copies) should be filed with: David P. Boergers, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

Please include the Project Number (2487-010) on any comments or motions filed.

k. *Description of Transfer:* John M. Skorupski (transferor), licensee of the Hoosick Falls Project, and Hydro Power, Inc. (transferee) jointly and severally apply for approval of the transfer of the project license to the transferee. The applicants state that the purpose of the transfer is to complete the transferor's withdrawal from the business of owning and operating hydroelectric projects. Further, the applicants maintain that the transfer will ensure that an entity with sufficient experience will be responsible for the continued operation of the project.

l. *Locations of the Application:* A copy of the application is available for inspection and reproduction at the Commission's Public Reference Room, located at 888 First Street, NE, Room 2A, Washington, DC 20426, or by calling (202) 208-1371. The application may be viewed on the web at www.ferc.fed.us/online/rims.htm. Call (202) 208-2222 for assistance. A copy is also available for inspection and reproduction at the address in item h above.

m. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

Comments, Protests, or Motions to Intervene—Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

Filing and Service of Responsive Documents—Any filing must bear in all capital letters the title "COMMENTS", "RECOMMENDATIONS FOR TERMS AND CONDITIONS", "PROTEST", OR "MOTION TO INTERVENE", as applicable, and the Project Number of the particular application to which the

¹ William Basin initially filed the application as a request under the prior notice procedure but asked that the request be treated as a Section 7(c) application in a supplement filed December 15, 2000.

filing refers. Any of the above-named documents must be filed by providing the original and the number of copies provided by the Commission's regulations to: The Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426. A copy of any motion to intervene must also be served upon each representative of the Applicant specified in the particular application.

Comments and protests may be filed electronically via the internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's web site at <http://www.ferc.fed.us/efi/doorbell.htm>.

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.

David P. Boergers,
Secretary.

[FR Doc. 00-32696 Filed 12-21-00; 8:45 am]

BILLING CODE 6717-01-M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Transfer of License and Soliciting Comments, Motions To Intervene, and Protests

December 18, 2000.

Take notice that the following application has been filed with the Commission and is available for public inspection:

a. *Application Type:* Transfer of License.

b. *Project No:* 8118-022.

c. *Date Filed:* November 27, 2000.

d. *Applicants:* Estate of Jerry B. Buckley, Ms. Brooke Buckley, Executrix, and Lake George Hydro, LLC.

e. *Name and Location of Project:* The Jerry B. Buckley Hydroelectric Project utilizes the Town of Georgetown, Colorado's Georgetown Dam and reservoir on Clear Creek in Clear Creek County, Colorado. The project does not occupy Federal or Tribal land.

f. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791(a)-825(r).

g. *Applicant Contact:* Mr. Nicholas G. Muller, 475 17th Street, Suite 940, Denver, CO 80202, (303) 297-1970.

h. *FERC Contact:* Any questions on this notice should be addressed to James Hunter at (202) 219-2839.

i. *Deadline for filing comments and or motions:* January 19, 2001.

All documents (original and eight copies) should be filed with: David P. Boergers, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE, Washington, DC 20426. Comments and protests may be filed electronically via the internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's web site at <http://www.ferc.fed.us/efi/doorbell.htm>.

Please include the project number (P-8118-022) on any comments or motions filed.

j. *Description of Proposal:* The applicants propose a transfer of the license for Project No. 8118 from Jerry B. Buckley, by and through Ms. Brooke Buckley, Executrix, to Lake George Hydro, LLC. Transfer is being sought in connection with the proposed sale of the project.

k. *Locations of the application:* A copy of the application is available for inspection and reproduction at the Commission's Public Reference Room, located at 888 First Street, NE, Room 2A, Washington, DC 20426, or by calling (202) 208-1371. The application may be viewed on the web at www.ferc.fed.us/online/rims.htm (Call (202) 208-2222 for assistance). A copy is also available for inspection and reproduction at the address in item g above.

l. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

Comments, Protests, or Motions to Intervene—Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

Filing and Service of Responsive Documents—Any filings must bear in all capital letters the title "COMMENTS", "RECOMMENDATIONS FOR TERMS AND CONDITIONS", "PROTEST", OR "MOTION TO INTERVENE", as applicable, and the Project Number of the particular application to which the

filing refers. Any of the above-named documents must be filed by providing the original and the number of copies provided by the Commission's regulations to: The Secretary, Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, DC 20426. A copy of any motion to intervene must also be served upon each representative of the Applicant specified in the particular application.

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.

David P. Boergers,
Secretary.

[FR Doc. 00-32697 Filed 12-21-00; 8:45 am]

BILLING CODE 6717-01-M

ENVIRONMENTAL PROTECTION AGENCY

[FRL-6921-7]

Agency Information Collection Activities: Proposed Collection; Comment Request; See List of ICRs Planned To Be Submitted in Section A

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), this document announces that EPA is planning to submit the following two continuing Information Collection Requests (ICR) to the Office of Management and Budget (OMB). Before submitting the ICRs to OMB for review and approval, EPA is soliciting comments on specific aspects of the information collections as described at the beginning of Supplementary Information.

DATES: Comments must be submitted on or before February 20, 2001.

ADDRESSES: U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, NW., Mail Code 2223A, Washington, DC 20460. A hard copy of an ICR may be obtained without charge by calling the identified information contact individual for each ICR in Section B of the Supplementary Information.

FOR FURTHER INFORMATION CONTACT: For specific information on the individual

ICRs see Section B of the Supplementary Information.

SUPPLEMENTARY INFORMATION:

For All ICRs

An Agency may not conduct or sponsor, and a person is not required to respond to, a collection information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations are displayed in 40 CFR part 9.

The EPA would like to solicit comments to:

(i) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility;

(ii) Evaluate the accuracy of the Agency's estimate of the burden of the proposed collection of information;

(iii) Enhance the quality, utility, and clarity of the information to be collected; and

(iv) Minimize the burden of the collection of information on those who are to respond, including through the use of automated collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

A. List of ICRs Planned To Be Submitted

In compliance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), this notice announces that EPA is planning to submit the following two continuing Information Collection Requests (ICR) to the Office of Management and Budget (OMB):

(1) NSPS Subpart Ka—Standards of Performance for Storage Vessels for Petroleum Liquids for Which Construction, Reconstruction, or Modification Commenced After May 18, 1978 and Prior to July 23, 1984, EPA ICR Number 1050.07 and OMB Control

Number 2060-0121 expiring on June 30, 2001.

(2) NSPS Subpart Kb—Standards of Performance for Volatile Organic Liquid Storage Vessels (Including Petroleum Liquid Storage Vessels) for Which Construction, Reconstruction, or Modification Commenced After July 23, 1984, EPA ICR 1132.05, and OMB Control Number 2060-0074 expiring on February 28, 2001.

B. Contact Individuals for ICRs

(1) NSPS Subpart Ka—Standards of Performance for Storage Vessels for Petroleum Liquids for Which Construction, Reconstruction, or Modification Commenced After May 18, 1978 and Prior to July 23, 1984, Everett Bishop, tele: 202-564-7032; fax: 202-564-0050 or email: bishop.everett@epa.gov. EPA ICR Number 1050.07 and OMB Control Number 2060-0121 expiring on June 30, 2001;

(2) NSPS Subpart Kb—Standards of Performance for Volatile Organic Liquid Storage Vessels (Including Petroleum Liquid Storage Vessels) for Which Construction, Reconstruction, or Modification Commenced After July 23, 1984. Everett Bishop, tele: 202-564-7032; fax: 202-564-0050 or email: bishop.everett@epa.gov. EPA ICR 1132.05, and OMB Control Number 2060-0074 expiring on February 28, 2001

C. Individual ICRs

(1) NSPS Subpart Ka—Standards of Performance for Storage Vessels for Petroleum Liquids for Which Construction, Reconstruction, or Modification Commenced After May 18, 1978 and Prior to July 23, 1984, Everett Bishop, tele: 202-564-7032; fax: 202-564-0050 or email: bishop.everett@epa.gov. EPA ICR Number 1050.07 and OMB Control Number 2060-0121 expiring on June 30, 2001

Affected Entities: Entities potentially affected by this action are storage vessels of petroleum liquids which have a storage capacity greater than 151,416 liters (40,000 gallons) and for which construction is commenced after May 18, 1978.

Abstract: Volatile Organic Compounds (VOCs) from storage vessels cause or contribute to air pollution that may reasonably be anticipated to endanger public health. VOC emissions are the result of evaporation of volatile organic liquids contained in the storage vessels. The control of VOCs requires not only the installation of properly designed equipment, but also the maintenance and operation of that

equipment. Information generated by the recordkeeping and reporting requirements is used by the Agency to ensure that facilities affected by this NSPS continue to operate the control equipment properly, thereby minimizing VOCs emissions into the atmosphere. Collection of this information is authorized at 40 CFR § 60.7 and § 60.110a. Any information submitted to the Agency, for which a claim of confidentiality is made, will be safeguarded according to the Agency policies set forth in Title 40, Chapter 1, Part 2, Subpart B—Confidentiality of Business Information (see 40 CFR 2: 41 FR 36902, September 1, 1976; amended by 43 FR 40000, September 8, 1978; 43 FR 42251, September 20, 1978; 44 FR 17674, March 23, 1979). An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations are listed in 40 CFR part 9 and 48 CFR Chapter 15.

Burden Statement: The projected burden cost to each owner and operator is approximately \$3,600 and 125 hours/year. The burden hours are identified as: 100 hours for secondary seal gap measurement, 20 hours for primary seal gap measurement and 5 hours for recording fill/refill information. It is estimated this information collection, recordkeeping and recording will affect approximately 183 owners and operators of petroleum storage vessels. Since there are no new facilities proposed under this NSPS, there is no capital or start-up cost component.

(2) NSPS Subpart Kb—Standards of Performance for Volatile Organic Liquid Storage Vessels (Including Petroleum Liquid Storage Vessels) for Which Construction, Reconstruction, or Modification Commenced After July 23, 1984. Everett Bishop, tele: 202-564-7032; fax: 202-564-0050 or email: bishop.everett@epa.gov. EPA ICR 1132.05, and OMB Control Number 2060-0074 expiring on February 28, 2001.

Affected entities: Entities potentially affected by this action are storage vessels with a capacity greater than or equal to 40 cubic meters that store volatile organic liquids (VOL's) for which construction, reconstruction, or modification is commenced after July 23, 1984.

Abstract: The notification of construction, reconstruction or modification indicates when a storage vessel becomes subject to the standards. The information generated by the inspecting, recordkeeping and reporting requirements is used by the Agency to

ensure that the storage vessel affected by the NSPS continues to operate the control equipment in a manner that helps achieve compliance with the NSPS.

Information is recorded in sufficient detail to enable owners or operators to demonstrate the means of complying with the applicable standards. Under this standard, the data collected by the affected owner/operator is retained at the facility for a minimum of two years and made available to the Administrator either on request or by inspection.

The information generated by the recordkeeping and reporting requirements are used by the Agency to ensure that facilities affected by the NSPS continue to operate in compliance with the NSPS.

The information collected from the recordkeeping and reporting requirements is also used for targeting inspections, and is of sufficient quality to be used as evidence in court. Collection of this information is authorized at 40 CFR 60.7 and 60.110b. Any information submitted to the Agency, for which a claim of confidentiality is made, will be safeguarded according to the Agency policies set forth in Title 40, Chapter 1, Part 2, Subpart B—Confidentiality of Business Information (see 40 CFR § 2: 41 FR 36902, September 1, 1976; amended by 43 FR 40000, September 8, 1978; 43 FR 42251, September 20, 1978; 44 FR 17674, March 23, 1979). An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations are listed in 40 CFR part 9 and 48 CFR Chapter 15.

Burden: For each respondent, it is estimated 139 hours are devoted to recording information and inspecting storage vessels subject to this NSPS. The frequency of reporting is approximately twice a year. The estimated number of respondents is 900. The estimated yearly cost per respondent for operations and maintenance is \$4,907. The average initial capital cost is \$20,000 for emission control devices, *i.e.*, internal or external floating roof or closed vent system.

Dated: December 13, 2000.

Michael Stahl,

Acting Director, Office of Compliance, Office of Enforcement and Compliance Assurance.
[FR Doc. 00-32669 Filed 12-21-00; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[ER-FRL-6613-8]

Environmental Impact Statements; Notice of Availability

Responsible Agency: Office of Federal Activities, General Information (202) 564-7167 or www.epa.gov/oeca/ofa. Weekly receipt of Environmental Impact Statements Filed December 11, 2000 Through December 15, 2000 Pursuant to 40 CFR 1506.9.

EIS No. 000447, DRAFT EIS, HUD, NY, City of Yonkers, Construction of a 524 Units of Mixed-Income Housing at 1105-1135 Warburton Avenue, River Club Apartment Complex, Westchester County, NY, Due: February 05, 2001, Contact: Lee Ellman (914) 377-6557.

EIS No. 000448, DRAFT EIS, HUD, CA, North Hollywood Arts and Entertainment District Project, Construction and Operation, North Hollywood Redevelopment Project, City of Los Angeles, CA, Due: February 05, 2001, Contact: Tony Kochinas (213) 847-4307.

EIS No. 000449, FINAL EIS, COE, NC, Randleman Lake and Dam Project, Construction, Piedmont Triad Regional Water Authority (PTRWA), Deep River, Guilford and Randolph Counties, NC, Due: January 22, 2001, Contact: John C. Meshaw (910) 251-4175.

EIS No. 000450, FINAL EIS, AFS, TX, Texas Blowdown Reforestation Project, Implementation, National Forests and Grasslands in Texas, Angeline and Sabine National Forests, San Augustine and Shelby Counties, TX, Due: January 22, 2001, Contact: Keith Baker (936) 344-6205.

EIS No. 000451, DRAFT EIS, DOE, TN, Programmatic EIS—Oak Ridge Y-12 Plant Mission, Processing and Storage Highly Enriched Uranium, U.S. Nuclear Weapons Stockpile, Anderson County, TN, Due: February 05, 2001, Contact: Gary S. Hartman (865) 576-0273.

EIS No. 000452, DRAFT EIS, AFS, SD, Jasper Fires Value Recovery Area Project, Implementation, Revised Forest Plan for the Black Hills National Forest, Hell Canyon and Mystic Ranger District, Custer and Pennington Counties, SD, Due: February 05, 2001, Contact: Alice Allen (605) 673-4853.

EIS No. 000453, FINAL EIS, AFS, PA, East Side Project, Improvements to Timber Management, Transportation System Development and Wildlife Habitat, From Existing Condition (EC)

to Desired Future Condition (DFC), Allegheny National Forest, Bradford and Marienville District, Elk, Forest, McKean and Warren Counties, PA, Due: January 22, 2001, Contact: Carl Leland (814) 776-6172.

EIS No. 000454, FINAL EIS, UAF, WY, F.E. Warren Air Force Base Deactivation and Dismantlement of the Peacekeeper Missile System, To Comply with the Strategic Arms Reduction Treaty (START), Laramie, Platte and Goshen Counties, WY, Due: January 22, 2001, Contact: Jonathan D. Farthing (210) 536-3069.

EIS No. 000455, FINAL EIS, AFS, MT, Ashland Post-Fire Project, Proposal to Implement Restoration Activities to Maintain Watershed, Custer National Forest, Powder River and Rosebud Counties, MT, Due: January 22, 2001, Contact: Kim Reid (406) 784-2344.

Amended Notices

EIS No. 000351, FINAL EIS, NPS, MN, WI, Lower Saint Croix National Scenic Riverway Cooperative Management Plan, Implementation, MN and WI, Due: January 31, 2000, Contact: Michael Madell (608) 441-5600. Revision of FR notice published on 10/20/2000: CEQ Comment Date has been Extended from 11/20/2000 to 01/31/2001.

EIS No. 000443, FINAL EIS, DOD, AK, ND, AS, National Missile Defense (NMD) Deployment System, Analysis of Possible Deployment Sites: AK, AS and ND, Due: January 16, 2001, Contact: Julia Hudson (256) 955-4822. Published FR 12-15-00 Correction to Title.

Dated: December 19, 2000.

Joseph C. Montgomery,

Director, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. 00-32770 Filed 12-21-00; 8:45 am]

BILLING CODE 6560-50-U

ENVIRONMENTAL PROTECTION AGENCY

[ER-FRL-6613-9]

Environmental Impact Statements and Regulations; Availability of EPA Comments

Availability of EPA comments prepared December 4, 2000 Through December 8, 2000 pursuant to the Environmental Review Process (ERP), under section 309 of the Clean Air Act and section 102(2)(c) of the National Environmental Policy Act as amended. Requests for copies of EPA comments can be directed to the Office of Federal Activities at (202) 564-7167. An

explanation of the ratings assigned to draft environmental impact statements (EISs) was published in FR dated April 14, 2000 (65 FR 20157).

Draft EISs

ERP No. D-AFS-L67039-ID Rating EO2, El Luky Duk Gold Suction Dredging, Proposal to Mine Gold, Plan-of-Operation, Implementation, Nez Perce National Forest, Red River Ranger District, ID.

Summary

EPA expressed objections due to the potential of the project to further degrade water quality and fish habitat in the South Fork Clearwater River, a listed water body due to sediment, temperature, and habitat alteration. EPA recommend that the EIS better quantify the risk to water quality, listed species, and their habitats from proposed suction dredging and demonstrate that water quality standards (e.g., turbidity) could be met at "end-of-pipe" allowing for the issuance of an NPDES permit.

ERP No. D-JUS-L81012-WA Rating EC2, Tacoma/Seattle Area Detention Center, Construction and Leasing, Pierce County, WA.

Summary

EPA expressed concerns regarding the manner in which the proposed action alternatives were evaluated, how stormwater runoff would be managed, the lack of a clear strategy for site remediation, and the failure to initiate consultations with potentially affected Native American Tribes. EPA requested that the EIS be revised to better differentiate the potential effects of the action alternatives, clarify how stormwater discharges would be controlled, explain the relationship of hazardous waste cleanup to the site selection process, and reflect that appropriate consultations with the Nisqually and Puyallup Tribes have taken place.

ERP No. D-NPS-K61151-CA Rating LO, Lassen Volcanic National Park General Management Plan, Implementation, Lassen, Plumas, Shasta and Tehama Counties, CA.

Summary

EPA expressed no objection to the proposed action. However, EPA requested the inclusion of a cumulative impacts analysis and additional information on proposed actions and environmental impacts.

ERP No. D-UAF-G11039-TX Rating LO, Brooks City Base Project, To Improve Mission Effectiveness and Reduce Cost of Quality Installation

Support, Implementation, Brooks Air Force Base, Bexar County, TX.

Summary

EPA expressed no objection to the lead agency's proposed action. EPA requested some additional information to be included in the FEIS to strengthen the document.

ERP No. DR-NPS-K65212-CA Rating LO, Mojave National Preserve General Management Plan, Revised and New Alternatives the Proposed Management Approach and Two Alternatives for the Management of the 1.6 Million-Acre, Implementation, San Bernardino County, CA.

Summary

While EPA had no objection to the proposed action, EPA did request that the Final EIS include a more thorough description of the impacts to water resources and projections of future visitor use and traffic levels.

ERP No. DS-FTA-L40210-WA Rating NS, Central Link Light Rail Transit Project, (Sound Transit), Construction and Operation, Alternative Route Considered, Tukwila Freeway Route, COE Section 10 and 404 Permits, Cities of Tukwila, SeaTac, Seattle, King County, WA.

Summary

EPA Region 10 used a screening tool to conduct a limited review of this action. Based upon this screen, EPA does not foresee having any environmental objections to the proposed project. Therefore, EPA did not conduct a detailed review.

ERP No. DS-NPS-K65209-00 Rating LO, Death Valley National Park General Management Plan, Proposed Management Approach and Two Alternatives for the Management of the 3.3 Million Acres, Implementation, Mojave Desert, Inyo and San Bernardino Counties, CA and Nye and Esmeralda Counties, NV.

Summary

While EPA had no objection to the proposed action, EPA did request that the Final EIS include a comparison of current and expected levels of visitor activity and how changes in visitor use will be accommodated in area specific plans.

Final EISs

ERP No. F-AFS-J67028-MT Rocky Mountain Front Mineral Withdrawal, Implementation, Helena and Lewis and Clark National Forests, Great Falls, MT.

Summary:

EPA had no objection with the proposed action.

ERP No. F-AFS-L65362-ID West Mountain North Project, Timber Harvest, Road Construction and Reconstruction), Boise National Forest, Cascade Ranger District, Valley County, ID.

Summary

No formal comment letter was sent to the preparing agency.

ERP No. F-COE-H36109-MO Chesterfield Valley Flood Control Study, Improvement Flood Protection, City of Chesterfield, St. Louis County, MO.

Summary

EPA continues to express objections over three significant issues, cumulative impacts, floodplain management issues, and project alternatives.

Dated: December 19, 2000.

Joseph C. Montgomery,

Director, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. 00-32771 Filed 12-21-00; 8:45 am]

BILLING CODE 6560-50-U

ENVIRONMENTAL PROTECTION AGENCY

[OPPTS-00303; FRL-6762-4]

National Advisory Committee for Acute Exposure Guideline Levels for Hazardous Substances; Notice of Public Meeting

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: A meeting of the National Advisory Committee for Acute Exposure Guideline Levels for Hazardous Substances (NAC/AEGL Committee) will be held on January 8-10, 2001, in Washington, DC. At this meeting, the NAC/AEGL Committee will address, as time permits, the various aspects of the acute toxicity and the development of Acute Exposure Guideline Levels (AEGLs) for the following chemicals: Carbon monoxide, chlorine trifluoride, chloroacetic acid, ethyleneimine, hydrogen cyanide, hydrogen sulfide, isobutyronitrile, methacrylonitrile, phenol, phosgene, phosphine, propionitrile, xylenes, propyleneimine, and propylene oxide and sulfur mustard.

DATES: A meeting of the NAC/AEGL Committee will be held from 10:00 a.m. to 5 p.m. on January 8, 2001; from 8:30 a.m. to 5:00 p.m. on January 9, 2001 and from 8:30 a.m. to noon on January 10, 2001.

ADDRESSES: The meeting will be held at the U. S. Department of Transportation, DOT Headquarters, Nassif Building, Rooms 8236—8240, 400 7th Street SW., Washington, D.C. (L'Enfant Plaza Metro stop). Visitors should bring a photo ID for entry into the building and should contact the Designated Federal Officer (see below) to have their names added to a security entry list. Visitors must enter the building at the Southwest Entrance/Visitor's Entrance, 7th & E Sts. Quadrant.

FOR FURTHER INFORMATION CONTACT: *For general information contact:* Barbara Cunningham, Director, Office of Program Management and Evaluation, Office of Pollution Prevention and Toxics (7401), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (202) 554-1404; e-mail address: TSCA-Hotline@epa.gov.

For technical information contact: Paul S. Tobin, Designated Federal Officer (DFO), Office of Prevention, Pesticides and Toxic Substances (7406), 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (202) 260-1736; e-mail address: tobin.paul@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

This action is directed to the public in general. This action may be of particular interest to anyone who may be affected if the AEGL values are adopted by government agencies for emergency planning, prevention, or response programs, such as EPA's Risk Management Program under section 112r of the Clean Air Act and Amendments. It is possible that other Federal agencies besides EPA, as well as State agencies and private organizations, may adopt the AEGL values for their programs. As such, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the applicability of this action to a particular entity, consult the DFO listed under **FOR FURTHER INFORMATION CONTACT**.

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

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at <http://www.epa.gov/>. To access this document, on the Home Page select "Laws and Regulations," "Regulations

and Proposed Rules," and then look up the entry for this document under the "**Federal Register**—Environmental Documents." You can also go directly to the **Federal Register** listings at <http://www.epa.gov/fedrgstr/>.

2. *In person.* The Agency has established an official record for this action under docket control number OPPTS-00303. The official record consists of the documents specifically referenced in this action, any public comments received during an applicable comment period, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period, is available for inspection in the TSCA Non confidential Information Center, North East Mall Rm. B-607, Waterside Mall, 401 M St., SW., Washington, DC. The Center is open from noon to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number of the Center is (202) 260-7099.

II. Meeting Procedures

For additional information on the scheduled meeting, the agenda of the NAC/AEGL Committee, or the submission of information on chemicals to be discussed at the meeting, contact the DFO listed under **FOR FURTHER INFORMATION CONTACT**.

The meeting of the NAC/AEGL Committee will be open to the public. Oral presentations or statements by interested parties will be limited to 10 minutes. Interested parties are encouraged to contact the DFO to schedule presentations before the NAC/AEGL Committee. Since seating for outside observers may be limited, those wishing to attend the meeting as observers are also encouraged to contact the DFO at the earliest possible date to ensure adequate seating arrangements. Inquiries regarding oral presentations and the submission of written statements or chemicals specific information should be directed to the DFO.

III. Future Meetings

Another meeting of the NAC/AEGL Committee is tentatively scheduled for March, 2001.

List of Subjects

Environmental protection, Chemicals, Hazardous substances, Health.

Dated: December 18, 2000.

William H. Sanders, III,
Director, Office of Pollution Prevention and Toxics.

[FR Doc. 00-32677 Filed 12-20-00; 8:45 am]

BILLING CODE 6560-50-S

ENVIRONMENTAL PROTECTION AGENCY

[FRL-6920-2]

Proposed Prospective Purchaser Agreement Pursuant to the Comprehensive Environmental Response, Compensation and Liability Act of 1980, as Amended by the Superfund Amendments and Reauthorization Act, Leavenworth Auto Parts Superfund Site, Leavenworth, KS

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of proposed settlement and request for public comment.

SUMMARY: Notice is hereby given that a proposed Prospective Purchaser Agreement ("Agreement") associated with the Leavenworth Auto Parts Superfund Site, located at 777 Cherokee Street, Leavenworth, Kansas, was signed by the Agency on October 31, 2000, and subsequently signed by the United States Department of Justice on December 4, 2000. This Agreement is subject to final Agency approval after a public comment period. The Agreement would resolve certain potential EPA claims under the Comprehensive Environmental Response, Compensation and Liability Act of 1980 as amended ("CERCLA") against Ricky D. Jackson, the prospective purchaser ("the purchaser"). The Agreement includes a covenant not to sue the purchaser under Sections 106 and 107(a) of CERCLA, 42 U.S.C. 9606 and 9607(a).

The settlement Agreement requires the purchaser to provide access to the EPA, its authorized officials, employees, representatives, and all other persons performing response actions under EPA oversight. The purchaser also agrees to a deed restriction limiting future use of the property, which may not be used for residential purposes, as a day-care center, or as a playground. In addition, the settlement would require the purchaser to pay to the CERCLA Hazardous Substance Superfund a cash sum of \$1,000.00.

DATES: For thirty (30) days following the date of publication of this notice, the Agency will receive written comments relating to this proposed settlement. Comments must be submitted on or before January 22, 2001.

ADDRESSES: Comments should reference the "Leavenworth Auto Parts Superfund Site Prospective Purchaser Agreement" and should be forwarded to Kathy Robinson, Regional Hearing Clerk, U.S. Environmental Protection Agency, Region VII, 901 North 5th Street, Kansas City, Kansas 66101.

This proposed settlement Agreement is available for public inspection at the U.S. Environmental Protection Agency, Region VII, 901 North 5th Street, Kansas City, Kansas 66101. A copy of this Agreement may be obtained from the Region VII office. To view this document or obtain a copy, contact Kathy Robinson, Regional Hearing Clerk, U.S. Environmental Protection Agency, Region VII, 901 North 5th Street, Kansas City, Kansas 66101, (913) 551-7567.

FOR FURTHER INFORMATION CONTACT: Jonathan Kahn, Assistant Regional Counsel, United States Environmental Protection Agency, Region VII, 901 North 5th Street, Kansas City, Kansas 66101, (913) 551-7252.

Dated: December 12, 2000.

Nat Scurry,

Acting Regional Administrator, Region VII.

[FR Doc. 00-32672 Filed 12-21-00; 8:45 am]

BILLING CODE 6560-50-U

ENVIRONMENTAL PROTECTION AGENCY

[OPPTS-51960; FRL-6761-5]

Certain New Chemicals; Receipt and Status Information

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: Section 5 of the Toxic Substances Control Act (TSCA) requires any person who intends to manufacture (defined by statute to include import) a new chemical (i.e., a chemical not on the TSCA Inventory) to notify EPA and comply with the statutory provisions pertaining to the manufacture of new chemicals. Under sections 5(d)(2) and 5(d)(3) of TSCA, EPA is required to publish a notice of receipt of a premanufacture notice (PMN) or an application for a test marketing exemption (TME), and to publish periodic status reports on the chemicals under review and the receipt of notices of commencement to manufacture those

chemicals. This status report, which covers the period from November 13, 2000 to November 21, 2000, consists of the PMNs and TMEs, both pending or expired, and the notices of commencement to manufacture a new chemical that the Agency has received under TSCA section 5 during this time period. The "S" and "G" that precede the chemical names denote whether the chemical identity is specific or generic.

ADDRESSES: Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I. of the **SUPPLEMENTARY INFORMATION.** To ensure proper receipt by EPA, it is imperative that you identify docket control number OPPTS-51960 and the specific PMN number in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: Barbara Cunningham, Director, Office of Program Management and Evaluation, Office of Pollution Prevention and Toxics (7401), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (202) 554-1404; e-mail address: TSCA-Hotline@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

This action is directed to the public in general. As such, the Agency has not attempted to describe the specific entities that this action may apply to. Although others may be affected, this action applies directly to the submitter of the premanufacture notices addressed in the action. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT.**

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

1. *Electronically.* You may obtain copies of this document and certain other available documents from the EPA Internet Home Page at <http://www.epa.gov/>. On the Home Page select "Laws and Regulations," "Regulations and Proposed Rules," and then look up the entry for this document under the "Federal Register—Environmental Documents." You can also go directly to the **Federal Register** listings at <http://www.epa.gov/fedrgstr/>.

2. *In person.* The Agency has established an official record for this action under docket control number OPPTS-51960. The official record

consists of the documents specifically referenced in this action, any public comments received during an applicable comment period, any test data submitted by the manufacturer/importer and other information related to this action, including any information claimed as confidential business information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period, is available for inspection in the TSCA Nonconfidential Information Center, North East Mall Rm. B-607, Waterside Mall, 401 M St., SW., Washington, DC. The Center is open from noon to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number of the Center is (202) 260-7099.

C. How and to Whom Do I Submit Comments?

You may submit comments through the mail, in person, or electronically. To ensure proper receipt by EPA, it is imperative that you identify docket control number OPPTS-51960 and the specific PMN number in the subject line on the first page of your response.

1. *By mail.* Submit your comments to: Document Control Office (7407), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

2. *In person or by courier.* Deliver your comments to: OPPT Document Control Office (DCO) in East Tower Rm. G-099, Waterside Mall, 401 M St., SW., Washington, DC. The DCO is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the DCO is (202) 260-7093.

3. *Electronically.* You may submit your comments electronically by e-mail to: "oppt.ncic@epa.gov," or mail your computer disk to the address identified in this unit. Do not submit any information electronically that you consider to be CBI. Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comments and data will also be accepted on standard disks in WordPerfect 6.1/8.0 or ASCII file format. All comments in electronic form must be identified by docket control number OPPTS-51960 and the specific PMN number. Electronic comments may also be filed

online at many Federal Depository Libraries.

D. How Should I Handle CBI that I Want to Submit to the Agency?

Do not submit any information electronically that you consider to be CBI. You may claim information that you submit to EPA in response to this document as CBI by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public version of the official record. Information not marked confidential will be included in the public version of the official record without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person listed under **FOR FURTHER INFORMATION CONTACT.**"

E. What Should I Consider as I Prepare My Comments for EPA?

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.

2. Describe any assumptions that you used.

3. Provide copies of any technical information and/or data you used that support your views.

4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.

5. Provide specific examples to illustrate your concerns.

6. Offer alternative ways to improve the notice or collection activity.

7. Make sure to submit your comments by the deadline in this document.

8. To ensure proper receipt by EPA, be sure to identify the docket control number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

II. Why is EPA Taking this Action?

Section 5 of TSCA requires any person who intends to manufacture (defined by statute to include import) a new chemical (i.e., a chemical not on the TSCA Inventory to notify EPA and comply with the statutory provisions pertaining to the manufacture of new chemicals. Under sections 5(d)(2) and 5(d)(3) of TSCA, EPA is required to publish a notice of receipt of a PMN or an application for a TME and to publish periodic status reports on the chemicals under review and the receipt of notices

of commencement to manufacture those chemicals. This status report, which covers the period from November 13, 2000 to November 21, 2000, consists of the PMNs and TMEs, both pending or expired, and the notices of commencement to manufacture a new chemical that the Agency has received under TSCA section 5 during this time period.

III. Receipt and Status Report for PMNs

This status report identifies the PMNs and TMEs, both pending or expired, and the notices of commencement to manufacture a new chemical that the Agency has received under TSCA section 5 during this time period. If you are interested in information that is not included in the following tables, you may contact EPA as described in Unit II. to access additional non-CBI information that may be available. The "S" and "G" that precede the chemical names denote whether the chemical identity is specific or generic.

In table I, EPA provides the following information (to the extent that such information is not claimed as CBI) on the PMNs received by EPA during this period: the EPA case number assigned to the PMN; the date the PMN was received by EPA; the projected end date for EPA's review of the PMN; the submitting manufacturer; the potential uses identified by the manufacturer in the PMN; and the chemical identity.

TABLE I. 36 PREMANUFACTURE NOTICES RECEIVED FROM: 11/13/00 TO 11/21/00

Case No.	Received Date	Projected Notice End Date	Manufacturer/Importer	Use	Chemical
P-01-0098	11/14/00	02/12/01	CBI	(S) Raw material used in the manufacture of dry film resist	(G) Polypropyleneglycol diacrylate
P-01-0099	11/13/00	02/11/01	CBI	(G) Recycle stream	(G) Vinyl ester distillation residues
P-01-0100	11/13/00	02/11/01	Air Products and Chemicals Inc.	(S) Curing agent for epoxy coating systems	(G) Polyamine adduct
P-01-0101	11/14/00	02/12/01	CBI	(G) Component of coating with open use	(G) Acrylic copolymer
P-01-0102	11/14/00	02/12/01	CBI	(G) Component of coating with open use	(G) Aromatic polyacrylurea
P-01-0103	11/14/00	02/12/01	Solutia Inc.	(S) Binder for industrial printing inks	(G) Phenolic resin modified rosin resin
P-01-0104	11/14/00	02/12/01	CBI	(S) Paint resin	(G) Alkylsilyl acrylate.alkylmethacrylate.alkylacrylate copolymer
P-01-0105	11/14/00	02/12/01	BASF Corporation	(G) Internal press release	(G) Substituted polyether polyurethane
P-01-0106	11/14/00	02/12/01	Wacker Silicones Corporation	(S) Crosslinking agent for liquid silicone rubber	(G) Hydrogen-functional polysiloxane(s)
P-01-0107	11/15/00	02/13/01	CBI	(G) Crosslinker	(G) Modified aliphatic isocyanate
P-01-0108	11/15/00	02/13/01	CIBA Specialty Chemicals Corporation	(S) Colorant in polymers	(G) Diketo-pyrrolopyrrol pigment derivative
P-01-0109	11/15/00	02/13/01	CBI	(G) Dye intermediate	(G) Naphthalic anhydride
P-01-0110	11/15/00	02/13/01	CBI	(G) Dye intermediate	(G) Benzimidazole
P-01-0111	11/15/00	02/13/01	CBI	(G) Fluorescent dye	(G) Benzothiazine

TABLE I. 36 PREMANUFACTURE NOTICES RECEIVED FROM: 11/13/00 TO 11/21/00—Continued

Case No.	Received Date	Projected Notice End Date	Manufacturer/Importer	Use	Chemical
P-01-0112	11/16/00	02/14/01	CBI	(G) Polyester additive	(S) Phosphonium, tetrabutyl-, salt with 5-sulfo-1,3-benzenedicarboxylic acid (1:1)
P-01-0113	11/15/00	02/13/01	CBI	(G) Lubricant oil additive	(G) Vinyl acetate copolymer
P-01-0114	11/16/00	02/14/01	CBI	(G) Electric device	(G) Substituted phenylepoxyde
P-01-0115	11/17/00	02/15/01	Loctite Corporation	(S) A component of adhesive formulations	(S) Poly[oxy(methyl-1,2-ethanediyl)], α -hydro-omega-hydroxy-, ether with 2-ethyl-2-(hydroxymethyl)-1,3-propanediol (3:1), polymer with 5-isocyanato-1-(isocyanatomethyl)-1,3,3-trimethylcyclohexane, 2-hydroxyethyl acrylate-blocked
P-01-0116	11/17/00	02/15/01	CBI	(G) Additive, open, non-dispersive	(G) Fluorinated polyalkyl silicones
P-01-0117	11/17/00	02/15/01	CBI	(S) Chemical used in the synthesis of raw materials for the electronic industry	(G) Alkyl ester
P-01-0118	11/15/00	02/13/01	H.B. Fuller Company	(S) Moisture-cure adhesive for lamination	(G) Polyester isocyanate polymer
P-01-0119	11/15/00	02/13/01	H.B. Fuller Company	(S) Intermediate polyol for manufacture of moisture-cure adhesives	(G) Polyester isocyanate polymer
P-01-0120	11/17/00	02/15/01	CBI	(G) Paper coating resin	(G) Styrene-methacrylate-copolymer
P-01-0121	11/20/00	02/18/01	CBI	(G) Prepolymer of polyester urethane	(G) Aromatic saturated copolymer
P-01-0122	11/20/00	02/18/01	CBI	(S) Specialty polymer	(G) Acetate-substituted bicyclic olefin
P-01-0123	11/20/00	02/18/01	CBI	(G) Leather dyestuff	(G) Resorcinol azo dye
P-01-0124	11/20/00	02/18/01	Huntsman Petrochemical Corporation	(S) Component of polyurethane foam insulation	(G) Aromatic amino polyol
P-01-0125	11/20/00	02/18/01	Huntsman Petrochemical Corporation	(S) Component of polyurethane foam insulation	(G) Aromatic amino polyol
P-01-0126	11/20/00	02/18/01	Huntsman Petrochemical Corporation	(S) Component of polyurethane foam insulation	(G) Aromatic amino polyol
P-01-0127	11/20/00	02/18/01	Huntsman Petrochemical Corporation	(S) Component of polyurethane foam insulation	(G) Aromatic amino polyol
P-01-0128	11/20/00	02/18/01	Huntsman Petrochemical Corporation	(S) Component of polyurethane foam insulation	(G) Aromatic amino polyol
P-01-0129	11/20/00	02/18/01	Huntsman Petrochemical Corporation	(S) Component of polyurethane foam insulation	(G) Aromatic amino polyol
P-01-0130	11/21/00	02/19/01	Air Products and Chemicals Inc.	(S) Deoxofluorination of pharmaceutical intermediates; deoxofluorination of chemical intermediates; deoxofluorination of electronics intermediates	(S) Sulfur, trifluoro[2-methoxy-n-(2-methoxyethyl)ethanaminato-kn]-, (t-4)-
P-01-0131	11/21/00	02/19/01	CBI	(G) Diluent for alkyd	(G) Fatty acid esters of hydroxy functional carboxylic acid
P-01-0132	11/21/00	02/19/01	Dow Corning Corporation	(S) Termoplastic resin additive	(S) Siloxanes and silicones, di-me, me vinyl, vinyl group-terminated, polymers with ethylene and me methacrylate
P-01-0133	11/21/00	02/19/01	BASF Corporation	(S) Additive for carbon black dispersions	(G) Alkoxylated amine

In table II, EPA provides the following information (to the extent that such information is not claimed as CBI) on the TMEs received:

TABLE II. 1 TEST MARKETING EXEMPTION NOTICES RECEIVED FROM: 11/13/00 TO 11/21/00

Case No.	Received Date	Projected Notice End Date	Manufacturer/Importer	Use	Chemical
T-01-0006	11/14/00	12/29/00	CBI	(G) Component of coating with open use	(G) Aromatic polyacrylurea

In table III, EPA provides the following information (to the extent that such information is not claimed as CBI) on the Notices of Commencement to manufacture received:

TABLE III. 23 NOTICES OF COMMENCEMENT FROM: 11/13/00 TO 11/21/00

Case No.	Received Date	Commencement/ Import Date	Chemical
P-00-0439	11/17/00	11/01/00	(G) Polymer of acrylamido alkyl propane sulfonic acid ammonium salt and two acrylic monomers
P-00-0485	11/21/00	11/01/00	(S) Phenol, 4,4'-(1-methylethylidene)bis-, styrenated
P-00-0494	11/21/00	10/24/00	(G) Copolymer of acrylic esters and styrene
P-00-0551	11/16/00	10/26/00	(S) Butaneperoxoic acid, 2-ethyl-, 1,1-dimethylethyl ester
P-00-0626	11/14/00	11/06/00	(G) Polyurethane acrylate ester
P-00-0801	11/15/00	10/16/00	(S) Rosin, fumarated, c ⁹ ndash;11-isoalkyl esters, c ¹⁰ -rich, compds. with 2-(dimethylamino)ethanol
P-00-0827	11/15/00	10/20/00	(G) Substituted alcohol
P-00-0831	11/17/00	11/14/00	(G) Polyether modified dimethylpolysiloxane
P-00-0832	11/17/00	11/14/00	(G) Polyether modified polydimethylsiloxane
P-00-0847	11/21/00	10/25/00	(G) Cresol-blocked isocyanate
P-00-0860	11/16/00	11/07/00	(G) Alkylsiloxane-modified polyalkylene resin
P-00-0867	11/16/00	11/08/00	(G) Dimethyl, methylalkyl, methylaryl siloxane
P-00-0913	11/14/00	10/28/00	(G) Polyalkoxylated aromatic amine tint
P-00-0941	11/21/00	11/13/00	(G) Aliphatic urethane
P-00-0956	11/14/00	11/03/00	(G) Polyester polyurethane prepolymer
P-00-0986	11/17/00	10/25/00	(G) Dialkyl diether
P-00-0988	11/14/00	11/07/00	(G) Polyester, hydroxy functional
P-00-1023	11/14/00	10/26/00	(G) Acrylic polyol
P-99-0351	11/21/00	11/13/00	(S) Amines, coco, n-[2-(2-hydroxyethoxy)ethyl]-
P-99-0353	11/21/00	11/08/00	(S) Decanamide, n-[2-(2-hydroxyethoxy)ethyl]-
P-99-0801	11/14/00	10/12/00	(G) Polyester polyol
P-99-0802	11/14/00	10/12/00	(G) Polyester polyol
P-99-0803	11/14/00	10/12/00	(G) Polyester polyol

List of Subjects

Environmental protection, Chemicals, Premanufacturer notices.

Dated: December 14, 2000.

Deborah A. Williams,

Acting Director, Information Management Division, Office of Pollution Prevention and Toxics.

[FR Doc. 00-32710 Filed 12-21-00; 8:45 am]

BILLING CODE 6560-50-S

ENVIRONMENTAL PROTECTION AGENCY

[FRL-6920-5]

Public Water Supply Supervision Program; Program Revision for the State of Oregon

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of tentative approval.

SUMMARY: Notice is hereby given that the State of Oregon has revised its approved State Public Water Supply Supervision (PWSS) Primacy Program. Oregon has revised its PWSS program with respect to administrative penalty authority, has adopted a revised definition of public water system, and has adopted drinking water regulations requiring consumer confidence reports

from all community water systems. EPA has determined that these revisions are no less stringent than the corresponding federal regulations. Therefore, EPA intends on approving these State program revisions. This approval action does not extend to public water systems (PWSs) in Indian Country, as that term is defined in 18 U.S.C. 1151. EPA interprets its past approvals as not extending to Indian Country unless the State has made an explicit demonstration of jurisdiction over Indian Country and EPA has specifically approved the State's Drinking Water program over that area. EPA is aware that, historically, certain non-Indian owned PWSs in Indian Country may have followed the State's PWS program. EPA is currently developing a plan to secure EPA oversight of all of these systems in a manner which will ensure that the public health and welfare of all PWS users are protected.

All interested parties may request a public hearing. A request for a public hearing must be submitted by January 22, 2001, to the Regional Administrator at the address shown below. Frivolous or insubstantial requests for a hearing may be denied by the Regional Administrator. However, if a substantial request for a public hearing is made by January 22, 2001, a public hearing will be held. If no timely and appropriate

request for a hearing is received and the Regional Administrator does not elect to hold a hearing on his own motion, this determination shall become final and effective on January 22, 2001. Any request for a public hearing shall include the following information:

(1) The name, address, and telephone number of the individual, organization, or other entity requesting a hearing; (2) a brief statement of the requesting person's interest in the Regional Administrator's determination and a brief statement of the information that the requesting person intends to submit at such hearing; (3) the signature of the individual making the request, or, if the request is made on behalf of an organization or other entity, the signature of a responsible official of the organization or other entity.

ADDRESSES: All documents relating to this determination are available for inspection between the hours of 9 a.m. and 4 p.m., Monday through Friday, at the following offices:

Oregon Health Division, Drinking Water Section, 800 N.E. Oregon Street, Portland, Oregon 97232, and

U.S. Environmental Protection Agency, Region 10 Library, 1200 Sixth Avenue, Seattle, Washington 98101.

FOR FURTHER INFORMATION CONTACT: Wendy Marshall, EPA Region 10, Drinking Water Unit, at the Seattle

address given above; telephone (206) 553-1890.

Authority: Section 1420 of the Safe Drinking Water Act, as amended (1996), and 40 CFR Part 142 of the National Primary Drinking Water Regulations.

Dated: December 12, 2000.

Ronald A. Kreizenbeck,

Acting Regional Administrator, Region 10.

[FR Doc. 00-32671 Filed 12-21-00; 8:45 am]

BILLING CODE 6560-50-U

FEDERAL COMMUNICATIONS COMMISSION

Notice of Public Information Collection(s) Being Reviewed by the Federal Communications Commission for Extension Under Delegated Authority, Comments Requested

December 15, 2000.

SUMMARY: The Federal Communications Commission, as part of its continuing effort to reduce paperwork burden invites the general public and other Federal agencies to take this opportunity to comment on the following information collection(s), as required by the Paperwork Reduction Act of 1995, Public Law 104-13. An agency may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act (PRA) that does not display a valid control number. Comments are requested concerning (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's burden estimate; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology.

DATES: Persons wishing to comment on this information collection should submit comments February 20, 2001. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all comments to Judy Boley, Federal Communications Commission, 445 12th Street, SW, Room

1-C804, Washington, DC 20554 or via internet to jboley@fcc.gov.

FOR FURTHER INFORMATION CONTACT: For additional information or copies of the information collections contact Judy Boley at 202-418-0214 or via internet at jboley@fcc.gov.

SUPPLEMENTARY INFORMATION:

OMB Control No: 3060-0959.

Title: Compatibility Between Cable Systems and Consumer Electronics Equipment.

Form No.: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit and not-for-profit institutions.

Number of Respondents: 104.

Estimated Time Per Response: 14-80 hours.

Frequency of Response: Third party disclosure requirement, on occasion and semi-annual reporting requirements.

Cost to Respondent: N/A.

Total Annual Burden: 1,720 hours.

Needs and Uses: The Commission imposes labeling requirements on digital television (DTV) receivers and other consumer electronics receiving devices. The requirements are designed to ensure that consumers understand the capability of digital television equipment to operate with cable television systems. The Commission also requires the cable and consumer electronics industries to report at intervals on progress in implementing earlier agreements on technical standards for direct connection of digital television receivers to digital cable systems and on providing tuning and program scheduling information to support the navigation function of DTV receivers.

Federal Communications Commission.

Magalie Roman Salas,

Secretary.

[FR Doc. 00-32675 Filed 12-21-00; 8:45 am]

BILLING CODE 6712-01-P

FEDERAL HOUSING FINANCE BOARD

[No. 2000-N-8]

Proposed Collection; Comment Request

AGENCY: Federal Housing Finance Board.

ACTION: Notice.

SUMMARY: In accordance with the requirements of the Paperwork Reduction Act of 1995, the Federal Housing Finance Board (Finance Board) hereby gives notice that it is seeking public comments concerning a three-

year extension by the Office of Management and Budget (OMB) of the information collection entitled "Members of the Banks."

DATES: Interested persons may submit comments on or before February 20, 2001.

ADDRESSES: Address comments and requests for copies of the information collection to Elaine L. Baker, Secretary to the Board, by telephone at 202/408-2837, by electronic mail at bakere@fhfb.gov, or by regular mail at the Federal Housing Finance Board, 1777 F Street, NW., Washington, DC 20006.

FOR FURTHER INFORMATION CONTACT:

Jonathan F. Curtis, Senior Financial Analyst, Market Research and System Analysis Division, Office of Policy, Research and Analysis, by telephone at 202/408-2866, by electronic mail at curtisj@fhfb.gov, or by regular mail at the Federal Housing Finance Board, 1777 F Street, NW., Washington, DC 20006. A telecommunications device for deaf persons (TDD) is available at 202/408-2579.

SUPPLEMENTARY INFORMATION:

A. Need For and Use of the Information Collection

Section 4 of the Federal Home Loan Bank Act (Bank Act), 12 U.S.C. 1424, establishes the eligibility requirements an institution must meet in order to become a member of a Federal Home Loan Bank (Bank). Part 925 of the Finance Board's regulations implements section 4 of the Bank Act. See 12 CFR part 925. The membership rule provides uniform requirements an applicant for Bank membership must meet and review criteria a Bank must apply to determine whether the applicant satisfies the statutory and regulatory membership eligibility requirements.

More specifically, the membership rule implements the statutory eligibility requirements and provides guidance to an applicant on how it may satisfy such requirements. The rule authorizes a Bank to approve or deny each membership application subject to the statutory and regulatory requirements and permits an applicant to appeal to the Finance Board a Bank's decision to deny certification as a Bank member. The rule also imposes a continuing obligation on a current Bank member to provide information necessary to determine if it remains in compliance with applicable statutory and regulatory eligibility requirements.

The information collection, which is contained in § 925.2 through § 925.31 of the membership rule, 12 CFR 925.2-925.31, is necessary to enable a Bank to

determine whether a respondent satisfies the statutory and regulatory requirements to be certified initially and maintain its status as a member eligible to obtain Bank advances. The Finance Board requires and uses the information collection to determine whether to uphold or overrule a Bank's decision to deny member certification to an applicant.

The OMB number for the information collection is 3069-004. The OMB clearance for the information collection expires on April 30, 2001.

The likely respondents are institutions that want to be certified as or are members of a Bank.

B. Burden Estimate

The Finance Board estimates the total annual average number of applicants at 800, with one response per applicant. The estimate for the average hours per application is 21.5 hours. The Finance Board estimates the total annual average number of maintenance respondents, *i.e.*, current Bank members, at 7,800, with one response per member. The estimate for the average hours per maintenance response is 0.6 hours. The estimate for the total annual hour burden is 21,880 hours (7,800 members x 1 response per member x approximately 0.6 hours plus 800 applicants x 1 response per applicant x approximately 21.5 hours).

C. Comment Request

The Finance Board requests written comments on the following: (1) Whether the collection of information is necessary for the proper performance of Finance Board functions, including whether the information has practical utility; (2) the accuracy of the Finance Board's estimates of the burdens of the collection of information; (3) ways to enhance the quality, utility and clarity of the information collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

By the Federal Housing Finance Board.

Dated: December 15, 2000.

James L. Bothwell,
Managing Director.

[FR Doc. 00-32657 Filed 12-21-00; 8:45 am]

BILLING CODE 6725-01-P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval,

pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 et seq.) (BHC Act), Regulation Y (12 CFR Part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The application also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States. Additional information on all bank holding companies may be obtained from the National Information Center website at www.ffiec.gov/nic/.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than January 16, 2001.

A. Federal Reserve Bank of Dallas
(Genie D. Short, Vice President) 2200 North Pearl Street, Dallas, Texas 75201-2272:

1. *Sterling Bancshares, Inc.*, Houston, Texas; and *Sterling Bancorporation, Inc., Inc.*, Wilmington, Delaware, to merge with *CaminoReal Bancshares, Inc.*, San Antonio, Texas; and thereby indirectly acquire *CaminoReal Delaware, Inc.*, Wilmington, Delaware; and *CaminoReal Bank National Association*, San Antonio, Texas.

Board of Governors of the Federal Reserve System, December 18, 2000.

Robert deV. Frierson

Associate Secretary of the Board.

[FR Doc. 00-32633 Filed 12-21-00; 8:45 am]

BILLING CODE 6210-01-S

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company

Act of 1956 (12 U.S.C. 1841 et seq.) (BHC Act), Regulation Y (12 CFR Part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The application also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States. Additional information on all bank holding companies may be obtained from the National Information Center website at www.ffiec.gov/nic/.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than January 19, 2001.

A. Federal Reserve Bank of New York
(Betsy Buttrill White, Senior Vice President) 33 Liberty Street, New York, New York 10045-0001:

1. *Chinatrust Commercial Bank, Ltd.*, Taipei, Republic of China; to become a bank holding company by merging with *China Trust Holdings N.V.*, Curacao, Netherlands Antilles, and thereby indirectly acquire *Chinatrust Bank (U.S.A.)*, Torrance, California.

B. Federal Reserve Bank of Richmond
(A. Linwood Gill, III, Vice President) 701 East Byrd Street, Richmond, Virginia 23261-4528:

1. *Wachovia Corporation*, Winston-Salem, North Carolina; to acquire 100 percent of the voting shares of *Republic Security Financial Corporation*, West Palm Beach, Florida, and thereby indirectly acquire voting shares of *Republic Security Bank*, West Palm Beach, Florida.

C. Federal Reserve Bank of St. Louis
(Randall C. Sumner, Vice President) 411 Locust Street, St. Louis, Missouri 63166-2034:

1. *Lea M. McMullan Trust*, Shelbyville, Kentucky, and its subsidiary, *Citizens Union Bancorp of*

Shelbyville, Inc., Shelbyville, Kentucky; to acquire 100 percent of the voting shares of Dupont State Bank, Dupont, Indiana.

Board of Governors of the Federal Reserve System, December 19, 2000.

Robert deV. Frierson

Associate Secretary of the Board.

[FR Doc. 00-32748 Filed 12-21-00; 8:45 am]

BILLING CODE 6210-01-S

FEDERAL RESERVE SYSTEM

Notice of Proposals to Engage in Permissible Nonbanking Activities or to Acquire Companies that are Engaged in Permissible Nonbanking Activities

The companies listed in this notice have given notice under section 4 of the Bank Holding Company Act (12 U.S.C. 1843) (BHC Act) and Regulation Y, (12 CFR Part 225) to engage de novo, or to acquire or control voting securities or assets of a company, including the companies listed below, that engages either directly or through a subsidiary or other company, in a nonbanking activity that is listed in § 225.28 of Regulation Y (12 CFR 225.28) or that the Board has determined by Order to be closely related to banking and permissible for bank holding companies. Unless otherwise noted, these activities will be conducted throughout the United States.

Each notice is available for inspection at the Federal Reserve Bank indicated. The notice also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether the proposal complies with the standards of section 4 of the BHC Act. Additional information on all bank holding companies may be obtained from the National Information Center website at www.ffiec.gov/nic/.

Unless otherwise noted, comments regarding the applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than January 16, 2001.

A. Federal Reserve Bank of Minneapolis (Karen L. Grandstrand, Vice President) 250 Marquette Avenue, Minneapolis, Minnesota 55480-2171:

1. *Glacier Bancorp, Inc.*, Kalispell, Montana; to merge with WesterFed Financial Corporation, Missoula, Montana, and thereby indirectly acquire Western Security Bank, Missoula, Montana and thereby engage in controlling, owning, and operating a savings association pursuant to § 225.28(b)(4) of Regulation Y.

Board of Governors of the Federal Reserve System, December 18, 2000.

Robert deV. Frierson

Associate Secretary of the Board.

[FR Doc. 00-32632 Filed 12-21-00; 8:45 am]

BILLING CODE 6210-01-S

HARRY S. TRUMAN SCHOLARSHIP FOUNDATION

Harry S. Truman Scholarship 2001 Competition

AGENCY: Harry S. Truman Scholarship Foundation.

ACTION: Notice of closing for nominations from eligible institutions of higher education.

SUMMARY: Notice is hereby given that, pursuant to the authority contained in the Harry S. Truman Memorial Scholarship Act, Pub. L. 93-642 (20 U.S.C. 2001), nominations are being accepted from eligible institutions of higher education for 2001 Truman Scholarships. Procedures are prescribed at 45 CFR 1801.

In order to be assured consideration, all documentation in support of nominations must be received by the Truman Scholarship Foundation, 712 Jackson Place, NW, Washington, DC 20006 no later than January 29, 2001 from participating institutions.

Dated: December 18, 2000.

Louis H. Blair,

Executive Secretary.

[FR Doc. 00-32639 Filed 12-21-00; 8:45 am]

BILLING CODE 6820-AD-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Minority Health; National Standards on Culturally and Linguistically Appropriate Services (CLAS) in Health Care

AGENCY: HHS/OS/Office of Public Health and Science, Office of Minority Health, DHHS.

ACTION: Final report.

SUMMARY: The HHS Office of Minority Health announces the publication of final national standards on culturally and linguistically appropriate services (CLAS) in health care, following a 120-day comment period on draft standards in 2000 and revisions to the standards. The CLAS standards, with a brief background summary of the development and comment process, are printed below.

FOR FURTHER INFORMATION CONTACT: Guadalupe Pacheco, Office of Minority

Health, 5515 Security Lane, Suite 1000, Rockville, MD 20852, Attn: CLAS; Office Telephone: (301) 443-5084, FAX: (301) 594-0767, E-Mail:

gpacheco@osophs.dhhs.gov. The standards, the public comments from the regional meetings, and a complete report on the project can be found online at [www.omhrc.gov/CLAS].

SUPPLEMENTARY INFORMATION:

Table of Contents

- Background
- Public Comment Period and Regional Informational Meetings
- National Project Advisory Committee (NPAC)
- Analysis and Response to Public Comments on the CLAS Standards
- National Standards for Culturally and Linguistically Appropriate Services in Health Care

Background

Cultural and linguistic competence is the ability of health care providers and health care organizations to understand and respond effectively to the cultural and linguistic needs brought by patients to the health care encounter. As health providers begin to treat a more diverse clientele as a result of demographic shifts and changes in insurance program participation, interest is increasing in culturally and linguistically appropriate services that lead to improved outcomes, efficiency, and satisfaction. The provision of culturally and linguistically appropriate services is in the interest of providers, policymakers, accreditation and credentialing agencies, purchasers, patients, advocates, educators and the general health care community.

Many health care providers do not have clear guidance on how to prepare for, or respond to, culturally sensitive situations. Until now, no comprehensive nationally recognized standards of cultural and linguistic competence in health care service delivery have been developed. Instead, Federal health agencies, State policymakers, and national organizations have independently developed their own standards and practices. Some have developed definitions of cultural competence while others mandate providing language services to limited English proficient (LEP) speakers. Some specify collection of language, race, and ethnicity data. Many approaches attempt to be comprehensive, while others target only a specific issue, geographic area, or subfield of health care such as mental health. The result is a wide spectrum of ideas about what constitutes culturally appropriate health services, including significant

differences with respect to target population, scope, and quality of services. Although limited in their jurisdiction, many excellent policies do exist, and the increasing numbers of model programs and practices demonstrate that culturally competent health services are viable, beneficial, and important to health care consumers.

In 1997, the U.S. Department of Health and Human Services' (HHS) Office of Minority Health (OMH) asked Resources for Cross Cultural Health Care and the Center for the Advancement of Health to review and compare existing cultural and linguistic competence standards and measures in a national context, propose draft national standard language where appropriate, assess the information or research needed to relate these guidelines to outcomes, and develop an agenda for future work in this area. Assuring Cultural Competence in Health Care: Recommendations for National Standards and an Outcomes-Focused Research Agenda was the result of this request, with a two-part report submitted to OMH in May 1999.

The first part of the 1999 report contained draft national standards for culturally and linguistically appropriate services in health care. Based on an analytical review of key laws, regulations, contracts, and standards currently in use by Federal and State agencies and other national organizations, these draft standards were developed with input from a national project advisory committee of policymakers, health care providers, and researchers. Each standard was accompanied by a discussion that addressed the proposed guideline's relationship to existing laws and standards, and offered recommendations for implementation and oversight to providers, policymakers, and advocates.

Public Comment Period and Regional Informational Meetings

The Office of Minority Health determined that the appropriate next step for the draft CLAS standards was to undergo a national process of public comment that would result in a broader awareness of HHS interest in CLAS in health care, significant input from stakeholder groups on the draft standards, and a final revision of the standards and accompanying commentary supported by the expertise of a National Project Advisory Committee.

The draft CLAS standards were published in the **Federal Register** on December 15, 1999 (Volume 64, Number 240, pages 70042–70044), and the full report was made available for review

online at [www.omhrc.gov/CLAS]. Individuals and organizations desiring to comment on the standards were encouraged to read the standards and full report, and to send comments during the public comment period, which ran from January 1 to April 30, 2000. During this period, written comments sent by e-mail and regular mail were received from 104 individuals and organizations.

Individuals also had the opportunity to participate in one of three regional meetings on the CLAS standards. The purpose of these one-day meetings was to present information on the standards' development process, and for participants to discuss and provide feedback on issues related to the standards themselves or their implementation. Meetings were publicized in the **Federal Register** notice, on the website, and in letters mailed to more than 3,000 stakeholders. The meetings were held on January 21, 2000, in San Francisco, California; March 10, 2000, in Baltimore, Maryland; and April 7, 2000, in Chicago, Illinois. More than 309 individuals, representing themselves or their organizations, participated in the three meetings. All sessions of each meeting were audiotaped and transcribed for inclusion in the analysis of public comments.

Following the closure of the public comment period on April 30, 2000, the project team (consisting of staff members of OMH, IQ Solutions, Inc., and its subcontractor Resources for Cross Cultural Health Care) implemented the following steps to analyze the public comments on the CLAS standards received through the three regional meetings, mail, and e-mail.

The public comments received from all sources were organized according to the following categories (the numbers used to identify the standards pertain to the numbering system of the draft standards. The standards have been reordered in the final revision):

- General Comments (made on the overall report).
- Diverse and Culturally Competent Staff (Standards 1, 4, and 5).
- Consumer and Community Input (Standard 3).
- Bilingual/Interpreter Services (Standards 6, 7, and 9).
- Translated Written Materials (Standard 8).
- The Culturally Competent Organization (Standards 2 and 13).
- Data Collection and Performance Evaluation (Standards 10, 11, 12, and 14).

Within these categories, comments were organized by individual standards and within standards by major identified themes. Staff reviewed the compilations of comments to identify issues and controversies for each standard, and the original comments were organized topically for each standard and for the General Comments. The project team then conducted a series of meetings to discuss comments on topically grouped sets of standards. Deliberations on the CLAS Standards addressed the following set of questions:

- Is there a powerful consensus from public comments to change the standard in any way? If so, what are the issues?
- Are there any meaningful secondary issues that are so compelling or sensible that they need to be considered in terms of changes to the standard?
- Are there any other issues that should be addressed (e.g., controversies raised by the standard) by the CLAS Standards National Project Advisory Committee (NPAC)?

Deliberations on the general comments addressed the following set of questions:

- What are the major themes or issues related to the previous process of developing the standards, and how should these issues be addressed in the final CLAS standards report?
- What are major themes related to contextual issues, and how should these themes be addressed in the final CLAS standards report?
- What are major issues related to the subsequent standards development process, and how should these themes be addressed?

National Project Advisory Committee

Based on the discussions related to these questions, the project team prepared a deliberation report for the NPAC that included an analysis of comments on the general comments and each standard. Each analysis:

- Makes recommendations for changes to the standards when clearly indicated by a consensus in either public comments or project team deliberations;
- Identifies key themes, issues, and controversies; and
- Provides rationales for changes or controversies that the NPAC is being asked to consider.

The CLAS Standards National Project Advisory Committee was composed of 27 individuals representing State and Federal agencies, health care organizations, health care professionals, consumers, unions, and health care accrediting agencies. A complete list of NPAC members is available at [www.omhrc.gov/CLAS]. The NPAC

met with the project team in Washington, DC, on July 21–22, 2000. Together, the group:

- Considered the recommendations proposed in the deliberation report and either concurred on the suggested changes to the standard or offered an alternative approach to responding to public comments on the issues;
- Examined key issues for which recommendations were not presented in the analysis (due to a lack of clear consensus) and, when possible, recommended changes to the standards that were responsive to public comments;
- Identified and addressed other issues not raised in the deliberation report; and
- Made recommendations for next steps.

Following the meeting the project team revised the standards based on the public comments and the deliberations of the NPAC, whose members were given the opportunity to review and comment on subsequent revisions. No formal consensus was obtained from the NPAC after the meeting, although most comments were integrated into the final standards by the project team, and the NPAC was given the opportunity to review and comment on the final revisions. The final revisions are now being published in the **Federal Register** as recommended national standards for adoption or adaptation by stakeholder organizations and agencies.

The project team will also produce a comprehensive final report documenting all phases of the project and discussing issues related to the standards in depth. This report will be available in early January 2000 online at [www.omhrc.gov/CLAS] and in hard copy by request to: Guadalupe Pacheco, Office of Minority Health, 5515 Security Lane, Suite 1000, Rockville, MD 20852, Attn: CLAS; Office: Telephone (301) 443–5084, FAX: (301) 594–0767, E-Mail: gpacheco@osophs.dhhs.gov.

Analysis and Response to Public Comments on the CLAS Standards

In response to publication in the **Federal Register** of the CLAS Standards on December 15, 1999, OMH received public comments from 413 individuals or organizations, along with comments from the NPAC. Comments were received from a broad range of stakeholders, including hospitals, community-based clinics, managed care organizations, home health agencies, and other types of health care organizations; physicians, nurses, and other providers; professional associations; state health departments; government and other purchasers of

health care; accreditation and credentialing agencies; patient advocates and advocacy groups; policymakers; and educators. We present comments and responses generally in the order in which the issues appeared in the recommended CLAS Standards.

General Comments

The comments called for more specificity regarding terms such as culture and competence. Two comments affirmed the choice of definition used by the report; there were other votes for and against culturally sensitive/effective/appropriate/competent. Culturally and linguistically appropriate services (CLAS) was retained as the overall descriptor for the package of activities described by standards. Cultural competence remains the mainstream term for this area, and will be used within standards and defined in the glossary. The NPAC generally agreed with the continued use of the definition of cultural and linguistic competence from the original report.

Comments suggested that the scope of the project include other consumer groups/issues such as the poor, homeless, disabled, gender, socioeconomic status, HIV, gay, bisexual, transgender, immigrants, American Indians, different ages, countercultures, cultures within cultures, individuals within cultures. In the discussion for this section, the final report on the CLAS standards will articulate an inclusive definition of culture that promotes a broad understanding of the whole person. The report will note that every aspect of culture does not need to be addressed in each standard in order for them to apply to different groups, although we will emphasize the original focus on racial, ethnic, and linguistic issues.

Comments asked that the standards be more precise and directive and include more discussion in the standards themselves. To provide added details without encumbering the language of the standards, the format for presenting the revised CLAS standard was revised to continue using concise language for the standard itself and incorporate wordsmithing changes that enhance the clarity of each standard. Additional clarification of key issues or requirements are provided in a brief commentary accompanying the standard. It is our intent that the commentary will not be separated from the standard in executive summaries or other abbreviations of the full report. We also moved many important points from the discussion section of each standard in the original report into the

commentary and will include more examples of models and implementation practices in the discussion section of the final report. However, much of the research on and verification of this information should be conducted within the context of the anticipated pilot tests of the standards by health care organizations. Suggestions also were made for reorganizing the standards by topic area; the revised standards reflect this reorganization, with three main categories (culturally competent care, language assistance, and organizational supports for cultural competence).

Comments raised concerns about too much emphasis on foreign language issues, and it was suggested that they be broadened to include other communication issues. The policies from which the standards were derived are much more specific on the issue of language than culture, and this reflects the current abstract nature of cultural competence and the clear mandates that exist on language issues. We have tried to strengthen the commentary and discussions on cultural competence generally, separate the general cultural competence and language issues into different categories, and call for more work on developing national standards for cultural competence training and other aspects of cultural competence.

Comments raised questions about several implementation issues, including the cost burden and the applicability of the CLAS standards to different kinds of health care organizations (e.g., community clinics/community-based organizations (CBOs), mono-ethnic or “already” culturally competent providers, with extensive ethnic diversity/little diversity, rural providers, home health care agencies). Although the comments raise valid issues, we cannot address cost implications and the implementation nuances according to organization type within the scope of this project. Follow-up projects to pilot test implementation of the CLAS standards and address such issues are planned.

Commenters suggested that additional groups might have participated in the development and comment process, including: health care providers, practicing clinicians, CBOs, community health centers, consumer groups, ethnic organizations, grassroots advocacy groups, Indian reservations, tribal organizations, primary consumers, direct service personnel, Native Americans, Asians, and people who don't speak English. They also suggested that the outreach/public comment process could have been more inclusive by using more participatory

approaches to getting information, offering interpreters, doing a better job of informing people about the process, and targeting certain audiences. The final report will detail the public comment process used and its limitations. For example, alternative methods to get input, such as focus groups, ethnic media advertising, were constrained by resource limitations. We used recommendations from public meetings and developed a matrix to assist with our analysis and inclusion of different stakeholder groups in the NPAC. We attempted to recruit representatives from key groups and added additional stakeholders to the NPAC who provided community- and patient-based perspectives.

Comments indicated that many people are not aware of existing laws that addressed issues raised by the CLAS standards, and some standards can be strengthened on the basis of Federal legislation. The commentary of the revised standards identifies the relationship between each standard and any existing Federal laws or regulations. Input from the NPAC was used to identify relevant Federal requirements.

Comments raised concerns about whether the recommended CLAS standards should be guidelines, standards, or mandates. Overall, there was a broad continuum of support for and opposition to different conceptualizations of the standards. Fifty comments supported the standards as mandates, with another 37 expressing endorsement, support for their adoption, agreement with the intent, and other general expressions of praise. Thirty-four comments expressed some level of concern about seeing the standards as national standards or requirements. Some prefer the standards as guidelines, and others disliked them in any format. Among the reasons for their concern or opposition include: The potential costs/burden of implementation; the standards are too broad, too narrow, or too prescriptive; and the lack of research evidence to support the CLAS activities. These issues were raised in the pre-NPAC analytical report and discussed by the committee. The NPAC offered up a consensus on three types of standards of varying stringency: mandates, guidelines, and recommendations. The revised CLAS standards are identified according to these types.

Several comments were raised about elevating the issues of racism, bias, discrimination, and the issues of gender, social class, and socioeconomic status more directly into the standards. Unconscious and conscious referral bias and its impact on health disparities was

emphasized, as well as a tension between recognizing the needs of newcomers vs. English-speaking individuals who may still not be respectfully treated in health care. The revised preamble highlights bias and discrimination issues, and the final report will further discuss these issues.

Preamble

Public comments offered a variety of suggestions on how to revise the preamble to the CLAS standards. The principal themes focused on describing the purpose and desired outcomes of the standards, elucidating the standards' overarching principles, and providing definitions to key terms. Other comments suggested that the preamble should include a list of stakeholders and specifically address issues such as bias, ethics and confidentiality, and access. We have revised the preamble to provide both a visionary and practical foundation for understanding the CLAS standards while focusing on a principal theme rather than the array of issues identified. We also have added explanations of the three types of standards (mandates, guidelines, and recommendations), definitions of key concepts used in the standards, and a list of intended stakeholders.

Standard 1

Public comments took issue with the overall language of the standard, questioning whether its vague language will render it difficult to implement and enforce. Various comments cited the lack of operationally defined and measurable requirements, recommended that the standard be moved to the preamble or combined with Standard 5, and suggested ways that the standard could be strengthened. The revised standard, along with the accompanying Commentary, is intended to encompass the spirit and overall purpose of the CLAS standards as well as the details that can help organizations "actualize" and "operationalize" the requirements of Standard 1. As suggested in public comments and by the NPAC, portions of the discussion in the CLAS standards report have been incorporated into the standard's Commentary, including actions organizations can take to support culturally competent encounters. The intent of the standard is more fully explicated in the discussion section of the final report.

Public comments focused on the term "attitudes" or the phrase "attitudes, behaviors, knowledge, and skills" of staff. The lack of definitions and measures for these terms was cited as an obstacle to implementing Standard 1. The revised standard deletes this phrase

and focuses instead on concrete actions as reflected in the commentary.

Comments requested that the CLAS standards address the issue of traditional health practices. The response to these comments was to include a reference to traditional health practices in the Commentary to Standard 1. The Commentary cites "being familiar with and respectful of various traditional healing systems and beliefs and, where appropriate, integrating these approaches into treatment plans." The discussion section for this standard in the final report will include additional information and examples.

NPAC members emphasized the need to define "respectful," "effective," "understandable," and "culturally competent" care. The revised standard calls more explicitly for "care that is provided in a manner compatible with [patients'/consumers'] cultural health beliefs and practices and preferred language" rather than merely culturally competent care. This language was recommended by a NPAC member and supported by the committee. The definition and assessment of cultural competence are discussed more fully in the final report. Further explanation of the other terms provided in the Commentary as well as the discussion section of the final report.

Standard 2

One comment pointed out that "diverse staff" and "culturally competent staff" are two distinct concepts that have been combined in a single standard. The conceptual issues raised by combining in one standard two distinct notions about the staff of a culturally competent organization were addressed by separating the two different notions. With the deletion of "culturally competent," Standard 2 now focuses on the need for a diverse staff that reflects the racial/ethnic and cultural profile of the communities being served and is primarily concerned with strategies for staff recruitment and retention. Standard 3 now focuses on the need for cultural competence in that staff and addresses issues related to education and training.

Comments raised concerns about the definition of diverse staff in Standard 2. With additional input from the NPAC, the standard now defines a diverse staff within the standard as one that is "representative of the demographic characteristics of the service area." The standard's accompanying Commentary provides numerous examples of the types of staff members who should reflect the communities' diversity.

Comments criticized the use of the phrase “administrative, clinical, and support staff” in the original draft standard. Although comments differ in their suggested approach, they expressed a consensus that the standard needs to be inclusive of all position levels in an organization. The revised standard substitutes “at all levels of the organization” for “administrative, clinical, and support staff.” The commentary accompanying the standard provides more detailed information about the various position levels and types of staff members that are included in this specification.

Public comments recommended making Standard 2 more inclusive by deleting the words “racial and ethnic.” The phrase was considered too limiting a descriptor of communities and not synonymous with culture or diversity. The term was deleted to encompass all cultural groups in the communities being served.

Public comments indicate that use of the term “qualified” staff within Standard 3 is controversial. Another issue is that the term “qualified” raises questions about its definition, including the different levels of qualification that might be required for various types of staff. NPAC input was sought on whether the term “qualified” should be included within the standard and, if it was to be included, how it should be defined in the Commentary. However, no consensus among the group was reached. One member urged that the issue be addressed in the final report if not in the commentary.

Standard 3

Public comments focused on the nature of the organization’s responsibility in arranging for ongoing education and training. Interpretations differed on whether the original terminology, “arrange for,” implies that the organization itself should conduct in-service training or should be responsible merely for making arrangements and paying for the training to be offered (possibly outside of the organization) to staff members. Substitution of the term “ensure,” along with an explanation in the Commentary of the intent of the standard, clarifies the role of the health care organization.

Comments questioned whether specific types of staff members should be specified in Standard 3. Comments addressed the need to define who should be included in the various staff categories and to include all position levels in an organization. Similar comments were made about Standard 2, and a similar approach was used to revise Standard 3 with the substitution

of “staff at all levels and across all disciplines” for “administrative, clinical, and support staff.”

More than 50 public comments on Standard 3 dealt with ways to offer more explicit guidance on cultural competency education and training. Comments emphasized the need to develop a standard or measures for cultural competency training; offered recommendations on the process of cultural competency education and training as well as specific topics that should be included in cultural competency trainings. Despite the preponderance of comments related to providing greater specificity about the conduct and evaluation of cultural competency education and training, the fact remains that there is no consensus on the definition of cultural competency or what constitutes a culturally competent health professional. Moreover, there are no standard curricula or universally accepted certification or credentialing for cultural competence and no standardized measures for evaluating the effectiveness of cultural competency trainings. Given the lack of certainty or consensus in this area, we sought NPAC advice on whether Standard 3 or its accompanying Commentary should be more prescriptive about the content and process of cultural competency education and training. The Commentary reflects suggestions by NPAC members.

Standards 4 and 5

Comments raised questions about the relationship between standards 4, 5, and 6. The project team originally decided to combine standards 4 and 5 as a complete articulation of the healthcare organization’s responsibility to advertise, offer, and provide language services as stipulated in Title VI of the Civil Rights Act of 1964. However, the NPAC thought that the obligation to provide verbal and written notices was sufficiently important to warrant its own standard. Thus, Standard 4 now addresses the organization’s obligation to offer and provide language assistance services, and standard 5 addresses the obligation to provide verbal and written notices of patients’/consumers’ rights to such services.

Public comments emphasized the need to clarify the link between Standards 4 and 5 and Title VI of the Civil Rights Act of 1964. The link between these standards and Title VI and VII is explicitly highlighted in the Commentary, and organizations are referred to the August 30, 2000 Office for Civil Rights (OCR) guidance on Title VI with respect to LEP individuals

[www.hhs.gov/ocr/lep]. Because of this reference, language in the standard and commentary for standards 4–7 was changed to reflect requirements of terminology in the guidance. For example, the term “language assistance services,” taken from the OCR guidance, was chosen as a generic term for bilingual interpreter services, and written materials in other languages.

A reference to the needs of patience/consumers speaking American Sign Language (ASL) was made in the commentary in response to public comments.

Standard 6

Comments indicated confusion related to the abilities and responsibilities of bilingual staff who do not function as interpreters. Abilities and responsibilities of bilingual staff who communicate directly with patients/consumers are now specified in a paragraph in the commentary. NPAC comments were incorporated into descriptions of what constitutes the competence of these staff members as well as of interpreters. The abilities and responsibilities of interpreter staff are similarly addressed. The commentary now also addresses the need for assuring competence, and the requirements of Title VI with respect to assuring competence.

Numerous public comments and the NPAC raised issues related to the use of family and friends as interpreters. The wording in the standard about family and friends was revised, and additional details are provided in the commentary.

Standard 7

Comments suggested the deletion of the term “translated” and raised concerns about the advisability of merely translating materials versus creating original documents in non-English languages. The new standard no longer uses the term “translated.”

The term “signage” was cited in comments for being too vague and needing clarification. Public comments were addressed by including guidance in the commentary on the types of signage that should be translated. The NPAC suggested that signage in Standard 7 should not include the posted notices already addressed in Standard 5. The language of the standard was further refined to reflect NPAC input, and in the commentary, other types of notices (e.g., regarding patients rights) have been added to examples of way-finding signage.

Comments cited the term “commonly used” as being too “broad” or “unclear.” One concern is that the term could be interpreted as requiring

translation of every document, however insignificant or large. Other comments raised questions about what constituted "patient education materials and other materials." These comments have been addressed by deleting the term "commonly used" and using the broader term "patient-related materials" instead of patient education materials. "Patient-related materials" encompasses alternative formats (see below) as well as various forms, notifications, and health prevention and promotion materials. The standard's commentary refers organizations to the OCR guidance for examples of the types of documents that may be important to translate.

The term "predominant language groups" was commonly cited in public comments, many of which were concerned about the vagueness of the term. However, suggestions for defining the term varied. Public comments have been addressed by revising the language of the standard and including the clarification of requirements in the accompanying commentary. The term "commonly encountered," as suggested in one comment, addresses the need for organizations and providers to assess needs in their particular service areas. It also is consistent with language in OCR Title VI policy guidance, which refers to "regularly encountered" language groups. Because there is existing policy guidance on the Federal mandate for translated materials, the standard's commentary refers to that document for guidance in determining for which language groups materials should be translated.

There was a general consensus among commenters that materials should be consistent with a patient's culture and literacy level. Comments emphasized that literal translation of patient information is not sufficient. Signage and materials also must use culturally appropriate images and take into account people's acculturation levels, medical beliefs, and practice systems. The inappropriately high reading level for forms and health education materials in English was cited often, and this problem is compounded when materials with inappropriate reading levels are translated. The need for consistency with a patient's culture and literacy levels was addressed in the discussion section of the original CLAS standards report. In response to public comments, the wording of the standard itself has been revised to include "easily understood." The new terminology mirrors that used in the first article in the Consumer Bill of Rights and Responsibilities, which states that "Consumers have the right to receive

accurate, *easily understood* information * * *". The term is intended to emphasize the need to help ensure the patient's comprehension of information, a requirement that goes beyond mere literal translation. For further emphasis on this issue, the accompanying commentary for the standard specifies that signage and patient information should be responsive not only to language differences but also to patients' cultures and literacy levels.

Comments called attention to the need for alternative formats to address the needs of people with sensory, developmental, and/or cognitive impairments and persons whose languages lack a written version. Public comments have been addressed by including in the standard's commentary a reference to the need to develop alternative materials as a detail of the standard's requirements. Deletion of the word "written" also addresses the issue raised in comments of providing information for people who are illiterate or whose language has no written form.

Public comments addressed issues concerning the appropriate translation process. In response to such comments, the commentary accompanying the standard now specifies three important aspects of the translation process: use of a trained translator, back translation and/or review by a target audience group, and periodic updates.

Comments expressed concern that standard 7 could be interpreted as a way to replace oral interpretation with translated written materials. Rather than address this important concern by complicating the language of the standard itself, specific reference to the continued importance of oral interpretation is contained in the commentary accompanying the standard.

Standard 8

Comments suggested that a rationale for the standard should be provided. Language from comments and the original report articulate the central nature of this standard, which is now stated in the first paragraph of the commentary.

Comments observed that the word "have" in the original standard lacked the power to convey the critical importance of the activities described in this standard. The response to these comments was to replace "have" with "develop, implement, and promote."

Many comments spoke to the need for integrating CLAS into the mission and activities of the organization. This concept is now articulated in the commentary.

Nearly half of the comments on Standard 8 addressed the issue of internal and external accountability for cultural competence in an organization. Some comments identified a bottom-up or line-staff approach to initiating cultural competence activities, although most comments recognized the need for top management support for cultural competence to assure accountability and longevity, and shared responsibility for implementation throughout the organization. This issue is now raised in the commentary.

One comment directly addressed the need to involve communities and patient/consumers in the development of an organization's management strategy on cultural competence. This issue is now mentioned in the commentary, with a reference to Standard 12, which more fully explores the role of community involvement.

In accordance with suggestions from the NPAC, "management strategy" has been changed to "strategic plan."

Standard 9

Comments pointed out the need to identify the purpose and use of the data collection activities called for in the CLAS standards. These comments have been addressed by describing the purpose of organizational self-assessment at the beginning of the standard's commentary. The role of initial and ongoing organizational self-assessment is described in more detail in the discussion section of the final report.

The NPAC was divided on whether to classify Standard 9 as a guideline or recommendation. The two aspects of the standard—conducting an initial and ongoing self-assessment and integrating measures of cultural and linguistic competence into existing quality improvement activities—were supported by different levels of evidence. Self-assessment was considered by some committee members to be a prerequisite for developing the strategic plan called for in Standard 8. Consequently, this aspect of the standard has been identified as a guideline. Many public comments and NPAC members emphasized the importance of taking organizational self-assessment to another level by assessing the impact of CLAS services on patient care, access, satisfaction, and health outcomes. Because the current evidence base does not support a guideline to link organizational self-assessment with the impact of CLAS on patients, building such links is a recommendation of this standard.

Comments raised issues about the use of patient surveys in organizational self-

assessments. Concerns were expressed about the need for the surveys to be culturally and linguistically appropriate, to be suitable for measuring patient acceptance or compliance, and to be jointly designed with the appropriate patient population. Comments also pointed out the difficulties in identifying valid patient surveys that can be used across cultures and the possibility that a qualitative approach might be more appropriate than patient surveys for finding out how serious organizations are about implementing the CLAS standards. The response to these comments is to include in the commentary a statement that patient/consumer and other community surveys are an important component of organizational self-assessment of cultural and linguistic competence, but they should not constitute the only self-assessment tool. The commentary also notes that these surveys should be culturally and linguistically appropriate. The final report will contain a discussion on patient satisfaction surveys.

Organizational self-assessment appears to be an issue for which many commenters sought clarification. Comments called for more specificity in Standard 9, made suggestions about the processes and components of self-assessment, addressed self-assessment tools, and discussed the need for and appropriateness of indicators and measures of organizational competence in CLAS. Although the general consensus of these comments was that the standard should be more prescriptive regarding the organizational self-assessment, no preferred process, tool, or measures emerged. This situation is mirrored in the field, where there also is a lack of consensus about what constitutes valid tools and measures for organizational cultural competence. Given the lack of information and consensus, we requested NPAC input on what specific details, if any, should be provided to help organizations implement the standard. Input from NPAC members and other experts contributed to a discussion in the final report that will provide examples of ways that some organizations are linking self-assessment with CLAS impact.

Standard 10

Public comments focused on how the standard should describe the data collected on language. Clarification was requested on what was meant by "primary spoken language," and several comments cited the need to address both written and spoken languages. Comments suggested using the term

"preferred" language. The term "preferred" has the advantage of implying that the patient/consumer, rather than the organization's staff, makes the decision about which language is noted in the management information system (MIS) and patient record. The response to the public comments is to use the term "preferred language" as well as both spoken and written languages in the standard. The commentary describes what is meant by "preferred" and "written" language.

One public comment raised the important issue of the potential for variations in data, depending on when they are collected. This comment recognizes that there may be multiple points of entry (e.g., physician's office, pharmacy, and enrollment office) into a health care organization and that information may not be routinely shared across the various service components. To address this issue, the commentary calls for data to be collected at the patient's/consumer's first point of contact with the health care organization and be collected in health records and integrated into the organization's MIS. This requirement is designed to ensure consistency and continuity of information across appropriate service components of the organization.

Public comments emphasized the importance of explaining the purpose of data collection, particularly to populations that may fear negative reprisals for providing personal information. To respond to this important concern, the commentary accompanying the standard lists five purposes for the collection of data on race/ethnicity and language.

More public comments addressed the issue of race/ethnicity data than any other topic related to this standard. Comments focused on how these data should be collected, including the need to collect information on subpopulations and to standardize race/ethnicity data, recommended systems for classifying race and ethnicity, and the importance of self-identified race/ethnicity. To respond to these concerns, the standard's commentary recommends using the standard procedures and racial/ethnic categories specified in the Office of Management and Budget (OMB) standards for maintaining, collecting, and presenting Federal data on race and ethnicity (revision to OMB directive #15) and adapted in the U.S. Census 2000. In keeping with the OMB requirements and Census 2000, the commentary calls for organizations to allow individuals to select more than one race/ethnic category. The commentary also encourages

organizations to enhance their information on subpopulations by collecting additional identifiers such as country of origin.

Comments and NPAC members suggested that data on language be inclusive of diverse dialects or languages such as American Sign Language (ASL). The response to these comments is to specify in the commentary that data collected on language should include dialects and ASL.

Public comments raised the issue of special data collection considerations that should be made in certain cases involving minor children. The response to these comments is to include in the commentary a statement calling for the collection and documentation of information about the preferred language and interpretation needs of non-English-speaking parents of an English-speaking minor child. NPAC input helped modify this statement.

Comments raised concerns about the confidentiality and privacy of individual data collected on language and race/ethnicity. In addition to clarifying the purpose of such data collection, the commentary for Standard 10 requires that health care organizations maintain all patient data according to the highest standard of confidentiality and privacy. In response to NPAC concerns, organizations also are asked to inform patients/consumers about the purposes of data collection and to emphasize that the data will not be used for discriminatory purposes. Additionally, the commentary states that no patient/consumer should be required to provide data on race, ethnicity, or language or be denied care or services if he or she chooses not to provide such information.

Standard 11

Comments cited a lack of clarity in the draft of Standard 11, but no consensus emerged on how to reframe the standard. Our deliberations on how to rewrite Standard 11 centered first on its purpose, which is now stated at the beginning of the commentary. Based on this identified goal, we have honed the focus of the standard on the maintenance of two tools for helping organizations understand their communities (i.e., a demographic, cultural, and epidemiological profile of the community, and a needs assessment) and on the use to which this information should be put (i.e., to plan for and implement responsive services). Additional details provided in the commentary are intended to further clarify the language of the standard.

Public comments suggested that the aggregate data collected under the terms of Standard 11 should be updated regularly. Two comments specifically suggested annual updates. Because many characteristics of a community change over time, it is important that health care organizations ensure that information on their community is up to date. However, some organizations might consider an annual update too burdensome. To address this issue without being too prescriptive, the revised standard requires organizations to maintain a current profile of the community and needs assessment, and the commentary calls for organizations to obtain baseline data and update it regularly.

Comments and the NPAC discussed various methods and information sources that could be used to maintain the profile and the needs assessment. To respond to these comments, the commentary calls for health care organizations to use a variety of methods and information sources and presents examples of each.

Comments suggested that both qualitative and quantitative methods should be used to collect information on the community. These comments have been addressed by calling for the use of qualitative and quantitative methods in the standard's commentary.

Comments emphasized the need to involve the community in data collection efforts. This issue is addressed by including in the standard's commentary the reminder that health care organizations should involve the community in the design and implementation of the community profile and needs assessment in accordance with Standard 12.

At the request of the NPAC, the commentary includes a statement that organizations should not use the collected data for discriminatory purposes.

Standard 12

Many comments focused on wordsmithing changes to the language of the draft standard. The standard has been streamlined, although the major thrust is the same. As rewritten, the standard is intended to be directive, but not prescriptive. The commentary provides a rationale for the standard, examples that elucidate key words, and examples of the types of activities in which communities might become involved.

Comments suggested that both informal and formal mechanisms should be used to facilitate community and patient/consumer involvement. This language has been added to the

standard, along with examples of such mechanisms in the commentary.

Comments suggested using a stronger term than "involvement." At the suggestion of the NPAC, the standard was revised to recommend "participatory, collaborative partnerships" to strengthen the standard.

The NPAC did not achieve consensus on whether Standard 12 should be a guideline or recommendation. Although a summary chart developed by the NPAC at the committee meeting listed Standard 12 under guidelines, some individual members voiced a minority opinion that it should be a recommendation. Given the overwhelming number of public comments about the critical role of community in CLAS, in the final report, this standard is listed as a guideline.

Standard 13

Comments noted the ambiguity of certain terms used in the standard. The standard was rewritten based on several suggestions provided by commenters. "Develop structures and procedures to address" was replaced with "provide a process to identify, prevent, and resolve," and additional details of staff and patient complaints were included in the commentary.

In response to public comments, language was included in the commentary that recognizes that many existing legal requirements cover some of the issues raised in the standard.

NPAC members recommended that staff issues be separated from patient/consumer issues because there are many mechanisms (e.g., EEO, labor grievance processes) within organizations to work with staff-staff problems. The revised standard focuses on conflict and grievance resolution processes for patients/consumers and does not refer to staff issues.

NPAC members expressed concerns that the draft standard did not provide a sufficient link with existing organizational mechanisms for patient complaint/grievance processes. Although it was suggested that complaint processes for cross-cultural issues should be integrated with existing mechanisms rather than be separate parallel systems, it was agreed that the key was that the process be culturally competent and include culturally competent staff. The revised standard calls for organizations to ensure that conflict and grievance resolution processes are culturally and linguistically sensitive and capable of identifying, preventing, and resolving cross-cultural conflicts or complaints by patients/consumers, rather than develop

structures and procedures to address cross-cultural issues.

Standard 14

The requirement in Standard 14 did not appear in any of the source documents for the original CLAS standards report. However, its inclusion as a CLAS standard was recommended and approved by the National Advisory Committee that met in July 1998. The original intent of the standard was to address the accountability of health care organizations to their patients/consumers and communities by calling for organizations to publish an annual report. However, opinions expressed in the public comments differed on the need for this standard as well as on the nature of the report and the extent to which its preparation should involve the community. A major issue was believed to be the fear that the standard would become a mandated process that would be used by Federal agencies as a monitoring tool. The general consensus of comments is that the standard must be more specific if it is to have any meaning.

Given the level of uncertainty about the report's intended purpose and lack of specificity in the draft standard, the NPAC was requested to provide input on the purpose of the annual report and on any details that should be added to the standard or commentary to help organizations implement this standard. The revised standard reflects the NPAC's consensus that the standard should be a recommendation rather than a guideline and that organizations should be encouraged not to make an annual report but rather to regularly make available to the public information about their progress in implementing the CLAS standards. The commentary explains the potential purposes of the standard and provides examples of ways that organizations could report this information.

After consideration of the comments received and further analysis of specific issues, the revised CLAS Standards are presented below.

National Standards for Culturally and Linguistically Appropriate Services in Health Care

Preamble

The following national standards issued by the U.S. Department of Health and Human Services' (HHS) Office of Minority Health (OMH) respond to the need to ensure that all people entering the health care system receive equitable and effective treatment in a culturally and linguistically appropriate manner. These standards for culturally and

linguistically appropriate services (CLAS) are proposed as a means to correct inequities that currently exist in the provision of health services and to make these services more responsive to the individual needs of all patients/consumers. The standards are intended to be inclusive of all cultures and not limited to any particular population group or sets of groups; however, they are especially designed to address the needs of racial, ethnic, and linguistic population groups that experience unequal access to health services. Ultimately, the aim of the standards is to contribute to the elimination of racial and ethnic health disparities and to improve the health of all Americans.

The CLAS standards are primarily directed at health care organizations; however, individual providers are also encouraged to use the standards to make their practices more culturally and linguistically accessible. The principles and activities of culturally and linguistically appropriate services should be integrated throughout an organization and undertaken in partnership with the communities being served.

The 14 standards are organized by themes: Culturally Competent Care (Standards 1–3), Language Access Services (Standards 4–7), and Organizational Supports for Cultural Competence (Standards 8–14). Within this framework, there are three types of standards of varying stringency: mandates, guidelines, and recommendations as follows:

CLAS mandates are current Federal requirements for all recipients of Federal funds (Standards 4, 5, 6, and 7).

CLAS guidelines are activities recommended by OMH for adoption as mandates by Federal, State, and national accrediting agencies (Standards 1, 2, 3, 8, 9, 10, 11, 12, and 13).

CLAS recommendations are suggested by OMH for voluntary adoption by health care organizations (Standard 14).

The standards are also intended for use by:

- Policymakers, to draft consistent and comprehensive laws, regulations, and contract language. This audience would include Federal, State and local legislators, administrative and oversight staff, and program managers
- Accreditation and credentialing agencies, to assess and compare providers who say they offer culturally competent services and to assure quality for diverse populations. This audience would include the Joint

Commission on Accreditation of Healthcare Organizations, the National Committee for Quality Assurance, professional organizations such as the American Medical Association and American Nurses Association, and quality review organizations such as peer review organizations

- Purchasers, to advocate for the needs of ethnic consumers of health benefits, and leverage responses from insurers and health plans. This audience would include government and employer purchasers of health benefits, including labor unions
- Patients, to understand their right to receive accessible and appropriate health care services, and to evaluate whether providers can offer them
- Advocates, to promote quality health care for diverse populations and to assess and monitor care being delivered by providers. The potential audience is wide, including legal services and consumer education/protection agencies; local and national ethnic, immigrant, and other community-focused organizations; and local and national nonprofit organizations that address health care issues.
- Educators, to incorporate cultural and linguistic competence into their curricula and to raise awareness about the impact of culture and language on health care delivery. This audience would include educators from health care professions and training institutions, as well as educators from legal and social services professions
- The health care community in general, to debate and assess the applicability and adoption of culturally and linguistically appropriate health services into standard health care practice

The CLAS standards employ key concepts that are defined as follows:

CLAS standards: The collective set of CLAS mandates, guidelines, and recommendations issued by the HHS Office of Minority Health intended to inform, guide, and facilitate required and recommended practices related to culturally and linguistically appropriate health services.

Culture: “The thoughts, communications, actions, customs, beliefs, values, and institutions of racial, ethnic, religious, or social groups. Culture defines how health care information is received, how rights and protections are exercised, what is considered to be a health problem, how symptoms and concerns about the problem are expressed, who should provide treatment for the problem, and

what type of treatment should be given. In sum, because health care is a cultural construct, arising from beliefs about the nature of disease and the human body, cultural issues are actually central in the delivery of health services treatment and preventive interventions. By understanding, valuing, and incorporating the cultural differences of America’s diverse population and examining one’s own health-related values and beliefs, health care organizations, practitioners, and others can support a health care system that responds appropriately to, and directly serves the unique needs of populations whose cultures may be different from the prevailing culture” (Katz, Michael. Personal communication, November 1998).

Cultural and linguistic competence: “Cultural and linguistic competence is a set of congruent behaviors, attitudes, and policies that come together in a system, agency, or among professionals that enables effective work in cross-cultural situations. ‘Culture’ refers to integrated patterns of human behavior that include the language, thoughts, communications, actions, customs, beliefs, values, and institutions of racial, ethnic, religious, or social groups. ‘Competence’ implies having the capacity to function effectively as an individual and an organization within the context of the cultural beliefs, behaviors, and needs presented by consumers and their communities” (Based on Cross, T., Bazron, B., Dennis, K., & Isaacs, M., (1989). *Towards A Culturally Competent System of Care* Volume I. Washington, DC: Georgetown University Child Development Center, CASSP Technical Assistance Center)

Culturally and linguistically appropriate services: Health care services that are respectful of and responsive to cultural and linguistic needs.

Health care organizations: Any public or private institution involved in any aspect of delivering health care services.

Patients/consumers: Individuals, including accompanying family members, guardians, or companions, seeking physical or mental health care services, or other health-related services.

Staff: Individuals employed directly by a health care organization, as well as those subcontracted or affiliated with the organization.

1. Health Care Organizations Should Ensure That Patients/Consumers Receive From All Staff Members Effective, Understandable, and Respectful Care That Is Provided in a Manner Compatible With Their Cultural Health Beliefs and Practices and Preferred Language

This standard constitutes the fundamental requirement on which all activities specified in the other CLAS standards are based. Its intent is to ensure that all patients/consumers receiving health care services experience culturally and linguistically competent encounters with an organization's staff. The standard is relevant not only to staff, who ultimately are responsible for the kinds of interactions they have with patients, but also to their organizations, which must provide the managers, policies, and systems that support the realities of culturally competent encounters.

Respectful care includes taking into consideration the values, preferences, and expressed needs of the patient/consumer. Understandable care involves communicating in the preferred language of patients/consumers and ensuring that they understand all clinical and administrative information. Effective care results in positive outcomes for patients/consumers, including satisfaction; appropriate preventive services, diagnosis, and treatment; adherence; and improved health status.

Cultural competence includes being able to recognize and respond to health-related beliefs and cultural values, disease incidence and prevalence, and treatment efficacy. Examples of culturally competent care include striving to overcome cultural, language, and communications barriers; providing an environment in which patients/consumers from diverse cultural backgrounds feel comfortable discussing their cultural health beliefs and practices in the context of negotiating treatment options; using community workers as a check on the effectiveness of communication and care; encouraging patients/consumers to express their spiritual beliefs and cultural practices; and being familiar with and respectful of various traditional healing systems and beliefs and, where appropriate, integrating these approaches into treatment plans. When individuals need additional assistance, it may be appropriate to involve a patient advocate, case manager, or ombudsperson with special expertise in cross-cultural issues.

Ways to operationalize this standard include implementing all the other

CLAS standards. For example, in accordance with Standard 3, ensure that staff and other personnel receive cross-cultural education and training, and that their skills in providing culturally competent care are assessed through testing, direct observation, and monitoring of patient/consumer satisfaction with individual staff/personnel encounters. Assessment of staff and other personnel could also be done in the context of regular staff performance reviews or other evaluations that could be included in the organizational self-assessment called for in Standard 9. Health care organizations should provide patients/consumers with information regarding existing laws and policies prohibiting disrespectful or discriminatory treatment or marketing/enrollment practices.

2. Health Care Organizations Should Implement Strategies To Recruit, Retain, and Promote at All Levels of the Organization a Diverse Staff and Leadership That Are Representative of the Demographic Characteristics of the Service Area

The diversity of an organization's staff is a necessary, but not sufficient, condition for providing culturally and linguistically appropriate health care services. Although hiring bilingual and individuals from different cultures does not in itself ensure that the staff is culturally competent and sensitive, this practice is a critical component to the delivery of relevant and effective services for all patients/consumers. Diverse staff is defined in the standard as being representative of the diverse demographic population of the service area and includes the leadership of the organization as well as its governing boards, clinicians, and administrative personnel. Building staff that adequately mirrors the diversity of the patient/consumer population should be based on continual assessment of staff demographics (collected as part of organizational self-assessment in accordance with Standard 9) as well as demographic data from the community maintained in accordance with Standard 11. Staff refers not only to personnel employed by the health care organization but also its subcontracted and affiliated personnel.

Staff diversity at all levels of an organization can play an important role in considering the needs of patients/consumers from various cultural and linguistic backgrounds in the decisions and structures of the organization. Examples of the types of staff members whose backgrounds should reflect the community's diversity include clinical

staff such as doctors, nurses, and allied health professionals; support staff such as receptionists; administrative staff such as individuals in the billing department; clergy and lay volunteers; and high-level decisionmakers such as senior managers, corporate executives, and governing bodies such as boards of directors.

Acknowledging the practical difficulties in achieving full racial, ethnic, and cultural parity within the workforce, this standard emphasizes commitment and a good-faith effort rather than specific outcomes. It focuses not on numerical goals or quotas, but rather on the continuing efforts of an organization to design, implement, and evaluate strategies for recruiting and retaining a diverse staff as well as continual quality evaluation of improvements in this area. The goal of staff diversity should be incorporated into organizations' mission statements, strategic plans, and goals. Organizations should use proactive strategies, such as incentives, mentoring programs, and partnerships with local schools and employment programs, to build diverse workforce capacity. Organizations should encourage the retention of diverse staff by fostering a culture of responsiveness toward the ideas and challenges that a culturally diverse staff offers.

3. Health Care Organizations Should Ensure That Staff at All Levels and Across All Disciplines Receive Ongoing Education and Training in Culturally and Linguistically Appropriate Service Delivery

Hiring a diverse staff does not automatically guarantee the provision of culturally competent care. Staff education and training are also crucial to ensuring CLAS delivery because all staff will interact with patients/consumers representing different countries of origin, acculturation levels, and social and economic standing. Staff refers not only to personnel employed by the health care organization but also its subcontracted and affiliated personnel.

Health care organizations should either verify that staff at all levels and in all disciplines participate in ongoing CME-or CEU-accredited education or other training in CLAS delivery, or arrange for such education and training to be made available to staff. This training should be based on sound educational (*i.e.*, adult learning) principles, include pre- and post-training assessments, and be conducted by appropriately qualified individuals. Training objectives should be tailored for relevance to the particular functions

of the trainees and the needs of the specific populations served, and over time should include the following topics:

- Effects of differences in the cultures of staff and patients/consumers on clinical and other workforce encounters, including effects of the culture of American medicine and clinical training;
- Elements of effective communication among staff and patients/consumers of different cultures and different languages, including how to work with interpreters and telephone language services;
- Strategies and techniques for the resolution of racial, ethnic, or cultural conflicts between staff and patients/consumers;
- Health care organizations' written language access policies and procedures, including how to access interpreters and translated written materials;
- The applicable provisions of:
 - (1) Title VI of the Civil Rights Act of 1964, 42 U.S.C. 2000d, 45 C.F.R. 80.1 *et seq.* (including Office for Civil Rights Guidance on Title VI of the Civil Rights Act of 1964, with respect to services for (LEP) individuals (65 FR 52762–52774, August 30, 2000).
 - Health care organizations' complaint/grievance procedures;
 - Effects of cultural differences on health promotion and disease prevention, diagnosis and treatment, and supportive, rehabilitative, and end-of-life care;
 - Impact of poverty and socioeconomic status, race and racism, ethnicity, and sociocultural factors on access to care, service utilization, quality of care, and health outcomes;
 - Differences in the clinical management of preventable and chronic diseases and conditions indicated by differences in the race or ethnicity of patients/consumers; and
 - Effects of cultural differences among patients/consumers and staff upon health outcomes, patient satisfaction, and clinical management of preventable and chronic diseases and conditions.

Organizations that conduct the trainings should involve community representatives in the development of CLAS education and training programs, in accordance with Standard 12.

4. Health Care Organizations Must Offer and Provide Language Assistance Services, Including Bilingual Staff and Interpreter Services, at No Cost to Each Patient/Consumer With Limited English Proficiency at All Points of Contact, in a Timely Manner During All Hours of Operation

Standards 4, 5, 6, and 7 are based on Title VI of the Civil Rights Act of 1964 (Title VI) with respect to services for limited English proficient (LEP) individuals. Title VI requires all entities receiving Federal financial assistance, including health care organizations, take steps to ensure that LEP persons have meaningful access to the health services that they provide. The key to providing meaningful access for LEP persons is to ensure effective communication between the entity and the LEP person. For complete details on compliance with these requirements, consult the HHS guidance on Title VI with respect to services for (LEP) individuals (65 FR 52762–52774, August 30, 2000) at [www.hhs.gov/ocr/lep].

Language services, as described below, must be made available to each individual with limited English proficiency who seeks services, regardless of the size of the individual's language group in that community. Such an individual cannot speak, read, or understand the English language at a level that permits him or her to interact effectively with clinical or nonclinical staff at a health care organization. (Patients needing services in American Sign Language would also be covered by this standard, although other Federal laws and regulations apply and should be consulted separately.)

Language services include, as a first preference, the availability of bilingual staff who can communicate directly with patients/consumers in their preferred language. When such staff members are not available, face-to-face interpretation provided by trained staff, or contract or volunteer interpreters, is the next preference. Telephone interpreter services should be used as a supplemental system when an interpreter is needed instantly, or when services are needed in an unusual or infrequently encountered language. The competence and qualifications of individuals providing language services are discussed in Standard 6.

5. Health Care Organizations Must Provide to Patients/Consumers in Their Preferred Language Both Verbal Offers and Written Notices Informing Them of Their Right To Receive Language Assistance Services

LEP individuals should be informed—in a language they can understand—that they have the right to free language services and that such services are readily available. At all points of contact, health care organizations should also distribute written notices with this information and post translated signage. Health care organizations should explicitly inquire about the preferred language of each patient/consumer and record this information in all records. The preferred language of each patient/consumer is the language in which he or she feels most comfortable in a clinical or nonclinical encounter.

Some successful methods of informing patients/consumers about language assistance services include: (a) using language identification or "I speak * * *" cards; (b) posting and maintaining signs in regularly encountered languages at all points of entry; (c) creating uniform procedures for timely and effective telephone communication between staff and LEP persons; and (d) including statements about the services available and the right to free language assistance services in appropriate non-English languages in brochures, booklets, outreach materials, and other materials that are routinely distributed to the public.

6. Health Care Organizations Must Assure the Competence of Language Assistance Provided to Limited English Proficient Patients/Consumers by Interpreters and Bilingual Staff. Family and Friends Should Not Be Used To Provide Interpretation Services (Except on Request by the Patient/Consumer)

Accurate and effective communication between patients/consumers and clinicians is the most essential component of the health care encounter. Patients/consumers cannot fully utilize or negotiate other important services if they cannot communicate with the nonclinical staff of health care organizations. When language barriers exist, relying on staff who are not fully bilingual or lack interpreter training frequently leads to misunderstanding, dissatisfaction, omission of vital information, misdiagnoses, inappropriate treatment, and lack of compliance. It is insufficient for health care organizations to use any apparently bilingual—person for delivering language services—they must assess and

ensure the training and competency of individuals who deliver such services.

Bilingual clinicians and other staff who communicate directly with patients/consumers in their preferred language must demonstrate a command of both English and the target language that includes knowledge and facility with the terms and concepts relevant to the type of encounter. Ideally, this should be verified by formal testing. Research has shown that individuals with exposure to a second language, even those raised in bilingual homes, frequently overestimate their ability to communicate in that language, and make errors that could affect complete and accurate communication and comprehension.

Prospective and working interpreters must demonstrate a similar level of bilingual proficiency. Health care organizations should verify the completion of, or arrange for, formal training in the techniques, ethics, and cross-cultural issues related to medical interpreting (a minimum of 40 hours is recommended by the National Council on Interpretation in Health Care). Interpreters must be assessed for their ability to convey information accurately in both languages before they are allowed to interpret in a health care setting.

In order to ensure complete, accurate, impartial, and confidential communication, family, friends or other individuals, should not be required, suggested, or used as interpreters. However, a patient/consumer may choose to use a family member or friend as an interpreter after being informed of the availability of free interpreter services unless the effectiveness of services is compromised or the LEP person's confidentiality is violated. The health care organization's staff should suggest that a trained interpreter be present during the encounter to ensure accurate interpretation and should document the offer and declination in the LEP person's file. Minor children should never be used as interpreters, nor be allowed to interpret for their parents when they are the patients/consumers.

7. Health Care Organizations Must Make Available Easily Understood Patient-Related Materials and Post Signage in the Languages of the Commonly Encountered Groups and/or Groups Represented in the Service Area

An effective language assistance program ensures that written materials routinely provided in English to applicants, patients/consumers, and the public are available in commonly encountered languages other than

English. It is important to translate materials that are essential to patients/consumers accessing and making educated decisions about health care. Examples of relevant patient-related materials include applications, consent forms, and medical or treatment instructions; however, health care organizations should consult OCR guidance on Title VI for more information on what the Office considers to be "vital" documents that are particularly important to ensure translation (65 FR 52762–52774, August 30, 2000) at [www.hhs.gov/ocr/lep].

Commonly encountered languages are languages that are used by a significant number or percentage of the population in the service area. Consult the OCR guidance for guidelines regarding the LEP language groups for which translated written materials should be provided. Persons in language groups that do not fall within these guidelines should be notified of their right to receive oral translation of written materials.

Signage in commonly encountered languages should provide notices of a variety of patient rights, the availability of conflict and grievance resolution processes, and directions to facility services. Way-finding signage should identify or label the location of specific services (e.g., admissions, pediatrics, emergency room). Written notices about patient/consumer rights to receive language assistance services are discussed in Standard 5.

Materials in commonly encountered languages should be responsive to the cultures as well as the levels of literacy of patients/consumers. Organizations should provide notice of the availability of oral translation of written materials to LEP individuals who cannot read or who speak nonwritten languages. Materials in alternative formats should be developed for these individuals as well as for people with sensory, developmental, and/or cognitive impairments.

The obligation to provide meaningful access is not limited to written translations. Oral communication often is a necessary part of the exchange of information, and written materials should never be used as substitutes for oral interpreters. A health care organization that limits its language services to the provision of written materials may not be allowing LEP persons equal access to programs and services available to persons who speak English.

Organizations should develop policies and procedures to ensure development of quality non-English signage and patient-related materials that are

appropriate for their target audiences. At a minimum, the translation process should include translation by a trained individual, back translation and/or review by target audience groups, and periodic updates.

It is important to note that in some circumstances verbatim translation may not accurately or appropriately convey the substance of what is contained in materials written in English. Additionally, health care organizations should be aware of and comply with existing State or local nondiscrimination laws that are not superceded by Federal requirements.

8. Health Care Organizations Should Develop, Implement, and Promote a Written Strategic Plan That Outlines Clear Goals, Policies, Operational Plans, and Management Accountability/Oversight Mechanisms To Provide Culturally and Linguistically Appropriate Services

Successful implementation of the CLAS standards depends on an organization's ability to target attention and resources on the needs of culturally diverse populations. The purpose of strategic planning is to help the organization define and structure activities, policy development, and goal setting relevant to culturally and linguistically appropriate services. It also allows the agency to identify, monitor, and evaluate system features that may warrant implementing new policies or programs consistent with the overall mission.

The attainment of cultural competence depends on the willingness of the organization to learn and adapt values that are explicitly articulated in its guiding mission. A sound strategic plan for CLAS is integrally tied to the organization's mission, operating principles, and service focus. Accountability for CLAS activities must reside at the highest levels of leadership including the governing body of the organization. Without the strategic plan, the organization may be at a disadvantage to identify and prioritize patient/consumer service need priorities.

Designated personnel or departments should have authority to implement CLAS-specific activities as well as to monitor the responsiveness of the whole organization to the cultural and linguistic needs of patients/consumers.

Consistent with Standard 12, the strategic plan should be developed with the participation of consumers, community, and staff who can convey the needs and concerns of all communities and all parts of the organization affected by the strategy.

And, consistent with Standards 9, 10, and 11, the results of data gathering and self-assessment processes should inform the development and refinement of goals, plans, and policies.

9. Health Care Organizations Should Conduct Initial and Ongoing Organizational Self-Assessments of CLAS-Related Activities and Are Encouraged To Integrate Cultural and Linguistic Competence-Related Measures Into Their Internal Audits, Performance Improvement Programs, Patient Satisfaction Assessments, and Outcomes-Based Evaluations

Ideally, these self-assessments should address all the activities called for in the 14 CLAS standards. Initial self-assessment, including an inventory of organizational policies, practices, and procedures, is a prerequisite to developing and implementing the strategic plan called for in Standard 8. Ongoing self-assessment is necessary to determine the degree to which the organization has made progress in implementing all the CLAS standards. The purpose of ongoing organizational self-assessment is to obtain baseline and updated information that can be used to define service needs, identify opportunities for improvement, develop action plans, and design programs and activities. The self-assessment should focus on the capacities, strengths, and weaknesses of the organization in meeting the CLAS standards.

Integrating cultural and linguistic competence-related measures into existing quality improvement activities will also help institutionalize a focus on CLAS within the organization. Linking CLAS-related measures with routine quality and outcome efforts may help build the evidence base regarding the impact of CLAS interventions on access, patient satisfaction, quality, and clinical outcomes.

Patient/consumer and community surveys and other methods of obtaining input are important components of organizational quality improvement activities. But they should not constitute the only method of assessing quality with respect to CLAS. When used, such surveys should be culturally and linguistically appropriate.

10. Health Care Organizations Should Ensure That Data on the Individual Patient's/Consumer's Race, Ethnicity, and Spoken and Written Language Are Collected in Health Records, Integrated Into the Organization's Management Information Systems, and Periodically Updated

The purposes of collecting information on race, ethnicity, and language are to:

- Adequately identify population groups within a service area;
- Ensure appropriate monitoring of patient/consumer needs, utilization, quality of care, and outcome patterns;
- Prioritize allocation of organizational resources;
- Improve service planning to enhance access and coordination of care; and
- Assure that health care services are provided equitably.

Collection of data on self-identified race/ethnicity should adhere to the standard procedures and racial and ethnic categories specified in the Office of Management and Budget's most current policy directive and adapted in the U.S. Census 2000. To improve the accuracy and reliability of race and ethnic identifier data, health care organizations should adapt intake and registration procedures to facilitate patient/consumer self-identification and avoid use of observational/visual assessment methods whenever possible. Individuals should be allowed to indicate all racial and ethnic categories that apply. Health care organizations can enhance their information on subpopulation differences by collecting additional identifiers such as self-identified country of origin, which provides information relevant to patient/consumer care that is unobtainable from other identifiers.

The purpose of collecting information on language is to enable staff to identify the preferred mode of spoken and written communication that a patient/consumer is most comfortable using in a health care encounter. Language data also can help organizations develop language services that facilitate LEP patients/consumers receiving care in a timely manner. To improve the accuracy and reliability of language data, health care organizations should adapt procedures to document patient/consumer preferred spoken and written language. Written language refers to the patient/consumer preference for receiving health-related materials. Data collected on language should include dialects and American Sign Language.

For health encounters that involve or require the presence of a legal parent or

guardian who does not speak English (e.g., when the patient/consumer is a minor or severely disabled), the management information system record and chart should document the language not only of the patient/consumer but also of the accompanying adult(s).

Health care organizations should collect data from patients/consumers at the first point of contact using personnel who are trained to be culturally competent in the data collection process. Health care organizations should inform patients/consumers about the purposes (as stated above) of collecting data on race, ethnicity, and language, and should emphasize that such data are confidential and will not be used for discriminatory purposes. No patient/consumer should be required to provide race, ethnicity, or language information, nor be denied care or services if he or she chooses not to provide such information. All patient/consumer data should be maintained according to the highest standards of ethics, confidentiality, and privacy, and should not be used for discriminatory purposes.

11. Health Care Organizations Should Maintain a Current Demographic, Cultural, and Epidemiological Profile of the Community as Well as a Needs Assessment to Accurately Plan for and Implement Services That Respond to the Cultural and Linguistic Characteristics of the Service Area

The purpose of this standard is to ensure that health care organizations obtain a variety of baseline data and update the data regularly to better understand their communities, and to accurately plan for and implement services that respond to the cultural and linguistic characteristics of the service area.

Health care organizations should regularly use a variety of methods and information sources to maintain data on racial and ethnic groups in the service area. It is important that health care organizations go beyond their own data, such as marketing, enrollment, and termination figures, which may provide an incomplete portrait of the potential patient/consumer population, many of whom may not be aware of or use the organization's services. A more useful and in-depth approach would use data sources such as census figures and/or adjustments, voter registration data, school enrollment profiles, county and State health status reports, and data from community agencies and organizations. Both quantitative and qualitative methods should be used to determine cultural factors related to

patient/consumer needs, attitudes, behaviors, health practices, and concerns about using health care services as well as the surrounding community's resources, assets, and needs related to CLAS. Methods could include epidemiological and ethnographic profiles as well as focus groups, interviews, and surveys conducted in the appropriate languages spoken by the patient/consumer population. Health care organizations should not use the collected data for discriminatory purposes.

In accordance with Standard 12, health care organizations should involve the community in the design and implementation of the community profile and needs assessment.

12. Health Care Organizations Should Develop Participatory, Collaborative Partnerships With Communities and Utilize a Variety of Formal and Informal Mechanisms to Facilitate Community and Patient/Consumer Involvement in Designing and Implementing CLAS—Related Activities

The culturally competent organization views responsive service delivery to a community as a collaborative process that is informed and influenced by community interests, expertise, and needs. Services that are designed and improved with attention to community needs and desires are more likely to be used by patients/consumers, thus leading to more acceptable, responsive, efficient, and effective care. As described below, this standard addresses two levels of consumer/patient and community involvement that are not token in nature, but involve working with the community in a mutual exchange of expertise that will help shape the direction and practices of the health care organization.

Patients/consumers and community representatives should be actively consulted and involved in a broad range of service design and delivery activities. In addition to providing input on the planning and implementation of CLAS activities, they should be solicited for input on broad organizational policies, evaluation mechanisms, marketing and communication strategies, staff training programs, and so forth. There are many formal and informal mechanisms available for this, including participation in governing boards, community advisory committees, ad hoc advisory groups, and community meetings as well as informal conversations, interviews, and focus groups.

Health care organizations should also collaborate and consult with community-based organizations,

providers, and leaders for the purposes of partnering on outreach, building provider networks, providing service referrals, and enhancing public relations with the community being served.

Related to Standard 11, health care organizations should involve relevant community groups and patients/consumers in the implementation of the community profile and needs assessment.

13. Health Care Organizations Should Ensure That Conflict and Grievance Resolution Processes Are Culturally and Linguistically Sensitive and Capable of Identifying, Preventing, and Resolving Cross-Cultural Conflicts or Complaints by Patients/Consumers

This standard requires health care organizations to anticipate and be responsive to the inevitable cross-cultural differences that arise between patients/consumers and the organization and its staff. Ideally, this responsiveness may be achieved by integrating cultural sensitivity and staff diversity into existing complaint and grievance procedures as well as into policies, programs, offices or committees charged with responsibility for patient relations, and legal or ethical issues. When these existing structures are inadequate, new approaches may need to be developed. Patients/consumers who bring racial, cultural, religious, or linguistic differences to the health care setting are particularly vulnerable to experiencing situations where those differences are not accommodated or respected by the health care institution or its staff. These situations may range from differences related to informed consent and advanced directives, to difficulty in accessing services or denial of services, to outright discriminatory treatment. Health care organizations should ensure that all staff members are trained to recognize and prevent these potential conflicts, and that patients are informed about and have access to complaint and grievance procedures that cover all aspects of their interaction with the organization. In anticipation of patients/consumers who are not comfortable with expressing or acting on their own concerns, the organization should have informal and formal procedures such as focus groups, staff-peer observation, and medical record review to identify and address potential conflicts.

Among the steps health care organizations can take to fulfill this standard are: providing cultural competence training to staff who handle complaints and grievances or other legal or ethical conflict issues; providing notice in other languages about the right

of each patient/consumer to file a complaint or grievance; providing the contact name and number of the individual responsible for disposition of a grievance; and offering ombudsperson services. Health care organizations should include oversight and monitoring of these culturally or linguistically related complaints/grievances as part of the overall quality assurance program for the institution.

14. Health Care Organizations Are Encouraged to Regularly Make Available to the Public Information About Their Progress and Successful Innovations in Implementing the CLAS Standards and To Provide Public Notice in Their Communities About the Availability of This Information

Sharing information with the public about a health care organization's efforts to implement the CLAS standards can serve many purposes. It is a way for the organization to communicate to communities and patients/consumers about its efforts and accomplishments in meeting the CLAS standards. It can help institutionalize the CLAS standards by prompting the organization to regularly focus on the extent to which it has implemented each standard. It also can be a mechanism for organizations to learn from each other about new ideas and successful approaches to implementing CLAS.

Health care organizations can exercise considerable latitude in both the information they make available and the means by which they report it to the public. For example, organizations can describe specific organizational changes or new programs that have been instituted in response to the standards, CLAS-related interventions or initiatives undertaken, and/or accomplishments made in meeting the needs of diverse populations. Organizations that wish to provide more in-depth information can report on the data collected about the populations and communities served in accordance with Standard 11 and the self-assessment results gathered from Standard 9. Organizations should not report scores or use data from self-assessment tools that have not been validated. However, as standard self-assessment instruments and performance measures are developed and validated, additional information gathered by using these tools could be made available to the public.

Health care organizations can use a variety of methods to communicate or report information about progress in implementing the CLAS standards, including publication of stand-alone documents focused specifically on cultural and linguistic competence or

inclusion of CLAS components within existing organizational reports and documents. Other channels for sharing this information include the organization's member publications; newsletters targeting the communities being served; presentations at conferences; newspaper articles; television, radio, and other broadcast media; and postings on Web sites.

The complete report, along with supporting material, is available online at www.OMHRC.gov/clas.

Dated: December 15, 2000.

Nathan Stinson, Jr.,

Deputy Assistant Secretary for Minority Health.

[FR Doc. 00-32685 Filed 12-21-00; 8:45 am]

BILLING CODE 4160-17-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control And Prevention

[60Day-01-12]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of Section 3506 (c)(2)(A) of the Paperwork reduction Act of 1995, the Center for Disease Control and Prevention is providing opportunity for public comment on proposed data collection projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call the CDC Reports Clearance Officer on (404) 639-7090.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques for other forms of information technology. Send comments to Anne O'Connor, CDC Assistant Reports

Clearance Officer, 1600 Clifton Road, MS-D24, Atlanta, GA 30333. Written comments should be received within 60 days of this notice.

Proposed Project

Applying Schema Matching to Latex Allergy Prevention -NEW- National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC). The mission of the National Institute for Occupational Safety and Health (NIOSH) is to promote safety and health at work for all people through research and prevention.

This project is a 3-year study that will investigate whether application of schema correspondence theory will increase the effectiveness of NIOSH natural rubber latex (NRL) allergy information brochures. Allergy to NRL has been identified as a significant health risk among workers using latex gloves. NRL allergy may involve the skin (redness, hives, or itching) and/or the respiratory track (runny nose, itchy eyes, sneezing, asthma). Reactions to NRL range from mild to severe enough to require medical attention. In rare instances, anaphylaxis (shock) can occur. A number of studies suggest prevalence of NRL sensitization among healthcare workers ranging from 5-12%. Non-healthcare workers are also at risk for NRL allergy. Prevalence rates of up to 7% for antibodies to NRL allergy have been reported among the general population.

In 1997, NIOSH published Alert: Preventing allergic reactions to natural rubber latex in the workplace. Despite the importance of such NIOSH recommendations, it is unclear how relevant this information is perceived to be by workers. Contemporary models of persuasion consider message relevance to be crucial in determining whether a message will be carefully thought about. Schema correspondence theory proposes that increasing the number of elements in a health and safety message that members of an occupational group can identify with should increase its relevance to that group. Messages are more effective, when individuals can think about themselves as they are presented with the information.

Message development and occupational group selection for this project will be guided by Holland's

Career Typology Theory. This theory postulates that both individuals and occupations may be described in terms of six primary work personality types, each of which is characterized by a distinctive clustering of work-related interests, values and activities. One occupational group from each of the six primary Holland types will be targeted in this study. These groups are: police officers, veterinary assistants, hairstylists, childcare workers, and food service workers. Occupational group specific information, such as work-related interests, values, and activities, will be combined with NRL allergy information to produce brochures tailored for each of the six groups. The effectiveness of the tailored NRL brochures developed by this study will be compared with a "generic", untailored NRL brochure, with the existing NIOSH NRL allergy brochure, Latex Allergy: A Prevention Guide, and with a NRL allergy brochure currently under development by another NIOSH research project.

In a Pretesting Phase, workers will assess statements that will be used to develop the study brochures. These brochures will be assessed in a small scale Pilot Study using samples from each of the six occupational groups. The tailored brochures will be finalized and assessed in a full scale Field Study using samples from each of the six occupational groups. Participants will be asked to read the brochures that have been tailored for their occupational group and then to complete attitude and behavior surveys immediately, and at one and three month follow ups.

This study will contribute significantly to the knowledge concerning the application of schema matching theory to occupational safety and health information. In addition, this study will also provide valuable information regarding the effectiveness of text-based occupational safety and health interventions over time. If proven successful, schema matching could be used by NIOSH to increase the effectiveness of a wide range of occupational safety and health communications. Based on an average hourly wage of \$10.00 among all occupational groups combined, the total annual cost to respondents is \$16,225. This is a 3-year study.

Phase	Number of respondents	Number of responses per respondent	Average time burden (hours) per response	Total burden (hours)
Pretesting	180	1	2.0	360

Phase	Number of respondents	Number of responses per respondent	Average time burden (hours) per response	Total burden (hours)
Pilot Study	375	1	30/60	187.5
Field Study	2,880	3	30/60	4,320
Total				4,867.5

Dated: December 18, 2000.

Chuck Gollmar,

*Deputy Associate Director for Policy,
Planning and Evaluation, Centers for Disease
Control and Prevention, (CDC).*

[FR Doc. 00-32757 Filed 12-21-00; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30DAY-13-01]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these

requests, call the CDC Reports Clearance Officer at (404) 639-7090. Send written comments to CDC, Desk Officer, Human Resources and Housing Branch, New Executive Office Building, Room 10235, Washington, DC 20503. Written comments should be received within 30 days of this notice.

Proposed Project

Nursing Homes' Access to Influenza Vaccine and Use of Rapid Influenza Tests and Antivirals—New—National Center for Infectious Diseases (NCID)—Uncontrolled nursing home influenza outbreaks can result in illness in ≥ 10 percent of residents. Vaccine is the primary means to prevent influenza and its complications. However, outbreaks can occur despite high vaccination levels. The use of rapid diagnostic tests and the timely administration of antiviral medications can lessen the impact of influenza outbreaks. In 1998, a study was conducted among nursing

homes in nine states to determine the use of rimantadine. Since that time, new rapid diagnostic tests and neuraminidase inhibitor antiviral medications have been approved. In addition, a substantial delay in the distribution of influenza vaccine and a possible vaccine shortage are anticipated for the 2000-01 influenza season.

The purpose of this study is to assess nursing homes' access to vaccine in 2000-01, the use of rapid influenza diagnostic tests, and the influenza inhibitor antivirals. A survey will be mailed to sample of randomly selected nursing homes in the same nine states surveyed in 1998. The results will be used to evaluate resident and staff vaccination levels and the use of rapid influenza tests and antiviral medications. We will also assess the relationship between access to vaccine and the concurrence of outbreaks. The total annual burden hours are 573.

Respondents	Number of respondents	Number of responses per respondent	Avg. burden/ respondents (in hrs)
NH Infection Control Nurse—mailed survey	1108	1	20/60
NH Infection Control Nurse—Validation study	204	1	1

Dated: December 18, 2000.

Chuck Gollmar,

*Deputy Associate Director for Policy,
Planning and Evaluation, Centers for Disease
Control and Prevention (CDC).*

[FR Doc. 00-32756 Filed 12-21-00; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control And Prevention

[60Day-01-13]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the

Paperwork reduction Act of 1995, the Center for Disease Control and Prevention is providing opportunity for public comment on proposed data collection projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call the CDC Reports Clearance Officer on (404) 639-7090.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the

burden of the collection of information on respondents, including through the use of automated collection techniques for other forms of information technology. Send comments to Anne O'Connor, CDC Assistant Reports Clearance Officer, 1600 Clifton Road, MS-D24, Atlanta, GA 30333. Written comments should be received within 60 days of this notice.

Proposed Project

Tailoring NIOSH Messages to Individual Health Construal —NEW— National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC). The mission of the the National Institute for Occupational Safety and Health is to promote safety and health at work for all people through research and prevention.

The overall goal of the current project is to examine the effectiveness of tailoring NIOSH web-based communications to the psychological characteristics of the individuals who receive the communications. Typically, NIOSH publications informing at-risk workers about health hazards and safety recommendations are distributed by mail using a printed format. However, the growing use of computers opens the door to a new format for distributing health and safety information to workers: communication of health information via the Web. Importantly, web-based communication makes it possible to tailor health information to particular users. Past research has demonstrated that health-related behavior may be construed positively by an individual, in terms of wellness, or negatively, in terms of illness. The current project tests the effectiveness of message tailoring on this dimension.

This project will examine the effectiveness of tailoring a web communication based on the NIOSH Alert "Preventing Needlestick Injuries in Health Care Settings" to the user's personal construal of this occupational safety issue in terms of wellness or

illness. Over 8 million workers in the United States are employed in health care settings, and it is estimated that between 600,000–800,000 needlestick injuries occur on an annual basis in these settings, mostly involving nurses [Henry and Campbell 1995; EPINet 1999]. These injuries pose both physical and emotional threats to health care workers, as serious infections from bloodborne pathogens may result. Through the use of message tailoring, the proposed project aims to increase health care workers' compliance with the safety recommendation provided in the NIOSH Alert "Preventing Needlestick Injuries in Health Care Settings."

In study 1, attitudinal predictors of needlestick injury prevention behaviors will be assessed for registered nurses who view this issue as a health maintenance issue versus an illness prevention issue. This data will be obtained from a sample of 500 registered nurses who will be asked to complete a mail survey assessing their attitudes and behaviors with regard to preventing needlestick injuries. In a second study, the NIOSH Alert "Preventing Needlestick Injuries in Health Care

Settings" will be modified from the original printed brochure to a web-based format. Two formats of this web-based document will be created that are tailored to nurses who construe the issue of needlestick injuries either positively (in terms of wellness) or negatively (in terms of illness). The impact of tailoring the message format to the nurse's construal of the issue of needlestick injury will be examined in a laboratory setting where 300 participants will indicate whether they construe this issue in terms of maintaining wellness (positively) or in terms of illness prevention (negatively), and will then be randomly assigned to gain or loss frame web communications. The impact of the tailored messages on participants' attitudes and behavioral intentions with regard to needle safety will be assessed.

The results of this project should provide NIOSH with information about how to develop effective Web-based communication strategies. This should have the consequence of enhancing occupational safety and health attitudes and behaviors among at-risk workers. The total cost to respondents is \$8000.

Respondents	No. of respondents	No. of responses/ respondent	Avg. burden per response	Total burden
Registered Nurses	800	1	30/60	400

Dated: December 18, 2000.

Chuck Gollmar,

*Deputy Associate Director for Policy,
Planning and Evaluation Centers for Disease
Control and Prevention, (CDC).*

[FR Doc. 00-32758 Filed 12-21-00; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 01013]

Grants for Acute Care, Rehabilitation and Disability Prevention Research; Notice of Availability of Funds

A. Purpose

The Centers for Disease Control and Prevention (CDC) announces that grant applications are being accepted for Injury Prevention and Control Research Grants for fiscal year (FY) 2001. This announcement is related to the Healthy

People 2010 focus areas of Injury and Violence Prevention.

The purposes of this program announcement are to:

1. Solicit research applications that address the priorities reflected under the heading, "Programmatic Interests."
2. Build the scientific base for the prevention of injuries, disabilities, and deaths.
3. Encourage professionals from a wide spectrum of disciplines such as engineering, bioengineering, medicine, health care, public health, health care research, behavioral and social sciences, and others, to undertake research to prevent and control injuries.

B. Eligible Applicants

Applications may be submitted by public and private nonprofit and for-profit organizations and by governments and their agencies; that is, universities, colleges, research institutions, hospitals, other public and private nonprofit and for-profit organizations, State and local governments or their bona fide agents, and federally recognized Indian tribal

governments, Indian tribes, or Indian tribal organizations, and small, minority, and women-owned businesses.

Current holders of CDC R49 Research grants and R49 Injury Control Research Center (ICRC) grants are eligible to apply for supplemental funding to enhance or expand existing projects or to conduct one year pilot studies. Grantees currently funded under announcements 00024 (Grants for Injury Control Training and Demonstration Center) and 00043 (Grants for National Academic Centers of Excellence on Youth Violence Prevention) are not eligible to apply for supplements.

Note: Public Law 104-65 states that an organization described in section 501(c)(4) of the Internal Revenue Code of 1986 that engages in lobbying activities is not eligible to receive Federal funds constituting an award, grant, cooperative agreement, contract, loan or any other form.

Applications that are incomplete or non-responsive to the below requirements will be returned to the applicant without further consideration.

The following are applicant requirements:

1. A principal investigator, who has conducted research, published the findings in peer-reviewed journals, and has specific authority and responsibility to carry out the proposed project.

2. Demonstrated experience on the applicant's project team in conducting, evaluating, and publishing injury control research in peer-reviewed journals.

3. Effective and well-defined working relationships within the performing organization and with outside entities which will ensure implementation of the proposed activities.

4. The ability to carry out injury control research projects as defined under Addendum 2, (1.a-c). The addendum is contained in the application package.

5. The overall match between the applicant's proposed theme and research objectives, and the program interests as described under the heading, "Programmatic Interests."

C. Availability of Funds

Approximately \$800,000 is expected to be available in FY 2001 for injury research grants to fund approximately three to four awards. The specific program priorities for these funding opportunities are outlined with examples in this announcement under the section, "Programmatic Interests."

It is expected that the awards will begin on or about September 30, 2001, and will be made for a 12-month budget period within a three-year project period. The maximum funding level will not exceed \$300,000 (including both direct and indirect costs) per year or \$900,000 for the three-year project period. Those grantees eligible for supplemental funding may request up to \$150,000 (including both direct and indirect costs) for one year. Supplemental awards will be made for the budget period to coincide with the actual budget period of the grant. Applications that exceed the funding caps of \$300,000 per year for full proposals or \$150,000 for supplemental applications will be excluded from the competition and returned to the applicant. The availability of Federal funding may vary and is subject to change.

Continuation awards within the project period will be made based on satisfactory progress demonstrated by investigators at work-in-progress monitoring workshops (travel expenses for this annual one-day meeting should be included in the applicant's proposed budget) and the achievement of

workplan milestones reflected in the continuation application.

Note: Grant funds will not be made available to support the provision of direct care. Eligible applicants may enter into contracts, including consortia agreements (as set forth in the PHS Grants Policy Statement, dated April 1, 1994), as necessary to meet the requirements of the program and strengthen the overall application.

Programmatic Interests

Acute Care

The National Center for Injury Prevention and Control is soliciting research that will enable emergency and trauma care professionals to maximize their contributions to injury prevention and control. The major areas of research interest are further development of (1) injury surveillance using patient records and population-based registries; (2) clinical prevention services for acute care patients aimed at reducing their risk of future injury; (3) cost-effective trauma care systems at the local, regional, and state levels; and (4) evidence-based practices in prehospital, emergency department, and inpatient trauma care. In the current funding cycle, high priority is placed on applications seeking to:

- Improve the uniformity, quality, and accessibility of emergency-department data for public health surveillance.
- Evaluate the impact of trauma care systems on patient outcomes and costs.

Rehabilitation and Disability

In rehabilitation research and disability prevention, population and community-based research is needed to prevent the occurrence and reduce the severity of disabilities and other adverse outcomes among persons with traumatic brain injury (TBI) and spinal cord injury (SCI). Adverse outcomes include secondary conditions such as pressure ulcers and contractures; cognitive, behavioral, or psychological disorders; and other definable conditions associated with TBI or SCI. In the current funding cycle, high priority is placed on applications seeking to:

- Develop measures for assessing longer-term outcomes of TBI among children ("longer-term" refers to outcomes measured after the acute and sub-acute phases of recovery following injury, e.g., in an interval from about six months to one or more years following injury.)

D. Application Content

Applications should follow the PHS-398 (Rev. 4/98) application and Errata sheet, and should include the following information:

1. The project's focus that justifies the research needs and describes the scientific basis for the research, the expected outcome, and the relevance of the findings to reduce injury morbidity, mortality, disability, and economic losses. This focus should be based on recommendations in "Healthy People 2010" and should seek creative approaches that will contribute to a national program for injury control.

2. Specific, measurable, and time-framed objectives.

3. A detailed plan describing the methods by which the objectives will be achieved, including their sequence. A comprehensive evaluation plan is an essential component of the application.

4. A description of the principal investigator's role and responsibilities.

5. A description of all the project staff regardless of their funding source. It should include their title, qualifications, experience, percentage of time each will devote to the project, as well as that portion of their salary to be paid by the grant.

6. A description of those activities related to, but not supported by the grant.

7. A description of the involvement of other entities that will relate to the proposed project, if applicable. It should include commitments of support and a clear statement of their roles.

8. A detailed first year's budget for the grant with future annual projections, if relevant.

9. An explanation of how the research findings will contribute to the national effort to reduce the morbidity, mortality and disability caused by injuries within three to five years from project start-up.

An applicant organization has the option of having specific salary and fringe benefit amounts for individuals omitted from the copies of the application which are made available to outside reviewing groups. To exercise this option: on the original and five copies of the application, the applicant must use asterisks to indicate those individuals for whom salaries and fringe benefits are not shown; however, the subtotals must still be shown. In addition, the applicant must submit an additional copy of page 4 of Form PHS-398, completed in full, with the asterisks replaced by the salaries and fringe benefits. This budget page will be reserved for internal staff use only.

E. Submission and Deadline

Letter of Intent: Although not a prerequisite of application, a non-binding letter of intent-to-apply is requested from potential applicants. The letter of intent shall be submitted on or before February 6, 2001, to the Grants

Management Specialist identified in the "Where to Obtain Additional Information" section of this announcement. The letter should identify the announcement number, name the principal investigator, and briefly describe the scope and intent of the proposed research work. The letter of intent does not influence review or funding decisions, but the number of letters received will enable CDC to plan the review more effectively and efficiently.

Application Submission: Submit the original and five copies of PHS 398 (OMB Number 0925-0001 and adhere to the instructions on the Errata Instruction sheet for PHS 398). Forms are in the application kit.

On or before March 6, 2001, submit the application to the Grants Management Specialist identified in the "Where to Obtain Additional Information" section of this announcement.

Applications shall be considered as meeting the deadline if they are received at the above address on or before the deadline date; or sent on or before the deadline date, and received in time for submission to the independent review group. Applicants must request a legibly dated U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or the U.S. Postal Service. Private metered postmarks will not be acceptable as proof of timely mailing.

Late Applications: Applications which do not meet the criteria above are considered late applications, will not be considered, and will be returned to the applicant.

F. Evaluation Criteria

Upon receipt, applications will be reviewed by CDC staff for completeness and responsiveness as outlined under the Eligible Applicants Section (Items 1-5).

Incomplete applications and applications that are not responsive will be returned to the applicant without further consideration. It is especially important that the applicant's abstract reflects the project's focus, because the abstract will be used to help determine the responsiveness of the application.

Applications which are complete and responsive may be subjected to a preliminary evaluation (triage) by a peer review committee, the Injury Research Grant Review Committee (IRGRC), to determine if the application is of sufficient technical and scientific merit to warrant further review by the IRGRC; CDC will withdraw from further consideration applications judged to be noncompetitive and promptly notify the

principal investigator/program director and the official signing for the applicant organization. Those applications judged to be competitive will be further evaluated by a dual review process.

Competing Supplemental grant awards may be made when funds are available, to support research work or activities not previously approved by the IRGRC. Applications should be clearly labeled to denote their status as requesting supplemental funding support. These applications will be reviewed by the IRGRC and the secondary review group.

Awards will be determined by the Director of the NCIPC based on priority scores assigned to applications by the primary review committee IRGRC, recommendations by the secondary review committee Advisory Committee for Injury Prevention and Control (ACIPC), consultation with NCIPC senior staff, and the availability of funds.

1. The primary review will be a peer review conducted by the IRGRC. All applications will be reviewed for scientific merit by a committee of no less than three reviewers with appropriate expertise using current National Institutes of Health (NIH) criteria to evaluate the methods and scientific quality of the application. Factors to be considered will include:

a. **Significance.** Does this study address an important problem? If the aims of the application are achieved, how will scientific knowledge be advanced? What will be the effect of these studies on the concepts or methods that drive this field?

b. **Approach.** Are the conceptual framework, design, methods, and analyses adequately developed, well-integrated, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics? Does the project include plans to measure progress toward achieving the stated objectives? Is there an appropriate work plan included?

c. **Innovation.** Does the project employ novel concepts, approaches or methods? Are the aims original and innovative? Does the project challenge or advance existing paradigms, or develop new methodologies or technologies?

d. **Investigator.** Is the principal investigator appropriately trained and well suited to carry out this work? Is the proposed work appropriate to the experience level of the principal investigator and other significant investigator participants? Is there a prior history of conducting injury-related research?

e. **Environment.** Does the scientific environment in which the work will be done contribute to the probability of success? Does the proposed research take advantage of unique features of the scientific environment or employ useful collaborative arrangements? Is there evidence of institutional support? Is there an appropriate degree of commitment and cooperation of other interested parties as evidenced by letters detailing the nature and extent of the involvement?

f. **Ethical Issues.** What provisions have been made for the protection of human subjects and the safety of the research environments? How does the applicant plan to handle issues of confidentiality and compliance with mandated reporting requirements, e.g., suspected child abuse? Does the application adequately address the requirements of 45 CFR 46 for the protection of human subjects?

g. **Study Samples.** Are the samples sufficiently rigorously defined to permit complete independent replication at another site? Have the referral sources been described, including the definitions and criteria? What plans have been made to include women and minorities and their subgroups as appropriate for the scientific goals of the research? How will the applicant deal with recruitment and retention of subjects?

h. **Dissemination.** What plans have been articulated for disseminating findings?

The IRGRC will also examine the appropriateness of the proposed project budget and duration in relation to the proposed research and the availability of data required for the project.

2. The secondary review will be conducted by the Science and Program Review Work Group (SPRWG) from the ACIPC. The ACIPC Federal ex officio members will be invited to attend the secondary review and will receive modified briefing books, (i.e., abstracts, strengths and weaknesses from summary statements, and project officer's briefing materials). Federal ex officio members will be encouraged to participate in deliberations when applications address overlapping areas of research interest so that unwarranted duplication in federally-funded research can be avoided and special subject area expertise can be shared. The NCIPC Division Associate Directors for Science (ADS) or their designees will attend the secondary review in a similar capacity as the Federal ex officio members to assure that research priorities of the announcement are understood and to provide background regarding current research activities. Only SPRWG

members will vote on funding recommendations, and their recommendations will be carried to the entire ACIPC for voting by the ACIPC members in closed session. If any further review is needed by the ACIPC, regarding the recommendations of the SPRWG, the factors considered will be the same as the factors that the SPRWG considered.

The committee's responsibility is to develop funding recommendations for the NCIPC Director based on the results of the primary review, the relevance and balance of proposed research relative to the NCIPC programs and priorities, and to assure that unwarranted duplication of federally-funded research does not occur. The Secondary Review Committee has the latitude to recommend to the NCIPC Director, to reach over better ranked proposals in order to assure maximal impact and balance of proposed research. The factors to be considered will include:

a. The results of the primary review including the application's priority score as the primary factor in the selection process.

b. The relevance and balance of proposed research relative to the NCIPC programs and priorities.

c. The significance of the proposed activities in relation to the priorities and objectives stated in "Healthy People 2010" and the Institute of Medicine report, "Reducing the Burden of Injury".

d. Budgetary considerations.

3. *Continued Funding*: Continuation awards made after FY 2001, but within the project period, will be made on the basis of the availability of funds and the following criteria:

a. The accomplishments reflected in the progress report of the continuation application indicate that the applicant is meeting previously stated objectives or milestones contained in the project's annual workplan and satisfactory progress demonstrated through presentations at work-in-progress monitoring workshops.

b. The objectives for the new budget period are realistic, specific, and measurable.

c. The methods described will clearly lead to achievement of these objectives.

d. The evaluation plan will allow management to monitor whether the methods are effective.

e. The budget request is clearly explained, adequately justified, reasonable and consistent with the intended use of grant funds.

G. Other Requirements

Technical Reporting Requirements

Provide CDC with an original plus two copies of

1. Progress report annually,
2. Financial status report, no more than 90 days after the end of the budget period, and

3. Final financial report and performance report, no more than 90 days after the end of the project period.

4. At the completion of the project, the grant recipient will submit a brief (2,500 to 4,000 words) summary highlighting the findings and their implications for research and policy. CDC will place the summary report and each grant recipient's final report with the National Technical Information Service (NTIS) to further the agency's efforts to make the information more available and accessible to the public.

Send all reports to the Grants Management Specialist identified in the "Where to Obtain Additional Information" section of this announcement.

The following additional requirements are applicable to this program. For a complete description of each see Addendum 1 in the application package.

AR-1 Human Subjects Certification

AR-2 Requirements for inclusion of Women and Racial and Ethnic Minorities in Research

AR-3 Animal Subjects Requirement

AR-7 Executive Order 12372

Review—not applicable for this program announcement

AR-10 Smoke-Free Workplace Requirement

AR-11 Healthy People 2010

AR-12 Lobbying Restrictions

AR-13 Prohibition on Use of CDC funds for Certain Gun Control Activities

AR-21 Small, Minority, and Women-owned Business

H. Authority and Catalog of Federal Domestic Assistance Number

In addition to being authorized under 301 (a) [42 U.S.C. 241(a)] of the Public Health Service Act, this program announcement is also authorized under 391 (a) [42 U.S.C. 280(b)] of the Public Service Health Act. The catalog of Federal Domestic Assistance number is 93.136.

I. Where To Obtain Additional Information

This and other CDC announcements are available through the CDC homepage on the Internet. The address for the CDC homepage is <http://www.cdc.gov>.

To receive additional written information and to request an application kit, call 1-888-GRANTS4 (1-888-472-6874). You will be asked to leave your name and address and will be instructed to identify the Announcement number of interest.

If you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained from:

Angela Webb, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Program Announcement #01013, Centers for Disease Control and Prevention (CDC), 2920 Brandywine Road, Room 3000, Atlanta, Georgia 30341, Telephone (770) 488-2784, Internet address: awebb@cdc.gov.

For program technical assistance, contact: Ted Jones, Program Manager, Office of Research Grants, National Center for Injury Prevention and Control, Centers for Disease Control and Prevention (CDC), 4770 Buford Highway, NE, Mailstop K-58, Atlanta, GA 30341-3724, Telephone (770) 488-4824, Internet address: tmj1@cdc.gov.

Dated: December 18, 2000.

John L. Williams,

Director, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 00-32753 Filed 12-21-00; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 01014]

Grants for Traumatic Injury Biomechanics Research; Notice of Availability of Funds

A. Purpose

The Centers for Disease Control and Prevention (CDC) announces that grant applications are being accepted for Injury Prevention and Control Research Grants for fiscal year (FY) 2001. This announcement is related to the Healthy People 2010 focus areas of Injury and Violence Prevention.

The purposes of this program announcement are to:

1. Solicit research applications that address the priorities reflected under the heading, "Programmatic Interests."

2. Build the scientific base for the prevention of injuries, disabilities, and deaths.

3. Encourage professionals from a wide spectrum of disciplines such as engineering, bioengineering, medicine, health care, public health, health care research, behavioral and social sciences, and others, to undertake research to prevent and control injuries.

B. Eligible Applicants

Applications may be submitted by public and private nonprofit and for-profit organizations and by governments and their agencies; that is, universities, colleges, research institutions, hospitals, other public and private nonprofit and for-profit organizations, State and local governments or their bona fide agents, and federally recognized Indian tribal governments, Indian tribes, or Indian tribal organizations, and small, minority, and women-owned businesses.

Current holders of CDC R49 Research grants and R49 Injury Control Research Center (ICRC) grants are eligible to apply for supplemental funding to enhance or expand existing projects or to conduct one year pilot studies. Grantees currently funded under announcements 00024 (Grants for Injury Control Training and Demonstration Center) and 00043 (Grants for National Academic Centers of Excellence on Youth Violence Prevention) are not eligible to apply for supplements.

Note: Public Law 104-65 states that an organization described in section 501(c)(4) of the Internal Revenue Code of 1986 that engages in lobbying activities is not eligible to receive Federal funds constituting an award, grant, cooperative agreement, contract, loan or any other form.

Applications that are incomplete or non-responsive to the below requirements will be returned to the applicant without further consideration. The following are applicant requirements:

1. A principal investigator, who has conducted research, published the findings in peer-reviewed journals, and has specific authority and responsibility to carry out the proposed project.
2. Demonstrated experience on the applicant's project team in conducting, evaluating, and publishing injury control research in peer-reviewed journals.
3. Effective and well-defined working relationships within the performing organization and with outside entities which will ensure implementation of the proposed activities.
4. The ability to carry out injury control research projects as defined under Addendum 2, (1.a-c). The addendum is contained in the application package.
5. The overall match between the applicant's proposed theme and research objectives, and the program interests as described under the heading, "Programmatic Interests."

C. Availability of Funds

Approximately \$1.2 million is expected to be available in FY 2001 for

injury research grants to fund approximately four to five awards. The specific program priorities for these funding opportunities are outlined with examples in this announcement under the section, "Programmatic Interests."

It is expected that the awards will begin on or about September 30, 2001, and will be made for a 12-month budget period within a three-year project period. The maximum funding level will not exceed \$300,000 (including both direct and indirect costs) per year or \$900,000 for the three-year project period. Those grantees eligible for supplemental funding may request up to \$150,000 (including both direct and indirect costs) for one year. Supplemental awards will be made for the budget period to coincide with the actual budget period of the grant. Applications that exceed the funding cap of \$300,000 per year will be excluded from the competition and returned to the applicant. The availability of Federal funding may vary and is subject to change.

Continuation awards within the project period will be made based on satisfactory progress demonstrated by investigators at work-in-progress monitoring workshops (travel expenses for this annual one-day meeting should be included in the applicant's proposed budget), and the achievement of workplan milestones reflected in the continuation application.

Note: Grant funds will not be made available to support the provision of direct care. Eligible applicants may enter into contracts, including consortia agreements (as set forth in the PHS Grants Policy Statement, dated April 1, 1994), as necessary to meet the requirements of the program and strengthen the overall application.

Programmatic Interests

The National Center of Injury Prevention and Control (NCIPC) is soliciting investigator-initiated research that will help expand and advance our understanding of injury causation. Traumatic injury biomechanics research is especially needed to understand the injury mechanisms that lead to long-term disability from brain and spinal cord injuries.

1. Research to advance the biomechanical understanding of traumatic brain and spinal cord injuries (TBI/SCI), thoracic and abdominal injuries resulting from blunt impact, and injuries occurring to the extremities and joints.

2. Evaluate, from a biomechanical perspective, intervention concepts and strategies such as multi-use recreational helmets, mouth- and face-protection devices for athletes, energy-absorbing

playground surfaces, hip pads, and motor vehicle side-impact and rollover countermeasures.

3. Define human tolerance limits for injury; develop biofidelic models to elucidate injury physiology as well as pharmacologic, surgical, rehabilitation, and other interventions; improve injury assessment technology; increase understanding of impact injury mechanisms; and quantify injury-related biomechanical responses for critical areas of the human body (e.g., brain and vertebral injury with spinal cord involvement).

Funding Preferences

While extending and adapting results and conclusions of the above efforts to the entire population is desirable, additional consideration will be given to proposals that emphasize research especially applicable to young children, women (and, in particular, pregnant women), and/or the elderly.

D. Application Content

Applications should follow the PHS-398 (Rev. 4/98) application and Errata sheet, and should include the following information:

1. The project's focus that justifies the research needs and describes the scientific basis for the research, the expected outcome, and the relevance of the findings to reduce injury morbidity, mortality, disability, and economic losses. This focus should be based on recommendations in "Healthy People 2010" and should seek creative approaches that will contribute to a national program for injury control.
2. Specific, measurable, and time-framed objectives.
3. A detailed plan describing the methods by which the objectives will be achieved, including their sequence. A comprehensive evaluation plan is an essential component of the application.
4. A description of the principal investigator's role and responsibilities.
5. A description of all the project staff regardless of their funding source. It should include their title, qualifications, experience, percentage of time each will devote to the project, as well as that portion of their salary to be paid by the grant.
6. A description of those activities related to, but not supported by the grant.
7. A description of the involvement of other entities that will relate to the proposed project, if applicable. It should include commitments of support and a clear statement of their roles.
8. A detailed first year's budget for the grant with future annual projections, if relevant.

9. An explanation of how the research findings will contribute to the national effort to reduce the morbidity, mortality and disability caused by injuries within three to five years from project start-up.

An applicant organization has the option of having specific salary and fringe benefit amounts for individuals omitted from the copies of the application which are made available to outside reviewing groups. To exercise this option: on the original and five copies of the application, the applicant must use asterisks to indicate those individuals for whom salaries and fringe benefits are not shown; however, the subtotals must still be shown. In addition, the applicant must submit an additional copy of page 4 of Form PHS-398, completed in full, with the asterisks replaced by the salaries and fringe benefits. This budget page will be reserved for internal staff use only.

E. Submission and Deadline

Letter of Intent

Although not a prerequisite of application, a non-binding letter of intent-to-apply is requested from potential applicants. The letter of intent shall be submitted on or before February 7, 2001, to the Grants Management Specialist identified in the "Where to Obtain Additional Information" section of this announcement. The letter should identify the announcement number, name the principal investigator, and briefly describe the scope and intent of the proposed research work. The letter of intent does not influence review or funding decisions, but the number of letters received will enable CDC to plan the review more effectively and efficiently.

Application Submission

Submit the original and five copies of PHS 398 (OMB Number 0925-0001 and adhere to the instructions on the Errata Instruction sheet for PHS 398). Forms are in the application kit.

On or before March 7, 2001, submit the application to the Grants Management Specialist identified in the "Where to Obtain Additional Information" section of this announcement.

Applications shall be considered as meeting the deadline if they are received at the above address on or before the deadline date; or sent on or before the deadline date, and received in time for submission to the independent review group. Applicants must request a legibly dated U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or the U.S. Postal Service. Private

metered postmarks will not be acceptable as proof of timely mailing.

Late Applications: Applications which do not meet the criteria above are considered late applications, will not be considered, and will be returned to the applicant.

F. Evaluation Criteria

Upon receipt, applications will be reviewed by CDC staff for completeness and responsiveness as outlined under the Eligible Applicants Section (Items 1-5). Incomplete applications and applications that are not responsive will be returned to the applicant without further consideration. It is especially important that the applicant's abstract reflects the project's focus, because the abstract will be used to help determine the responsiveness of the application.

Applications which are complete and responsive may be subjected to a preliminary evaluation (triage) by a peer review committee, the Injury Research Grant Review Committee (IRGRC), to determine if the application is of sufficient technical and scientific merit to warrant further review by the IRGRC; CDC will withdraw from further consideration applications judged to be noncompetitive and promptly notify the principal investigator/program director and the official signing for the applicant organization. Those applications judged to be competitive will be further evaluated by a dual review process.

Competing Supplemental grant awards may be made when funds are available, to support research work or activities not previously approved by the IRGRC. Applications should be clearly labeled to denote their status as requesting supplemental funding support. These applications will be reviewed by the IRGRC and the secondary review group.

Awards will be determined by the Director of the NCIPC based on priority scores assigned to applications by the primary review committee IRGRC, recommendations by the secondary review committee Advisory Committee for Injury Prevention and Control (ACIPC), consultation with NCIPC senior staff, and the availability of funds.

1. The primary review will be a peer review conducted by the IRGRC. All applications will be reviewed for scientific merit by a committee of no less than three reviewers with appropriate expertise using current National Institutes of Health (NIH) criteria to evaluate the methods and scientific quality of the application. Factors to be considered will include:

a. Significance. Does this study address an important problem? If the

aims of the application are achieved, how will scientific knowledge be advanced? What will be the effect of these studies on the concepts or methods that drive this field?

b. Approach. Are the conceptual framework, design, methods, and analyses adequately developed, well-integrated, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics? Does the project include plans to measure progress toward achieving the stated objectives? Is there an appropriate work plan included?

c. Innovation. Does the project employ novel concepts, approaches or methods? Are the aims original and innovative? Does the project challenge or advance existing paradigms, or develop new methodologies or technologies?

d. Investigator. Is the principal investigator appropriately trained and well suited to carry out this work? Is the proposed work appropriate to the experience level of the principal investigator and other significant investigator participants? Is there a prior history of conducting injury-related research?

e. Environment. Does the scientific environment in which the work will be done contribute to the probability of success? Does the proposed research take advantage of unique features of the scientific environment or employ useful collaborative arrangements? Is there evidence of institutional support? Is there an appropriate degree of commitment and cooperation of other interested parties as evidenced by letters detailing the nature and extent of the involvement?

f. Ethical Issues. What provisions have been made for the protection of human subjects and the safety of the research environments? How does the applicant plan to handle issues of confidentiality and compliance with mandated reporting requirements, *e.g.*, suspected child abuse? Does the application adequately address the requirements of 45 CFR 46 for the protection of human subjects?

g. Study Samples. Are the samples sufficiently rigorously defined to permit complete independent replication at another site? Have the referral sources been described, including the definitions and criteria? What plans have been made to include women and minorities and their subgroups as appropriate for the scientific goals of the research? How will the applicant deal with recruitment and retention of subjects?

h. Dissemination. What plans have been articulated for disseminating findings?

The IRGRC will also examine the appropriateness of the proposed project budget and duration in relation to the proposed research and the availability of data required for the project.

2. The secondary review will be conducted by the Science and Program Review Work Group (SPRWG) from the ACIPC. The ACIPC Federal ex officio members will be invited to attend the secondary review and will receive modified briefing books, (*i.e.*, abstracts, strengths and weaknesses from summary statements, and project officer's briefing materials). Federal ex officio members will be encouraged to participate in deliberations when applications address overlapping areas of research interest so that unwarranted duplication in federally-funded research can be avoided and special subject area expertise can be shared. The NCIPC Division Associate Directors for Science (ADS) or their designees will attend the secondary review in a similar capacity as the Federal ex officio members to assure that research priorities of the announcement are understood and to provide background regarding current research activities.

Only SPRWG members will vote on funding recommendations, and their recommendations will be carried to the entire ACIPC for voting by the ACIPC members in closed session. If any further review is needed by the ACIPC, regarding the recommendations of the SPRWG, the factors considered will be the same as the factors that the SPRWG considered.

The committee's responsibility is to develop funding recommendations for the NCIPC Director based on the results of the primary review, the relevance and balance of proposed research relative to the NCIPC programs and priorities, and to assure that unwarranted duplication of federally-funded research does not occur. The Secondary Review Committee has the latitude to recommend to the NCIPC Director, to reach over better ranked proposals in order to assure maximal impact and balance of proposed research. The factors to be considered will include:

a. The results of the primary review including the application's priority score as the primary factor in the selection process.

b. The relevance and balance of proposed research relative to the NCIPC programs and priorities.

c. The significance of the proposed activities in relation to the priorities and objectives stated in "Healthy People

2010" and the Institute of Medicine report, "Reducing the Burden of Injury".

d. Budgetary considerations.

3. *Continued Funding*

Continuation awards made after FY 2001, but within the project period, will be made on the basis of the availability of funds and the following criteria:

a. The accomplishments reflected in the progress report of the continuation application indicate that the applicant is meeting previously stated objectives or milestones contained in the project's annual workplan and satisfactory progress demonstrated through presentations at work-in-progress monitoring workshops.

b. The objectives for the new budget period are realistic, specific, and measurable.

c. The methods described will clearly lead to achievement of these objectives.

d. The evaluation plan will allow management to monitor whether the methods are effective.

e. The budget request is clearly explained, adequately justified, reasonable and consistent with the intended use of grant funds.

G. Other Requirements

Technical Reporting Requirements

Provide CDC with an original plus two copies of

1. Progress report annually,
2. Financial status report, no more than 90 days after the end of the budget period, and
3. Final financial report and performance report, no more than 90 days after the end of the project period.
4. At the completion of the project, the grant recipient will submit a brief (2,500 to 4,000 words) summary highlighting the findings and their implications for research and policy. CDC will place the summary report and each grant recipient's final report with the National Technical Information Service (NTIS) to further the agency's efforts to make the information more available and accessible to the public.

Send all reports to the Grants Management Specialist identified in the "Where to Obtain Additional Information" section of this announcement.

The following additional requirements are applicable to this program. For a complete description of each see Addendum 1 in the application package.

- AR-1 Human Subjects Certification
- AR-2 Requirements for inclusion of Women and Racial and Ethnic Minorities in Research
- AR-3 Animal Subjects Requirement

AR-7 Executive Order 12372 Review—not applicable for this program announcement

AR-10 Smoke-Free Workplace Requirement

AR-11 Healthy People 2010

AR-12 Lobbying Restrictions

AR-13 Prohibition on Use of CDC funds for Certain Gun Control Activities

AR-21 Small, Minority, and Women-owned Business

H. Authority and Catalog of Federal Domestic Assistance Number

In addition to being authorized under 301 (a) [42 U.S.C. 241(a)] of the Public Health Service Act, this program announcement is also authorized under 391 (a) [42 U.S.C. 280(b)] of the Public Service Health Act. The catalog of Federal Domestic Assistance number is 93.136.

I. Where To Obtain Additional Information

This and other CDC announcements are available through the CDC homepage on the Internet. The address for the CDC homepage is <http://www.cdc.gov>.

To receive additional written information and to request an application kit, call 1-888-GRANTS4 (1-888-472-6874). You will be asked to leave your name and address and will be instructed to identify the Announcement number of interest.

If you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained from:

Angela Webb, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office

Program Announcement #01014, Centers for Disease Control and Prevention (CDC), 2920 Brandywine Road, Room 3000, Atlanta, Georgia 30341, Telephone (770) 488-2784, Internet address: awebb@cdc.gov.

For program technical assistance, contact: Ted Jones, Program Manager, Office of Research Grants, National Center for Injury Prevention and Control, Centers for Disease Control and Prevention (CDC), 4770 Buford Highway, NE, Mailstop K-58, Atlanta, GA 30341-3724, Telephone (770) 488-4824, Internet address: tmj1@cdc.gov.

Dated: December 18, 2000.

John L. Williams,

Director, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 00-32752 Filed 12-21-00; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 01015]

Grants for Unintentional Injury Prevention Research; Notice of Availability of Funds

A. Purpose

The Centers for Disease Control and Prevention (CDC) announces that grant applications are being accepted for Injury Prevention and Control Research Grants for fiscal year (FY) 2001. This announcement is related to the Healthy People 2010 focus area of Injury and Violence Prevention.

The purposes of this program announcement are to:

1. Solicit research applications that address the priorities reflected under the heading, "Programmatic Interests."
2. Build the scientific base for the prevention of injuries, disabilities, and deaths.

3. Encourage professionals from a wide spectrum of disciplines such as engineering, bioengineering, medicine, health care, public health, health care research, behavioral and social sciences, and others, to undertake research to prevent and control injuries.

B. Eligible Applicants

Applications may be submitted by public and private nonprofit and for-profit organizations and by governments and their agencies; that is, universities, colleges, research institutions, hospitals, other public and private nonprofit and for-profit organizations, State and local governments or their bona fide agents, and federally recognized Indian tribal governments, Indian tribes, or Indian tribal organizations, and small, minority, and women-owned businesses.

Current holders of CDC R49 Research grants and R49 Injury Control Research Center (ICRC) grants are eligible to apply for supplemental funding to enhance or expand existing projects or to conduct one year pilot studies. Grantees currently funded under announcements 00024 (Grants for Injury Control Training and Demonstration Center) and 00043 (Grants for National Academic Centers of Excellence on Youth Violence Prevention) are not eligible to apply for supplements.

Note: Public Law 104-65 states that an organization described in section 501(c)(4) of the Internal Revenue Code of 1986 that engages in lobbying activities is not eligible to receive Federal funds constituting an

award, grant, cooperative agreement, contract, loan or any other form.

Applications that are incomplete or non-responsive to the below requirements will be returned to the applicant without further consideration. The following are applicant requirements:

1. A principal investigator, who has conducted research, published the findings in peer-reviewed journals, and has specific authority and responsibility to carry out the proposed project.
2. Demonstrated experience on the applicant's project team in conducting, evaluating, and publishing injury control research in peer-reviewed journals.
3. Effective and well-defined working relationships within the performing organization and with outside entities which will ensure implementation of the proposed activities.
4. The ability to carry out injury control research projects as defined under Addendum 2, (1.a-c). The addendum is contained in the application package.
5. The overall match between the applicant's proposed theme and research objectives, and the program interests as described under the heading, "Programmatic Interests."

C. Availability of Funds

Approximately \$800,000 is expected to be available in FY 2001 for injury research grants to fund approximately three to four awards. The specific program priorities for these funding opportunities are outlined with examples in this announcement under the section, "Programmatic Interests."

It is expected that the awards will begin on or about September 30, 2001, and will be made for a 12-month budget period within a three-year project period. The maximum funding level will not exceed \$275,000 (including both direct and indirect costs) per year or \$825,000 for the three-year project period. Those grantees eligible for supplemental funding may request up to \$150,000 (including both direct and indirect costs) for one year. Supplemental awards will be made for the budget period to coincide with the actual budget period of the grant. Applications that exceed the funding cap of \$275,000 per year will be excluded from the competition and returned to the applicant. The availability of Federal funding may vary and is subject to change.

Continuation awards within the project period will be made based on satisfactory progress demonstrated by investigators at work-in-progress monitoring workshops (travel expenses

for this annual one-day meeting should be included in the applicant's proposed budget), and the achievement of workplan milestones reflected in the continuation application.

Note: Grant funds will not be made available to support the provision of direct care. Eligible applicants may enter into contracts, including consortia agreements (as set forth in the PHS Grants Policy Statement, dated April 1, 1994), as necessary to meet the requirements of the program and strengthen the overall application.

Programmatic Interests

The National Center for Injury Prevention and Control (NCIPC) is soliciting research on unintentional injury that will contribute to the understanding of what works in community-based intervention trials. Primary research interest is the rigorous assessment of the effectiveness (i.e., the impact or outcome) of interventions to reduce unintentional injury. Research should focus on efficacy and effectiveness of interventions that affect risk behaviors and environments, such as the development and evaluation of promising new interventions or the evaluation of known and widely implemented interventions for which evaluation is needed.

When planning and evaluating interventions, applicants are encouraged to use a theoretical framework (i.e., applying "stages of change" theory, protection-motivation theory, behavioral analysis, elements of social learning or social cognitive theory to modify self-protective behaviors, or behavioral safety strategies in non-occupational settings). Proposals to implement interventions that creatively use several theoretical approaches simultaneously are also encouraged.

General Priorities: (applies to a variety of injury problems, in no particular order)

1. Application of human factors research (ergonomics, design, and engineering systems involving both technological and human components) to improve non-occupational safety such as safe bicycling, fall prevention, or to reduce distracted or drowsy driving.

2. Research on the effects of communications-based strategies that hold promise to reduce injury and injury risk behaviors (e.g., risk assessment and risk perception research, patient education, and screening and brief clinical interventions or counseling).

3. Research on the relationship between alcohol, depression and other psychological factors related to motor

vehicle injuries, falls, and other unintentional injuries.

Residential and Recreational Injury Prevention (in No Particular Order)

4. Develop models to understand the role of adult supervision and care giver behavior related to child and older adult injuries. Evaluate interventions to improve the amount and quality of supervision and care giving to reduce injuries. Develop interventions to modify safety skills and behaviors of care givers and of children and older adults to prevent unintentional injuries at home and/or in recreational settings.

5. Conduct research on the relationship of drowning or near drowning to risks and preventive strategies such as swimming skills, risky behaviors, alcohol use, pool environments (e.g., four-sided pool fencing, pool covers, pool alarms), parental education and skills related to supervision, life guard protection and practices, or legislation requiring personal flotation devices or residential pool fencing.

6. Evaluate the effectiveness of school injury-prevention curricula on changes in injury risk behaviors, knowledge, social norms, and attitudes.

7. Define risk and protective factors related to dog-bite injuries. Evaluate community-based dog-bite prevention programs.

Transportation Injury Prevention (in No Particular Order)

8. Conduct intervention research that leads to improvements in older adult driver safety, (e.g., testing, training, licensing, enforced or voluntary reductions in driving, and using alternative transportation) and their effects on mobility, crashes, and injuries.

9. Evaluate environmental and behavioral programs designed to modify pedestrian risks, especially among children, older adults, and persons with disabilities.

10. Research on the influence of alcohol use (and its reduction), on injuries to pedestrians, bicyclists, new drivers, (such as teens), child passengers, motorcyclists, and the older driver.

11. Conduct research to identify the short- and long-term medical sequelae and costs of non-fatal motor vehicle injuries to better determine the public health impact of motor vehicle crashes.

D. Application Content

Applications should follow the PHS-398 (Rev. 4/98) application and Errata sheet, and should include the following information:

1. The project's focus that justifies the research needs and describes the scientific basis for the research, the expected outcome, and the relevance of the findings to reduce injury morbidity, mortality, disability, and economic losses. This focus should be based on recommendations in "Healthy People 2010" and should seek creative approaches that will contribute to a national program for injury control.

2. Specific, measurable, and time-framed objectives.

3. A detailed plan describing the methods by which the objectives will be achieved, including their sequence. A comprehensive evaluation plan is an essential component of the application.

4. A description of the principal investigator's role and responsibilities.

5. A description of all the project staff regardless of their funding source. It should include their title, qualifications, experience, percentage of time each will devote to the project, as well as that portion of their salary to be paid by the grant.

6. A description of those activities related to, but not supported by the grant.

7. A description of the involvement of other entities that will relate to the proposed project, if applicable. It should include commitments of support and a clear statement of their roles.

8. A detailed first year's budget for the grant with future annual projections, if relevant.

9. An explanation of how the research findings will contribute to the national effort to reduce the morbidity, mortality and disability caused by injuries within three to five years from project start-up.

An applicant organization has the option of having specific salary and fringe benefit amounts for individuals omitted from the copies of the application which are made available to outside reviewing groups. To exercise this option: on the original and five copies of the application, the applicant must use asterisks to indicate those individuals for whom salaries and fringe benefits are not shown; however, the subtotals must still be shown. In addition, the applicant must submit an additional copy of page 4 of Form PHS-398, completed in full, with the asterisks replaced by the salaries and fringe benefits. This budget page will be reserved for internal staff use only.

E. Submission and Deadline

Letter of Intent

Although not a prerequisite of application, a non-binding letter of intent-to-apply is requested from potential applicants. The letter of intent

shall be submitted on or before February 8, 2001, to the Grants Management Specialist identified in the "Where to Obtain Additional Information" section of this announcement. The letter should identify the announcement number, name the principal investigator, and briefly describe the scope and intent of the proposed research work. The letter of intent does not influence review or funding decisions, but the number of letters received will enable CDC to plan the review more effectively and efficiently.

Application Submission

Submit the original and five copies of PHS 398 (OMB Number 0925-0001 and adhere to the instructions on the Errata Instruction sheet for PHS 398). Forms are in the application kit.

On or before March 8, 2001, submit the application to the Grants Management Specialist identified in the "Where to Obtain Additional Information" section of this announcement.

Applications shall be considered as meeting the deadline if they are received at the above address on or before the deadline date; or sent on or before the deadline date, and received in time for submission to the independent review group. Applicants must request a legibly dated U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or the U.S. Postal Service. Private metered postmarks will not be acceptable as proof of timely mailing.

Late Applications: Applications which do not meet the criteria above are considered late applications, will not be considered, and will be returned to the applicant.

F. Evaluation Criteria

Upon receipt, applications will be reviewed by CDC staff for completeness and responsiveness as outlined under the Eligible Applicants Section (Items 1-5). Incomplete applications and applications that are not responsive will be returned to the applicant without further consideration. It is especially important that the applicant's abstract reflects the project's focus, because the abstract will be used to help determine the responsiveness of the application.

Applications which are complete and responsive may be subjected to a preliminary evaluation (triage) by a peer review committee, the Injury Research Grant Review Committee (IRGRC), to determine if the application is of sufficient technical and scientific merit to warrant further review by the IRGRC; CDC will withdraw from further consideration applications judged to be

noncompetitive and promptly notify the principal investigator/program director and the official signing for the applicant organization. Those applications judged to be competitive will be further evaluated by a dual review process.

Competing Supplemental grant awards may be made when funds are available, to support research work or activities not previously approved by the IRGRC. Applications should be clearly labeled to denote their status as requesting supplemental funding support. These applications will be reviewed by the IRGRC and the secondary review group.

Awards will be determined by the Director of the NCIPC based on priority scores assigned to applications by the primary review committee IRGRC, recommendations by the secondary review committee Advisory Committee for Injury Prevention and Control (ACIPC), consultation with NCIPC senior staff, and the availability of funds.

1. The primary review will be a peer review conducted by the IRGRC. All applications will be reviewed for scientific merit by a committee of no less than three reviewers with appropriate expertise using current National Institutes of Health (NIH) criteria to evaluate the methods and scientific quality of the application. Factors to be considered will include:

a. Significance. Does this study address an important problem? If the aims of the application are achieved, how will scientific knowledge be advanced? What will be the effect of these studies on the concepts or methods that drive this field?

b. Approach. Are the conceptual framework, design, methods, and analyses adequately developed, well-integrated, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics? Does the project include plans to measure progress toward achieving the stated objectives? Is there an appropriate work plan included?

c. Innovation. Does the project employ novel concepts, approaches or methods? Are the aims original and innovative? Does the project challenge or advance existing paradigms, or develop new methodologies or technologies?

d. Investigator. Is the principal investigator appropriately trained and well-suited to carry out this work? Is the proposed work appropriate to the experience level of the principal investigator and other significant investigator participants? Is there a prior

history of conducting injury-related research?

e. Environment. Does the scientific environment in which the work will be done contribute to the probability of success? Does the proposed research take advantage of unique features of the scientific environment or employ useful collaborative arrangements? Is there evidence of institutional support? Is there an appropriate degree of commitment and cooperation of other interested parties as evidenced by letters detailing the nature and extent of the involvement?

f. Ethical Issues. What provisions have been made for the protection of human subjects and the safety of the research environments? How does the applicant plan to handle issues of confidentiality and compliance with mandated reporting requirements, *e.g.*, suspected child abuse? Does the application adequately address the requirements of 45 CFR part 46 for the protection of human subjects?

g. Study Samples. Are the samples sufficiently rigorously defined to permit complete independent replication at another site? Have the referral sources been described, including the definitions and criteria? What plans have been made to include women and minorities and their subgroups as appropriate for the scientific goals of the research? How will the applicant deal with recruitment and retention of subjects?

h. Dissemination. What plans have been articulated for disseminating findings?

The IRGRC will also examine the appropriateness of the proposed project budget and duration in relation to the proposed research and the availability of data required for the project.

2. The secondary review will be conducted by the Science and Program Review Work Group (SPRWG) from the ACIPC. The ACIPC Federal ex officio members will be invited to attend the secondary review and will receive modified briefing books, (*i.e.*, abstracts, strengths and weaknesses from summary statements, and project officer's briefing materials). Federal ex officio members will be encouraged to participate in deliberations when applications address overlapping areas of research interest so that unwarranted duplication in federally-funded research can be avoided and special subject area expertise can be shared. The NCIPC Division Associate Directors for Science (ADS) or their designees will attend the secondary review in a similar capacity as the Federal ex officio members to assure that research priorities of the announcement are understood and to

provide background regarding current research activities. Only SPRWG members will vote on funding recommendations, and their recommendations will be carried to the entire ACIPC for voting by the ACIPC members in closed session. If any further review is needed by the ACIPC, regarding the recommendations of the SPRWG, the factors considered will be the same as the factors that the SPRWG considered.

The committee's responsibility is to develop funding recommendations for the NCIPC Director based on the results of the primary review, the relevance and balance of proposed research relative to the NCIPC programs and priorities, and to assure that unwarranted duplication of federally-funded research does not occur. The Secondary Review Committee has the latitude to recommend to the NCIPC Director, to reach over better ranked proposals in order to assure maximal impact and balance of proposed research. The factors to be considered will include:

a. The results of the primary review including the application's priority score as the primary factor in the selection process.

b. The relevance and balance of proposed research relative to NCIPC programs and priorities.

c. The significance of the proposed activities in relation to the priorities and objectives stated in "Healthy People 2010" and the Institute of Medicine report, "Reducing the Burden of Injury".

d. Budgetary considerations.

3. Continued Funding.

Continuation awards made after FY 2001, but within the project period, will be made on the basis of the availability of funds and the following criteria:

a. The accomplishments reflected in the progress report of the continuation application indicate that the applicant is meeting previously stated objectives or milestones contained in the project's annual workplan and satisfactory progress demonstrated through presentations at work-in-progress monitoring workshops.

b. The objectives for the new budget period are realistic, specific, and measurable.

c. The methods described will clearly lead to achievement of these objectives.

d. The evaluation plan will allow management to monitor whether the methods are effective.

e. The budget request is clearly explained, adequately justified, reasonable and consistent with the intended use of grant funds.

G. Other Requirements

Technical Reporting Requirements

Provide CDC with an original plus two copies of:

1. Progress report annually,
 2. Financial status report, no more than 90 days after the end of the budget period, and
 3. Final financial report and performance report, no more than 90 days after the end of the project period.
4. At the completion of the project, the grant recipient will submit a brief (2,500 to 4,000 words) summary highlighting the findings and their implications for research and policy. CDC will place the summary report and each grant recipient's final report with the National Technical Information Service (NTIS) to further the agency's efforts to make the information more available and accessible to the public.

Send all reports to the Grants Management Specialist identified in the "Where to Obtain Additional Information" section of this announcement.

The following additional requirements are applicable to this program. For a complete description of each see Addendum 1 in the application package.

AR-1—Human Subjects Certification
AR-2—Requirements for inclusion of

Women and Racial and Ethnic Minorities in Research

AR-3—Animal Subjects Requirement
AR-7—Executive Order 12372

Review—not applicable for this program announcement

AR-10—Smoke-Free Workplace Requirement

AR-11—Healthy People 2010

AR-12—Lobbying Restrictions

AR-13—Prohibition on Use of CDC funds for Certain Gun Control Activities

AR-21—Small, Minority, Women-owned Business

H. Authority and Catalog of Federal Domestic Assistance Number

In addition to being authorized under 301 (a) [42 U.S.C. 241(a)] of the Public Health Service Act, this program announcement is also authorized under 391 (a) [42 U.S.C. 280(b)] of the Public Service Health Act. The catalog of Federal Domestic Assistance number is 93.136.

I. Where To Obtain Additional Information

This and other CDC announcements are available through the CDC homepage on the Internet. The address for the CDC homepage is <http://www.cdc.gov>.

To receive additional written information and to request an

application kit, call 1-888-GRANTS4 (1-888-472-6874). You will be asked to leave your name and address and will be instructed to identify the Announcement number of interest.

If you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained from: Angela Webb, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Program Announcement #01015, Centers for Disease Control and Prevention (CDC), 2920 Brandywine Road, Room 3000, Atlanta, Georgia 30341; Telephone (770) 488-2784. Internet address: awebb@cdc.gov.

For program technical assistance, contact: Ted Jones, Program Manager, Office of Research Grants, National Center for Injury Prevention and Control, Centers for Disease Control and Prevention (CDC), 4770 Buford Highway, NE, Mailstop K-58, Atlanta, GA 30341-3724; Telephone (770) 488-4824. Internet address: tmj1@cdc.gov.

Dated: December 18, 2000.

John L. Williams,

Director, Procurement and Grants Office; Centers for Disease Control and Prevention (CDC).

[FR Doc. 00-32755 Filed 12-21-00; 8:45 am]

BILLING CODE 4163-18-U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Announcement 01016]

Grants for Violence-Related Injury Prevention Research; Notice of Availability of Funds

A. Purpose

The Centers for Disease Control and Prevention (CDC) announces that grant applications are being accepted for Injury Prevention and Control Research Grants for fiscal year (FY) 2001. This announcement is related to the Healthy People 2010 priority areas of Violence and Abuse Prevention, visit the internet site: <http://www.health.gov/healthypeople>.

The purposes of this program are to:

1. Solicit research applications that address the priorities reflected under the section "Programmatic Interests."
2. Build the scientific base for the prevention of injuries, disabilities, and deaths due to violence.
3. Encourage professionals from a wide spectrum of disciplines such as public health, health care, medicine,

criminal justice, and behavioral and social sciences, to work together and undertake research to prevent and control injuries that result from violence.

B. Eligible Applicants

Applications may be submitted by public and private nonprofit and for-profit organizations and by governments and their agencies; that is, universities, colleges, research institutions, hospitals, other public and private nonprofit and for-profit organizations, State and local governments or their bona fide agents, and federally recognized Indian tribal governments, Indian tribes, or Indian tribal organizations, and small, minority, and women-owned businesses.

Current holders of CDC R49 Research grants and R49 Injury Control Research Center (ICRC) grants are eligible to apply for supplemental funding to enhance or expand existing projects or to conduct one year pilot studies. Grantees currently funded under announcements 00024 (Grants for Injury Control Training and Demonstration Center) and 00043 (Grants for National Academic Centers of Excellence on Youth Violence Prevention) are not eligible to apply for supplements.

Note: Public Law 104-65 states that an organization described in section 501(c)(4) of the Internal Revenue Code of 1986 that engages in lobbying activities is not eligible to receive Federal funds constituting an award, grant, cooperative agreement, contract, loan or any other form.

Applications that are incomplete or non-responsive to the below requirements will be returned to the applicant without further consideration. The following are applicant requirements:

1. A principal investigator, who has conducted research, published the findings in peer-reviewed journals, and has specific authority and responsibility to carry out the proposed project.
2. Demonstrated experience on the applicant's project team in conducting, evaluating, and publishing injury control research in peer-reviewed journals.
3. Effective and well-defined working relationships within the performing organization and with outside entities which will ensure implementation of the proposed activities.
4. The ability to carry out injury control research projects as defined under Addendum 2, (1.a-c). The addendum is contained in the application package.
5. The overall match between the applicant's proposed theme and research objectives, and the program

interests as described under the heading, "Programmatic Interests."

C. Availability of Funds

Approximately \$1.2 million is expected to be available in FY 2001 for injury research grants to fund approximately 4–5 awards. The specific program priorities for these funding opportunities are outlined with examples in this announcement under the section, "Programmatic Interests."

It is expected that the awards will begin on or about September 30, 2001, and will be made for a 12-month budget period within a 3-year project period. The maximum funding level will not exceed \$300,000 (including both direct and indirect costs) per year or \$900,000 for the 3-year project period. Those grantees eligible for supplemental funding may request up to \$150,000 (including both direct and indirect costs) for one year. Supplemental awards will be made for the budget period to coincide with the actual budget period of the grant. Applications that exceed the funding cap of \$300,000 per year will be excluded from the competition and returned to the applicant. The availability of Federal funding may vary and is subject to change.

Continuation awards within the project period will be made based on satisfactory progress demonstrated by investigators at work-in-progress monitoring workshops (travel expenses for this annual one-day meeting should be included in the applicant's proposed budget), and the achievement of workplan milestones reflected in the continuation application.

Note: Grant funds will not be made available to support the provision of direct care. Eligible applicants may enter into contracts, including consortia agreements (as set forth in the PHS Grants Policy Statement, dated April 1, 1994), as necessary to meet the requirements of the program and strengthen the overall application.

Programmatic Interests

Research is needed to better understand the etiology of violence and its consequences, to determine how best to prevent violence-related injuries among different segments of the population and in different settings, and how best to reduce the severity of emotional and physical consequences of violence.

In the areas of interpersonal youth violence, child abuse, intimate partner violence, suicide, and sexual assault, little is known about the independent, additive, interactive, and sequential effects of psychological, socioeconomic, and environmental risk and protective

factors. In addition, a better understanding of how these different types of violence are related to one another is needed. It is also important to determine which factors have differential effects on the onset, persistence, escalation, de-escalation, or desistance of violent offending at different ages. Understanding how risk and protective factors relate to one another and to violence, how different types of violence are connected, and the factors that influence the ebb and flow of violent behavior is necessary to develop and implement effective violence prevention strategies.

Interpersonal violent behavior has a disproportionate impact on communities in economic and social disarray. This suggests that further understanding of the role that risk and protective factors such as poverty, social contagion, social norms, and social capital play in the etiology of violence may be particularly important in formulating effective prevention strategies.

In the area of suicide, mental health determinants have been studied extensively. Much less attention, however, has been given to individual, social, and environmental determinants (*e.g.*, exposure to violence and suicidal behavior, geographic mobility, access to lethal weapons, social support) not directly related to mental health. These factors may be very important in developing effective prevention strategies for suicide.

An issue crosscutting the areas of interpersonal violence and suicidal behavior and that is associated with the severity of violence is the problem of firearm injuries. Research is needed to better understand the risk factors for firearm injury and to understand the risk and benefits of having access to or carrying a firearm.

Understanding of the effectiveness of interventions and policies designed to prevent violent behavior or to mitigate the physical and emotional consequences of violence remains at a rudimentary level. In the areas of intimate partner violence, sexual assault, and suicide there is a tremendous need to identify effective primary prevention strategies. In addition secondary prevention strategies for intimate partner violence and sexual violence are being implemented through health care providers and through public health, criminal justice, and social services for victims, perpetrators, and child witnesses to violence. Efforts have also been made to coordinate these community responses. However, few of these intervention programs and responses have been rigorously and

systematically evaluated for their efficacy.

While there has been great progress in the area of youth violence in identifying effective and promising prevention strategies much work remains to be done. For example, there is some evidence that programs that combine interventions for youth with interventions targeting parents and caregivers are more effective than either intervention alone. There is a need for effectiveness studies that examine different levels of intervention (individual, peer, family, school, community), the long-term impact of strategies showing initial promise, and the best combination and application of singularly effective violence prevention strategies so that resources for youth violence can be used most effectively. There is also a need to improve the diffusion of effective programs.

Research is needed to evaluate the effectiveness of existing national, state or local policies or programs designed to prevent firearm injuries. Of particular interest is the impact of policies and programs that promote safe storage of firearms, involve the application of safe gun technology, and educate youth using curricula to promote gun safety on injuries among children and adolescents.

The application of new or under-used research methods is also of substantial interest. In all areas of violence there is a need to go beyond establishing the efficacy and effectiveness of interventions and public policies and use state of the art methods to determine the cost effectiveness of approaches that have been found to be efficacious. The application of new methods of studying the spatial distribution of violence such as the use of geographic information systems (GIS) should be further explored. In addition, longitudinal study designs are needed to better disentangle the effects of various factors in the etiology of violence and monitor the long-term effects of violence prevention interventions and policies.

1. Improve understanding of the etiology of violence (*i.e.*, interpersonal youth violence, child abuse, intimate partner violence, suicide, and sexual assault) and its consequences through research that addresses:

- The independent, additive, interactive, and sequential effects of psychological, socioeconomic, and environmental risk and protective factors.
- Factors that have differential effects on the onset, persistence, escalation, de-escalation, or desistance of violent offending at different ages.

- Factors that increase the severity of the emotional and physical consequences of violence and suicidal behavior.

- The effect of social and economic risk and protective factors such as poverty, social contagion, social norms, and social capital on interpersonal violence.

- The effect of psychological, social, and environmental factors not directly related to mental health on suicide.

- The risks and benefits of firearm access or carrying.

2. Improve understanding of the relationships between different types of violence. Of particular concern are:

- The relationship between intimate partner violence victimization and perpetration to child abuse.

- The effects of exposure to child abuse and intimate partner violence on suicidal behavior.

- The effects of witnessing violence as a child in the home and community on violent behavior during adolescence and adulthood.

3. Design and test preventive interventions for intimate partner violence, sexual violence, suicidal behavior, and child abuse.

4. Evaluate the feasibility and impact of screening and intervention methods in the acute medical care setting for youth interpersonal violence, child abuse, suicidal ideation, and intimate partner violence.

5. Advance our understanding of the effectiveness of interventions to prevent youth violence by evaluating:

- The long-term impact of promising interventions.

- Multifaceted interventions to prevent youth violence.

- The effect of youth-violence-prevention strategies in diverse cultural and social settings.

- The cost effectiveness of promising interventions.

Funding Preferences

Priority will be given to studies which focus on under served population(s) including ethnic populations, persons with disabilities, gay, lesbian, transgender and bisexual populations, or immigrant and refugee populations. These populations are considered under served because substantial research has not been devoted to determining risk and protective factors or mediating or moderating influences which may affect intimate partner violence or sexual violence in these groups.

D. Application Content

Applications should follow the PHS-398 (Rev. 4/98) application and Errata sheet, and should include the following information:

1. The project's focus that justifies the research needs and describes the scientific basis for the research, the expected outcome, and the relevance of the findings to reduce injury morbidity, mortality, disability, and economic losses. This focus should be based on recommendations in Healthy People 2010 and should seek creative approaches that will contribute to a national program for injury control.

2. Specific, measurable, and time-framed objectives.

3. A detailed plan describing the methods by which the objectives will be achieved, including their sequence. A comprehensive evaluation plan is an essential component of the application.

4. A description of the principal investigator's role and responsibilities.

5. A description of all the project staff regardless of their funding source. It should include their title, qualifications, experience, percentage of time each will devote to the project, as well as that portion of their salary to be paid by the grant.

6. A description of those activities related to, but not supported by the grant.

7. A description of the involvement of other entities that will relate to the proposed project, if applicable. It should include commitments of support and a clear statement of their roles.

8. A detailed first year's budget for the grant with future annual projections, if relevant.

9. An explanation of how the research findings will contribute to the national effort to reduce the morbidity, mortality and disability caused by violence-related injuries within 3-5 years from project start-up.

An applicant organization has the option of having specific salary and fringe benefit amounts for individuals omitted from the copies of the application which are made available to outside reviewing groups. To exercise this option: on the original and five copies of the application, the applicant must use asterisks to indicate those individuals for whom salaries and fringe benefits are not shown; however, the subtotals must still be shown. In addition, the applicant must submit an additional copy of page 4 of Form PHS-398, completed in full, with the asterisks replaced by the salaries and fringe benefits. This budget page will be reserved for internal staff use only.

E. Submission and Deadline

Letter of Intent

Although not a prerequisite of application, a non-binding letter of intent-to-apply is requested from

potential applicants. The letter of intent shall be submitted on or before February 9, 2001, to the Grants Management Specialist identified in the "Where to Obtain Additional Information" section of this announcement. The letter should identify the announcement number, name the principal investigator, and briefly describe the scope and intent of the proposed research work. The letter of intent does not influence review or funding decisions, but the number of letters received will enable CDC to plan the review more effectively and efficiently.

Application Submission

Submit the original and five copies of PHS 398 (OMB Number 0925-0001 and adhere to the instructions on the Errata Instruction sheet for PHS 398). Forms are in the application kit.

On or before March 9, 2001, submit the application to the Grants Management Specialist identified in the "Where to Obtain Additional Information" section of this announcement.

Applications shall be considered as meeting the deadline if they are received at the above address on or before the deadline date; or sent on or before the deadline date, and received in time for the review process.

Applicants should request a legibly dated U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or the U.S. Postal Service. Private metered postmarks will not be acceptable as proof of timely mailing.

Late Applications: Applications which do not meet the criteria above are considered late applications, will not be considered, and will be returned to the applicant.

F. Evaluation Criteria

Upon receipt, applications will be reviewed by CDC staff for completeness and responsiveness as outlined under the Eligible Applicants Section (Items 1-5). Incomplete applications and applications that are not responsive will be returned to the applicant without further consideration. It is especially important that the applicant's abstract reflects the project's focus, because the abstract will be used to help determine the responsiveness of the application.

Applications which are complete and responsive may be subjected to a preliminary evaluation (triage) by a peer review committee, the Injury Research Grant Review Committee (IRGRC), to determine if the application is of sufficient technical and scientific merit to warrant further review by the IRGRC; CDC will withdraw from further

consideration applications judged to be noncompetitive and promptly notify the principal investigator/program director and the official signing for the applicant organization. Those applications judged to be competitive will be further evaluated by a dual review process.

Competing Supplemental grant awards may be made when funds are available, to support research work or activities not previously approved by the IRGRC. Applications should be clearly labeled to denote their status as requesting supplemental funding support. These applications will be reviewed by the IRGRC and the secondary review group.

Awards will be determined by the Director of the National Center for Injury Prevention and Control (NCIPC) based on priority scores assigned to applications by the primary review committee IRGRC, recommendations by the secondary review committee Advisory Committee for Injury Prevention and Control (ACIPC), consultation with NCIPC senior staff, and the availability of funds.

1. The primary review will be a peer review conducted by the IRGRC. All applications will be reviewed for scientific merit by a committee of no less than three reviewers with appropriate expertise using current National Institutes of Health (NIH) criteria to evaluate the methods and scientific quality of the application. Factors to be considered will include:

a. Significance. Does this study address an important problem? If the aims of the application are achieved, how will scientific knowledge be advanced? What will be the effect of these studies on the concepts or methods that drive this field?

b. Approach. Are the conceptual framework, design, methods, and analyses adequately developed, well-integrated, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics? Does the project include plans to measure progress toward achieving the stated objectives? Is there an appropriate work plan included?

c. Innovation. Does the project employ novel concepts, approaches or methods? Are the aims original and innovative? Does the project challenge or advance existing paradigms, or develop new methodologies or technologies?

d. Investigator. Is the principal investigator appropriately trained and well suited to carry out this work? Is the proposed work appropriate to the experience level of the principal investigator and other significant

investigator participants? Is there a prior history of conducting violence-related research?

e. Environment. Does the scientific environment in which the work will be done contribute to the probability of success? Does the proposed research take advantage of unique features of the scientific environment or employ useful collaborative arrangements? Is there evidence of institutional support? Is there an appropriate degree of commitment and cooperation of other interested parties as evidenced by letters detailing the nature and extent of the involvement?

f. Ethical Issues. What provisions have been made for the protection of human subjects and the safety of the research environments? How does the applicant plan to handle issues of confidentiality and compliance with mandated reporting requirements, *e.g.*, suspected child abuse? Does the application adequately address the requirements of 45 CFR 46 for the protection of human subjects?

g. Study Samples. Are the samples sufficiently rigorously defined to permit complete independent replication at another site? Have the referral sources been described, including the definitions and criteria? What plans have been made to include women and minorities, and their subgroups as appropriate for the scientific goals of the research? How will the applicant deal with recruitment and retention of subjects?

h. Dissemination. What plans have been articulated for disseminating findings?

The IRGRC will also examine the appropriateness of the proposed project budget and duration in relation to the proposed research and the availability of data required for the project.

2. The secondary review will be conducted by the Science and Program Review Work Group (SPRWG) from the ACIPC. The ACIPC Federal ex officio members will be invited to attend the secondary review, will receive modified briefing books, (*i.e.*, abstracts, strengths and weaknesses from summary statements, and project officer's briefing materials). Federal ex officio members will be encouraged to participate in deliberations when proposals address overlapping areas of research interest so that unwarranted duplication in federally-funded research can be avoided and special subject area expertise can be shared. The NCIPC Division Associate Directors for Science (ADS) or their designees will attend the secondary review in a similar capacity as the Federal ex officio members to assure that research priorities of the

announcement are understood and to provide background regarding current research activities. Only SPRWG members will vote on funding recommendations, and their recommendations will be carried to the entire ACIPC for voting by the ACIPC members in closed session. If any further review is needed by the ACIPC, regarding the recommendations of the SPRWG, the factors considered will be the same as the factors that the SPRWG considered.

The committee's responsibility is to develop funding recommendations for the NCIPC Director based on the results of the primary review, the relevance and balance of proposed research relative to the NCIPC programs and priorities, and to assure that unwarranted duplication of federally-funded research does not occur. The Secondary Review Committee has the latitude to recommend to the NCIPC Director, to reach over better ranked proposals in order to assure maximal impact and balance of proposed research. The factors to be considered will include:

a. The results of the primary review including the application's priority score as the primary factor in the selection process.

b. The relevance and balance of proposed research relative to the NCIPC programs and priorities.

c. The significance of the proposed activities in relation to the priorities and objectives stated in Healthy People 2010 and the Institute of Medicine report, Reducing the Burden of Injury.

d. Budgetary considerations.

3. Continued Funding. Continuation awards made after FY 2000, but within the project period, will be made on the basis of the availability of funds and the following criteria:

a. The accomplishments reflected in the progress report of the continuation application indicate that the applicant is meeting previously stated objectives or milestones contained in the project's annual workplan and satisfactory progress demonstrated through presentations at work-in-progress monitoring workshops.

b. The objectives for the new budget period are realistic, specific, and measurable.

c. The methods described will clearly lead to achievement of these objectives.

d. The evaluation plan will allow management to monitor whether the methods are effective.

e. The budget request is clearly explained, adequately justified, reasonable and consistent with the intended use of grant funds.

G. Other Requirements

Technical Reporting Requirements
Provide CDC with an original plus two copies of

1. Progress report annually,
2. Financial status report, no more than 90 days after the end of the budget period, and
3. Final financial report and performance report, no more than 90 days after the end of the project period.
4. At the completion of the project, the grant recipient will submit a brief (2,500 to 4,000 words) summary highlighting the findings and their implications for research and policy. CDC will place the summary report and each grant recipient's final report with the National Technical Information Service (NTIS) to further the agency's efforts to make the information more available and accessible to the public.

Send all reports to the Grants Management Specialist identified in the "Where to Obtain Additional Information" section of this announcement.

The following additional requirements are applicable to this program. For a complete description of each see Addendum 1 in the application package.

- AR-1 Human Subjects Certification
- AR-2 Requirements for inclusion of Women and Racial and Ethnic Minorities in Research
- AR-3 Animal Subjects Requirement
- AR-7 Executive Order 12372
Review—not applicable for this program announcement
- AR-10 Smoke-Free Workplace Requirement
- AR-11 Healthy People 2010
- AR-12 Lobbying Restrictions
- AR-13 Prohibition on Use of CDC funds for Certain Gun Control Activities
- AR-21 Small, Minority, and Women-owned Business

H. Authority and Catalog of Federal Domestic Assistance Number

In addition to being authorized under 301 (a) [42 U.S.C. 241(a)] of the Public Health Service Act, this program announcement is also authorized under 391 (a) [42 U.S.C. 280(b)] of the Public Service Health Act. The catalog of Federal Domestic Assistance number is 93.136.

I. Where to Obtain Additional Information

This and other CDC announcements are available through the CDC homepage on the Internet. The address for the CDC homepage is <http://www.cdc.gov>.

To receive additional written information and to request an

application kit, call 1-888-GRANTS4 (1-888-472-6874). You will be asked to leave your name and address and will be instructed to identify the Announcement number of interest.

If you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained from:

Angela Webb, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Program Announcement #01016, Centers for Disease Control and Prevention (CDC), 2920 Brandywine Road, Room 3000, Atlanta, Georgia 30341, Telephone (770) 488-2784, Internet address: awebb@cdc.gov

See also the CDC home page on the Internet: <http://www.cdc.gov>

For program technical assistance, contact:

Ted Jones, Program Manager, Office of Research Grants, National Center for Injury Prevention and Control, Centers for Disease Control and Prevention (CDC), 4770 Buford Highway, NE, Mailstop K-58 Atlanta, GA 30341-3724, Telephone (770) 488-4824, Internet address: tmj1@cdc.gov.

Dated: December 18, 2000.

John L. Williams,

Director, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 00-32754 Filed 12-21-00; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Centers for Disease Control and Prevention****Advisory Committee to the Director, Centers for Disease Control and Prevention; Meeting**

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (P.L. 92-463), the Centers for Disease Control and Prevention (CDC) announces the following Advisory Committee meeting.

Name: Advisory Committee to the Director, CDC.

Time and Date: 8:30 a.m.-4 p.m., January 18, 2001.

Place: The Sheraton Atlanta Hotel, 165 Courtland Street, Atlanta, Georgia 30303.

Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 50 people.

Purpose: The committee will anticipate, identify, and propose solutions to strategic and broad issues facing CDC.

Matters to be Discussed: Agenda items will include updates from Dr. Jeffrey P. Koplan, M.D., M.P.H., Director, CDC, regarding the current CDC Director's priorities with discussions of program activities including healthy aging and prevention research.

Agenda items are subject to change as priorities dictate.

CONTACT PERSON FOR MORE INFORMATION:

Kathy Cahill, Executive Secretary, Advisory Committee to the Director, CDC, 1600 Clifton Road, NE, M/S D-24, Atlanta, Georgia 30333. Telephone 404/639-7060.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: December 18, 2000.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 00-32751 Filed 12-21-00; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Centers for Disease Control and Prevention****Clinical Laboratory Improvement Advisory Committee (CLIAC): Meeting**

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease Control and Prevention (CDC) announces the following committee meeting.

Name: Clinical Laboratory Improvement Advisory Committee (CLIAC).

Times and Dates: 8:30 a.m.-5 p.m., February 7, 2001; 8:30 a.m.-3:30 p.m., February 8, 2001.

Place: Doubletree Hotel Atlanta Buckhead, 3342 Peachtree Road, NE, Atlanta, Georgia 30326. Phone: 404/231-1234.

Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 100 people.

Purpose: This committee is charged with providing scientific and technical advice and guidance to the Secretary of

Health and Human Services, the Assistant Secretary for Health and Surgeon General, and the Director, CDC, regarding the need for, and the nature of, revisions to the standards under which clinical laboratories are regulated; the impact on medical and laboratory practice of proposed revisions to the standards; and the modification of the standards to accommodate technological advances.

Matters to be Discussed: The agenda will include a discussion on waived testing and status of the process for making waiver determinations, a workgroup report on genetic testing, and updates from CDC, Food and Drug Administration and Health Care Financing Administration.

Agenda items are subject to change as priorities dictate.

Contact Person for Additional Information: Rhonda Whalen, Chief, Laboratory Practice Standards Branch, Division of Laboratory Systems, Public Health Practice Program Office, CDC, 4770 Buford Highway, NE, M/S F-11, Atlanta, Georgia 30341-3724, telephone 770/488-8042, fax 770/488-8279.

The Director, Management Analysis and Services office has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: December 18, 2000.

Julia M. Fuller,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 00-32750 Filed 12-21-00; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-4561-N-79]

Notice of Submission of Proposed Information Collection to OMB; Request for Construction Change

AGENCY: Office of the Chief Information Officer, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below has been submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: Comments Due Date: January 22, 2001.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB approval number (2502-0011) and should be sent to: Joseph F. Lackey, Jr., OMB Desk Officer, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT:

Wayne Eddins, Reports Management Officer, Q, Department of Housing and Urban Development, 451 Seventh Street, Southwest, Washington, DC 20410; e-mail Wayne.Eddins@HUD.gov; telephone (202) 708-2374. This is not a toll-free number. Copies of the proposed forms and other available documents submitted to OMB may be obtained from Mr. Eddins.

SUPPLEMENTARY INFORMATION: The Department has submitted the proposal for the collection of information, as described below, to OMB for review, as required by the Paperwork Reduction

Act (44 U.S.C. Chapter 35). The Notice lists the following information: (1) The Title of the information collection proposal; (2) the office of the agency to collect the information; (3) the OMB approval number, if applicable; (4) the description of the need for the information and its proposed use; (5) the agency form number, if applicable; (6) what members of the public will be affected by the proposal; (7) how frequently information submissions will be required; (8) an estimate of the total number of hours needed to prepare the information submission including number of respondents, frequency of response, and hours of response; (9) whether the proposal is new, an extension, reinstatement, or revision of an information collection requirement; and (10) the name and telephone number of an agency official familiar with the proposal and of the OMB Desk Officer for the Department.

This Notice also lists the following information:

Title of Proposal: Request for Construction Change.

OMB Approval Number: 2502-0011.

Form Numbers: HUD-92437, HUD-92442, HUD-9244A, HUD-92442-CA, HUD-92442-A-CA, 92441.

Description of the Need for the Information and Its Proposed Use: Authority for these reports are Section 207(b) of the National Housing Act (P.L. 470, 48 Stat. 12 U.S.C. 1701 *et seq.*). Submitted by contractors, mortgagers, 2nd mortgages to obtain approval of changes in approved contract drawings and/or specifications. Needed by HUD to on sure compliance with Article 1.E of the construction contract.

Respondents: Business or other for-profit, Not-for-profit institutions.

Frequency of Submission: On occasion.

Reporting Burden:

	Number of respondents	x	Frequency of response	x	Hours per response	=	Burden hours
Request for Construction Change	900		4.44		5		20,300

Total Estimated Burden Hours: 20,300.

Status: Reinstatement, with change.

Authority: Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. 35, as amended.

Dated: December 15, 2000.

Wayne Eddins,

Departmental Reports Management Officer, Office of the Chief Information Officer.

[FR Doc. 00-32635 Filed 12-21-00; 8:45 am]

BILLING CODE 4210-01-M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-4561-N-80]

Notice of Submission of Proposed Information Collection to OMB; Monthly Reports for Establishing Income

AGENCY: Office of the Chief Information Officer, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below has been submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: Comments Due Date: January 22, 2001.

ADDRESSES: Interested persons are invited to submit comments regarding

this proposal. Comments should refer to the proposal by name and/or OMB approval number (2502-0108) and should be sent to: Joseph F. Lackey, Jr., OMB Desk Officer, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT:

Wayne Eddins, Reports Management Officer, Q, Department of Housing and Urban Development, 451 Seventh Street, Southwest, Washington, DC 20410; e-mail Wayne_Eddins@HUD.gov; telephone (202) 708-2374. This is not a toll-free number. Copies of the proposed forms and other available documents submitted to OMB may be obtained from Mr. Eddins.

SUPPLEMENTARY INFORMATION: The Department has submitted the proposal for the collection of information, as described below, to OMB for review, as required by the Paperwork Reduction

Act (44 U.S.C. Chapter 35). The Notice lists the following information: (1) The title of the information collection proposal; (2) the office of the agency to collect the information; (3) the OMB approval number, if applicable; (4) the description of the need for the information and its proposed use; (5) the agency form number, if applicable; (6) what members of the public will be affected by the proposal; (7) how frequently information submissions will be required; (8) an estimate of the total number of hours needed to prepare the information submission including number of respondents, frequency of response, and hours of response; (9) whether the proposal is new, an extension, reinstatement, or revision of an information collection requirement; and (10) the name and telephone number of an agency official familiar with the proposal and of the OMB Desk Officer for the Department.

This Notice also lists the following information:

Title of Proposal: Monthly Reports for Establishing Income.

OMB Approval Number: 2502-0108.

Form Numbers: HUD-93479, 93480, 93481.

Description of the Need for the Information and Its Proposed Use: Accounting reports submitted by selected owners/agents of multifamily projects used to monitor compliance with contractual agreements and to analyze cash flow trends as well as occupancy and rent collection levels. Alert field staff to need for remedial actions to correct deficiencies or need for more aggressive servicing action.

Respondents: Business or other for-profit, Not-for-profit institutions.

Frequency of Submission: Monthly and Recordkeeping.

Reporting Burden:

	Number of respondents	×	Frequency of response	×	Hour per response	=	Burden hours
Monthly Reports	4,000		12		3.5		168,000

Total Estimated Burden Hours: 168,000.

Status: Reinstatement, without change.

Authority: Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. 35, as amended.

Dated: December 15, 2000.

Wayne Eddins,

*Departmental Reports Management Officer,
Office of the Chief Information Officer.*

[FR Doc. 00-32636 Filed 12-21-00; 8:45 am]

BILLING CODE 4210-01-M

**DEPARTMENT OF HOUSING AND
URBAN DEVELOPMENT**

[Docket No. FR-4561-N-81]

**Notice of Submission of Proposed
Information Collection to OMB; 24 CFR
Part 570—Community Development
Block Grant Entitlement Program**

AGENCY: Office of the Chief Information Officer, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below has been submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: *Comments Due Date:* January 22, 2001.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB approval number (2506-0077) and should be sent to: Joseph F. Lackey, Jr., OMB Desk Officer, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT:

Wayne Eddins, Reports Management Officer, Q, Department of Housing and Urban Development, 451 Seventh Street, Southwest, Washington, DC 20410; e-mail Wayne_Eddins@HUD.gov; telephone (202) 708-2374. This is not a toll-free number. Copies of the proposed forms and other available documents submitted to OMB may be obtained from Mr. Eddins.

SUPPLEMENTARY INFORMATION: The Department has submitted the proposal for the collection of information, as described below, to OMB for review, as required by the Paperwork Reduction Act (44 U.S.C. Chapter 35). The Notice lists the following information: (1) The title of the information collection proposal; (2) the office of the agency to collect the information; (3) the OMB approval number, if applicable; (4) the description of the need for the

information and its proposed use; (5) the agency form number, if applicable; (6) what members of the public will be affected by the proposal; (7) how frequently information submissions will be required; (8) an estimate of the total number of hours needed to prepare the information submission including number of respondents, frequency of response, and hours of response; (9) whether the proposal is new, an extension, reinstatement, or revision of an information collection requirement; and (10) the name and telephone number of an agency official familiar with the proposal and of the OMB Desk Officer for the Department.

This Notice also lists the following information:

Title of Proposal: 24 CFR Part 570—Community Development Block Grant Entitlement Program..

OMB Approval Number: 2506-0077.

Form Numbers: None.

Description of the Need for the Information and Its Proposed Use: Entitlement grantees are required to retain records on the use of CDBG funds and to submit an annual performance and evaluation report. Information previously submitted on GPR will now be submitted in the CAPER.

Respondents: State, Local or Tribal Government.

Frequency of Submission: Annually.

Reporting Burden:

Number of respondents	x	Frequency of response	x	Hours per response	=	Burden hours
1,008		1		430		434,040

Total Estimated Burden Hours:
434,040.

Status: Reinstatement, without
change.

Authority: Section 3507 of the Paperwork
Reduction Act of 1995, 44 U.S.C. 35, as
amended.

Dated: December 15, 2000.

Wayne Eddins,

*Departmental Reports Management Officer,
Office of the Chief Information Officer.*

[FR Doc. 00-32637 Filed 12-21-00; 8:45 am]

BILLING CODE 4210-01-M

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[Docket No. 001215356-0356-01 and I.D.
100500A]

RIN 1018-AH42

Notice of Proposed Interagency Policy on the Prescription of Fishways Under Section 18 of the Federal Power Act

AGENCIES: U.S. Fish and Wildlife
Service, Interior, and National Marine
Fisheries Service, National Oceanic and
Atmospheric Administration,
Commerce.

ACTION: Notice of proposed policy.

SUMMARY: This notice invites public
comment on proposed internal policy
for the U.S. Fish and Wildlife Service
and National Marine Fisheries Service
(the Services) regarding the prescription
of fishways pursuant to section 18 of the
Federal Power Act for non-Federal
hydropower projects licensed by the
Federal Energy Regulatory Commission
(FERC). The proposed policy is
intended to set forth the definition of
fishways in accordance with the 1992
National Energy Policy Act and the
procedures for the prescription of
fishways. The policy does not introduce
new procedures but standardizes
current practices and existing
procedures for providing fishway
prescriptions.

DATES: Written comments must be
received on or before February 20, 2001.

ADDRESSES: Comments should be sent
to, and copies of applicable documents
are available from, the Chief, Division of

Federal Program Activities (400
ARLSQ), U.S. Fish and Wildlife Service,
1849 C Street, NW, Washington, DC
20240 or the Director, Office of Habitat
Conservation, National Marine Fisheries
Service, 1315 East-West Highway, Silver
Spring, MD 20910-3282.

FOR FURTHER INFORMATION CONTACT: Dr.
Benjamin N. Tuggle, Chief, Division of
Federal Program Activities, telephone:
703/358-2161, or Dr. Stephen M. Waste,
Office of Habitat Conservation, National
Marine Fisheries Service, telephone:
301/713-2325.

SUPPLEMENTARY INFORMATION:

Background

The Department of the Interior, acting
through the Fish and Wildlife Service
(FWS), and the Department of
Commerce, National Oceanic and
Atmospheric Administration (NOAA),
acting through the National Marine
Fisheries Service (NMFS), are the
Federal Departments primarily
responsible for the conservation and
management of the Nation's fish and
wildlife resources. The FWS has broad
responsibilities to conserve, protect, and
enhance fish, wildlife, and their habitats
under authorities granted by the Fish
and Wildlife Act of 1956 (FWA) (16
U.S.C. 742a-742j, not including 742 d-1;
70 Stat.1119); the Fish and Wildlife
Coordination Act (FWCA) (16 U.S.C.
661 *et seq.*); the Federal Power Act
(FPA) (16 U.S.C. 791a *et seq.*); and the
Endangered Species Act (ESA) (16
U.S.C. 1531 *et seq.*). NMFS has Federal
responsibilities for marine, estuarine,
and anadromous fish resources pursuant
to the FPA, the ESA, and the Magnuson-
Stevens Fishery Conservation and
Management Act (Magnuson-Stevens
Act) (16 U.S.C. 1801 *et seq.*), and
Reorganization Plan Number 4 of 1970.

Section 18 of the FPA (16 U.S.C. 811)
expressly grants to the Departments of
Commerce and Interior (Departments)
exclusive authority to prescribe
fishways. Section 18 states that FERC
must require construction, maintenance,
and operation by a licensee at its own
expense of such fishways as may be
prescribed by the Secretary of
Commerce or the Secretary of the
Interior. Fishways prescribed under
section 18 of the FPA by the
Departments are mandatory upon FERC
for inclusion in license conditions.
Within the Department of the Interior,
the authority to prescribe fishways is
delegated from the Secretary of the

Interior to the FWS Regional Directors.
Within the Department of Commerce,
the authority to prescribe fishways is
delegated to the NMFS Regional
Administrators. Therefore, the FWS
develops all fishway prescriptions
issued by the Department of the Interior
under section 18, and NMFS develops
all of the Department of Commerce's
fishway prescriptions.

Discussion

The National Energy Policy Act of
1992, section 1701(b), rescinded FERC's
definition of fishways. Through this
proposed policy, the Services take this
opportunity to define fishways. This
proposed policy also sets forth the
general agency practice for developing
fishway prescriptions, and encourages
license participants to anticipate fish
passage needs and the Services'
procedures. This policy does not
introduce new procedures but
standardizes current practices to ensure
a consistent and effective process. The
policy does not expand the authorities
of the Departments or the Services
beyond those that currently exist and
does not place additional requirements
on anyone outside the Departments
beyond those that already exist in the
FPA and FERC's regulations under the
FPA at 18 CFR, Chapter I.

Additionally, the courts have recently
addressed several section 18 issues that
affect the Services' implementation of
the fishway prescription process. In
following *Escondido Mutual Water Co.,
et al. v. La Jolla Band of Mission Indians
et al.* 466 U.S. 765 (1984), the courts
have continued to hold that the exercise
by the Secretaries' authority under
section 18 is mandatory and requires
inclusion of fishway prescriptions in
any license issued by FERC. (*Bangor-
Hydroelectric Co., Inc. v. FERC*, 78 F.3d
659 (D.C.Cir. 1996); *American Rivers,
Inc. v. FERC*, 129 F.3d 99 (2nd Cir.
1997); *American Rivers v. FERC*, 187
F.3d 1007 [9th Cir. 1999]). The
Services' fishway prescriptions must be
supported by substantial evidence in the
administrative record before FERC and
be reasonably related to the Services'
fish passage goals. (*Bangor-
Hydroelectric Co., Inc. v. FERC*, 78 F.3d
659 (D.C.Cir. 1996).)

On September 1, 1994, NMFS and
FWS published an "Advanced Notice of
Proposed Rulemaking (ANPR) for
Prescribing Fishways Under section 18
of the Federal Power Act" in the

Federal Register (59 FR 45255).

Comments were received from natural resource and hydroelectric interests. The comments were supportive of a rule and provided suggestions for the proposed rule. Events subsequent to the ANPR, including the *Bangor-Hydroelectric Co.* litigation and court decision, contributed to the delay in further development and issuance of the ANPR and changed our course of action to policy issuance. The Departments have elected to proceed with issuance of a "Notice of Proposed Interagency Policy on the Prescription of Fishways Under Section 18 of the Federal Power Act." This proposed policy meets the same objectives described in the 1994 ANPR.

The proposed policy does not set forth new process or requirements. The fishway prescription process outlined in the proposed policy already occurs during FERC's existing licensing process and is included in FERC's current regulations. The proposed policy is a means to provide guidance to agency staff and ensure a consistent and effective fishway prescription process. The proposed policy will also help facilitate the consultative efforts between the Services, applicant or licensee, and other interested parties in the fishway prescription development process and promote understanding between agencies, license applicants, FERC, and the public of the process used to prescribe fishways.

On May 26, 2000, the Departments issued a **Federal Register** notice (65 FR 34151) requesting public comment on establishing a review process for mandatory conditions including section 18 fishway prescriptions. Such a review process may provide an additional and more formal opportunity for licensees and others to provide input on the Departments' mandatory conditions. When a review process is developed, it will be incorporated into this proposed interagency section 18 policy.

Applicability

The proposed policy applies to all the Services' activities related to the prescription of new and/or modification of existing fishways at non-Federal hydroelectric projects licensed by FERC pursuant to the Federal Power Act.

Record of Compliance

We have prepared a Record of Compliance documenting that this action complies with the various statutory, Executive Order, and Departments of the Interior and Commerce requirements that are applicable to rulemakings. A copy is available upon request (see **ADDRESSES**).

FERC issues licenses for new, previously unlicensed hydropower projects and issues new licenses for about 1,000 previously licensed non-Federal hydropower projects. Hydropower projects are issued licenses for a period of up to 50 years and then can be re-licensed in order to continue operating. All of the projects receiving licenses are subject to the Services' section 18 mandatory authority to prescribe fishways. The Services determine the need for fishways for hydropower projects on a case-by-case basis. In addition, the Services are required to evaluate fish passage for these hydropower projects based on current environmental laws and regulations. Therefore, it is likely that the Services may prescribe fishways for a fair number of these hydropower projects.

By establishing this proposed policy, the Services set forth existing procedures for providing fishway prescriptions to ensure a consistent and effective process. The policy does not introduce new procedures but standardizes current practices and provides a definition of fishway. Therefore, the numbers of fishways prescribed for hydropower projects will probably not change significantly with this proposed policy. The proposed policy would help to facilitate the consultative efforts among the Services, applicant or licensee, and other interested parties in the fishway prescription development process and promote understanding among agencies, license applicants, FERC, and the public of the process used to prescribe fishways.

The proposed policy was reviewed under Executive Order 12866. As discussed earlier, this proposed policy is a statement of current practice and, therefore, does not contain any additional requirements concerning the government, public, or any other party. Accordingly, this proposed policy will not have a significant economic effect on a substantial number of small entities as defined under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). Similarly, this policy is not a major rule under 5 U.S.C. 804(2), the Small Business Regulatory Enforcement Fairness Act.

In accordance with the Unfunded Mandates Reform Act (2 U.S.C. 1501, *et seq.*), this proposed policy does not affect small governments, nor does it require any additional management responsibilities. Therefore, the proposed policy will not result in any significant additional expenditures by entities that participate in the fishway prescription process. This proposed policy will not

produce a Federal mandate of \$100 million or greater in any year, that is, it is not a "significant regulatory action" under the Unfunded Mandates Reform Act.

In accordance with Executive Order 12630, this proposed policy does not have significant takings' implications. This proposed policy will not result in takings since it generally describes the current procedures used in the fishway prescription process for all involved parties.

In accordance with Executive Order 13132, this proposed policy does not have significant Federalism effects. This proposed policy will not affect other governments since no intrusion on state policy or administration is expected; roles or responsibilities of Federal or state governments will not change; and fiscal capacity will not be substantially directly affected. Therefore, the proposed policy does not have significant effects or implications on Federalism.

In accordance with Executive Order 12988, the proposed policy does not unduly burden the judicial system and meets the requirements of sections 3(a) and 3(b)(2) of the Order. This proposed policy does not require any information collection for which the Office of Management and Budget approval is required under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*). We have analyzed this proposed policy in accordance with the criteria of the National Environmental Policy Act (NEPA) and the Department of the Interior Manual (318 DM 2.2(g) and 6.3(D)). This proposed policy does not constitute a major Federal action significantly affecting the quality of the human environment. An environmental impact statement or assessment is not required. We have determined that the issuance of the proposed policy is categorically excluded under the Department of the Interior's NEPA procedures in 516 DM 2, Appendix 1.10. NOAA has determined that the issuance of this proposed policy qualifies for a categorical exclusion as defined by NOAA 216-6 Administrative Order, Environmental Review Procedure.

We have analyzed this proposed policy in accordance with section 7 consultation of the ESA. We have determined that issuance of this proposed policy will not affect species listed as threatened or endangered under the ESA, and, therefore, a section 7 consultation on this proposed policy is not required.

We have analyzed this proposed policy in accordance with section 305(b) of the Magnuson-Stevens Act. We have

determined that issuance of this proposed policy may not adversely affect the essential fish habitat (EFH) of federally managed species, and, therefore, an essential fish habitat consultation on this proposed policy is not required. If individual fishways prescriptions for specific projects may adversely affect EFH, then FERC would be required to conduct an EFH consultation with NMFS.

In accordance with the President's memorandum of April 29, 1994, "Government-to-Government Relations with Native American Tribal Governments" (59 FR 22951) and with the Department of the Interior Manual (512 DM 2), this proposed policy does not directly affect Tribal resources. We have evaluated effects on federally recognized Indian tribes and have determined that there are no potential effects. The proposed policy does not introduce new procedures but standardizes existing procedures for consultation concerning the fishway prescription process. The proposed policy will further facilitate consultative efforts between the Services and the Tribes and promote understanding of the process used to prescribe fishways.

PROPOSED INTERAGENCY POLICY FOR THE PRESCRIPTION OF FISHWAYS

I. Introduction

The purpose of this policy is to publish the Services' definition of fishway and procedures for the prescription of fishways by the U.S. Fish and Wildlife Service and National Marine Fisheries Service (the Services), pursuant to section 18 of the Federal Power Act (FPA) for non-Federal hydropower projects licensed by the Federal Energy Regulatory Commission (FERC).

Hydropower projects including their associated dams divide a river system into isolated segments, impede or block fish movement, and kill or injure fish. The viability and mobility of fish species that would otherwise move to and between different habitats within the river basin may diminish substantially, if not completely, due to the dams. Fishways help mitigate the impact of hydropower dams on aquatic ecosystems by providing fish passage. Fishways on dams serve a variety of public purposes and resource goals including, but not limited to, the safe and timely physical passage of fish past the project; the improvement/augmentation of existing populations within a basin; the reunification of fragmented populations; and the reintroduction/reestablishment of

viable fish runs in a basin or watershed. In addition, providing fish passage may be necessary to protect tribal resources 61 FR 58211 (1996) and the exercise of American Indian tribal rights.

Fishways are prescribed by the Services to ensure the safe, timely, and effective passage of fish at non-Federal hydropower projects. Fishways facilitate the effective movement of fish past a hydropower project and provide one or more ways for fish to move, upstream or downstream, for such purposes as spawning, rearing, feeding, dispersing, and the seasonal use of habitat.

The Services will determine whether or not fishways are required for specific hydropower projects. Fishway prescriptions are designed to support implementation of fisheries management and resource protection objectives. Often the objectives will ensure that hydropower projects meet the goals of restoring, maintaining, and enhancing fish populations. Fishway prescriptions address fish passage goals identified in national, regional, or watershed level planning documents or those provided by the Services on a site-specific basis. In determining the need for fishways, the Services should coordinate with the states, other Federal agencies, Tribes, and other interested parties in the development of basin-wide fish restoration plans and goals.

Accomplishing effective fish passage is in the public interest and is an appropriate project purpose. As such, this purpose should be an integral component of project design and operation, whenever possible and practical, for both existing and new projects. This purpose is best met when fishway plans are integrated into early project planning and design and continuously achieved through the term of the license. Accomplishing this purpose requires that both or either Services with statutory fishway responsibilities are involved in both pre- and post-licensing related activities. This involvement is traditionally through consultation with the applicant or licensee and communication with FERC.

After licensing, the Services work with the licensee on fishway-related planning, modeling, and design prior to construction, operation, and maintenance. After passage facilities are complete and operational, facility evaluation, monitoring, and inspection should be initiated by the applicant or licensee to the satisfaction of the Services to ensure that the fish passage facility is performing as intended. Each of these activities is important and can influence whether or not effective fish

passage is being, or will be, accomplished.

II. Definition of Fishway

In order to ensure the consistent implementation of the Services' fishway prescriptions, it is necessary to understand the elements of a fishway. Congress provided guidance as to what constitutes a fishway in the National Energy Policy Act (NEPA) of 1992 (Pub.L. 102-486). Section 1701(b) of the Act states:

... the items which may constitute a "fishway" under section 18 for the safe and timely upstream and downstream passage of fish shall be limited to physical structures, facilities, and devices necessary to maintain all life stages of such fish, and project operations and measures related to such structures, facilities, or devices which are necessary to ensure the effectiveness of such structures, facilities, or devices for such fish.

The fundamental purpose of a fishway is to provide for the movement of fish past a barrier. Fishways are intended to provide safe, timely, and effective access to and from habitat for such purposes as spawning, rearing, feeding, growth to maturity, dispersion, migration, seasonal use of habitat and connectivity within the aquatic ecosystem, but not for habitat protection. To be successful, fishways must be constructed, operated, and maintained considering the biological requirements of fish moving upstream and downstream and the manner in which these movements are influenced by the structural and nonstructural elements of a hydropower project. A variety or combination of facilities, structures, devices, measures, and operations are often necessary in order for a fishway to provide effective fish passage.

The fishway definition in this policy provides clarification of Congress' guidance on the elements of a fishway. The Services define fishway as:

Any facility, structure, device, measure, or project operation, or any combination thereof, necessary for safe, timely, and effective movement of fish, regardless of life stage, whether upstream or downstream, through, over, or around a reach affected by a hydropower project, including, but not limited to: (1) fish ladders, locks, lifts, bypasses, barriers, and screens; (2) breaches, notches, spillways, gates, tunnels, flumes, pipes, or other conveyances, and channel modifications; and (3) water spill, flow, temperature, and level; (4) operating schedules; and (5) any other facilities, structures, devices, measures, or project operations necessary to attract, guide, pass, repel, exclude, transport, or trap fish, or provide information—by monitoring, modeling, evaluating, and studying, to ensure safe, timely and effective passage of fish.

Facility, structure, device, operation, and measure are not the same (see III.

Other Definitions Used in the Policy). By way of example, and not limitation, a fishway may include: (1) facilities that are often used for conveying, bypassing, collecting (as in a gallery), counting, trapping, and transporting fish; (2) structures, such as fish ladders, screens, barriers, and spillways used for conveying, guiding, or excluding fish, or the super structure in a fish-lift that provides for physical support; and (3) devices, mechanical or electronic, such as pumps or valves of an attraction flow system, the gate and hoist and pulley of a fish-lift, or a vehicle for transporting fish, that are often necessary to run the system, and thus, part of a fishway.

Project operations and measures are often necessary to ensure the effectiveness of the facilities, structures, devices, and other operations. They may include the timing of when a power generation unit may be on or off (first unit on, last off) during the migration period to affect the routing of migrating fish. Also, as a measure to ensure that the structures, facilities, and devices will be designed and located to pass fish effectively, conditions requiring planning (including operations and maintenance), modeling, designing, and consultation can be included. In particular, hydraulic modeling of project operations can be effective in designing and locating structures, facilities, and devices and in adjusting the effect of project operations on fish routing and movement. The Services may include measures to ensure that flows for attraction and conveyance are adequate for fish passage.

To ensure that the structures, facilities, and devices will operate in synchrony with fish movement, the Services may include schedules for initial and/or seasonal fish-passage operations. The Services may also include mechanisms for scheduling any necessary seasonal changes, subject to an express requirement for the notification to, and approval by, the Services. In regard to these operations, a prescription may specify a maximum and minimum river flow at which upstream and downstream passage should be provided by the applicant or licensee. Evaluations of fish passage effectiveness and inspection may be included to ensure that passage measures perform in a manner consistent with the intent and specific criteria stipulated by the Services in their prescriptions.

III. Other Definitions Used in the Policy

For the purpose of this policy:

Departments means the Department of the Interior and the Department of

Commerce. *FERC* means the Federal Energy Regulatory Commission.

Devicemeans a piece of equipment or a mechanism designed to serve a particular purpose or perform a particular function.

Facility means a specific combination of structures, devices, operations, and/or measures designed to work together to perform a function.

Fish means fishes, mollusks, crustaceans, and all other forms of freshwater, estuarine, and marine animal life other than mammals and birds.

Hydropower project means a complete unit of development, consisting of a power house, all water conduits, all dams and appurtenant works and structures (including navigation structures) that are part of a said unit, and all storage, diverting, or forebay reservoirs directly connected therewith, the primary line or lines transmitting power therefrom to the point of junction with the distribution system or with the interconnected primary transmission system, all miscellaneous structures used and useful in connection with said unit or any part thereof, and all water-rights, rights-of-way, ditches, dams, reservoirs, lands, or interest in lands the use and occupancy of which are necessary or appropriate in the maintenance and operation of such unit - as defined in the FPA.

Measure means an amount, allotment, capacity, evaluation, intensity, measurement, quality, schedule, size, study, and action calculated to achieve an end.

Migratory means demonstrating any mass movement from one habitat to another with characteristic regularity in time or according to stages of life history.

Operation means a method or manner of functioning or performing.

Reach means a section or portion of a stream length.

Riverine fish means fish that live in freshwater systems, such as rivers and streams, that do not spend time at sea.

Services means the U.S. Fish and Wildlife Service within the Department of the Interior, and the National Marine Fisheries Service within the Department of Commerce.

Structure means a constructed physical feature.

IV. The Fishway Prescription Process

A. Scoping, Consultation, and Studies

The policy states in general terms the Services' fishway prescription process, which may occur concurrently with FERC's licensing or during the license term. The fishway prescription process

described in this document is generally applicable to both the traditional and the alternative licensing processes at 18 CFR, Chapter I. Because the FERC record is developed differently in these processes, the prescription process may be adjusted to reflect those differences. The fishway prescription process is a consultative, iterative effort among the Services, applicant or licensee, and other interested parties to adequately address resource management, biological, engineering, and design factors related to accomplishing effective fish passage at the project.

The Services typically begin the fishway prescription process by scoping the issues related to fish passage for the individual license proceeding. While each project is unique, some initial considerations for the Services include (1) the types of fish occurring currently or historically in the vicinity of the project or proposed project; (2) the biological status of the species under consideration; (3) the effect of the project, or proposed project, on fish and their habitat; (4) the status of the habitat upstream of the project; (5) the possibility for restoration of fish runs; (6) the need for fishways; and (7) what types of fishways are needed. As part of the scoping process, the Services evaluate the information available to answer these questions.

A critical component of the Services' fishway prescription process is the information available to the Services and existing in the FERC record. The information utilized by the Services comes from a variety of sources, including historical accounts, records, surveys, and other information; Federal, state, and tribal management plans; information obtained from scoping, consultation and coordination, project-specific surveys and studies, and the license application, as well as information already in the Services' possession. One of the Services' important objectives, as a participant in the licensing or amendment process, is to identify whether fish passage may be impacted by the project, to identify project features and operations that may impact fish passage, and to identify the means and measures to mitigate these impacts. Based upon the information available, the Services will identify resource management goals and fish passage concerns as early in the consultation process as the information gathering process allows. Where gaps in information are identified in the consultation process, the Services will work with the applicant or licensee, Indian tribes, affected Federal and state agencies, and other participants to

identify necessary information and needed studies, as appropriate.

Information requested by the Services should assist in identifying the necessary design or modification of the hydroelectric project (including potential fishways) to avoid and minimize project impacts on fish passage and protection and to allow for safe, timely, and effective fish passage. The Services may request studies to acquire information needed to ensure fish passage and expressly identify those studies necessary for the Services to exercise the FPA section 18 authority. The cost of studies is borne by the license applicant or licensee. The Services will consider the least costly study alternatives that will provide the needed information to accomplish their goals when the cost information is provided for review.

Studies are to be conducted over the period of time necessary to provide information needed to identify the fish that may be affected by the project, how they are affected, and the elements necessary for effective passage of these fish. The Services provide technical assistance in the form of review and comment on the applicant's or licensee's informational studies and proposed designs related to fish passage. When possible, the Services and applicant or licensee will work closely in all aspects of the study process. When information has been requested by the Services and that information is not provided by the applicant or licensee, fishway prescriptions may be based on the best information available and on the Services' best professional judgment.

B. Need for Fishways

The Services' determinations regarding the need for fishways will be made on a case-by-case basis and may be based on a number of factors. The Services may consider whether the proposed project is, or would be: (1) located on a water body that is presently used by or that provides habitat for migratory fish or has the potential to provide use or habitat through run restoration or fish passage improvements; (2) located on a water body that is presently used by or provides habitat for riverine fish or that has the potential to provide use or habitat through fish passage improvement; (3) located on a water body where fish passage is necessary to restore or otherwise protect the resources and the exercise of reserved rights of affected American Indian Tribes; (4) located in a river basin where the need for fish passage is articulated in natural resource plans; (5) located in

a river basin where the biological impact of the project without fish passage would affect, or has affected, fish distribution, production, and diversity within the river basin or surrounding river basins; (6) located in a river basin where a decision to prescribe fishways may conflict with state, regional, tribal, or Federal resource management priorities or affect other fish and wildlife resources through the introduction of non-native or exotic species, exposure to environmental contaminants, or other similar factors; (7) located on a water body where fish passage is necessary to conserve, recover, or continue the existence of species protected under the Endangered Species Act (ESA), or may adversely affect essential fish habitat as determined pursuant to the Magnuson-Stevens Act; (8) located in a river basin where the designated use, existing use, anti-degradation provisions, basin plans, or water quality criteria in applicable state, Federal, or tribal water quality standards developed pursuant to section 303 of the Clean Water Act include or are applicable to migratory fish or their habitat; and, (9) located in a river basin that is presently used by, or provides habitat for use by declining, depleted fish or interjurisdictional fish or that has the potential to provide use or habitat for declining, depleted, or interjurisdictional fish through restoration or fish passage improvements. Other factors may be considered based upon the specifics of the project and resources at issue.

C. Fishway Prescription Formulation

Fishway prescriptions may take the form of general directives, specific standards, or design criteria or plans. They may include site access, facilities, structures, devices, operations, and measures, including monitoring, evaluation, compliance, and modification, necessary to ensure fishways pass fish in a safe, timely, and effective manner. The Services will formulate fishway prescriptions based upon all relevant information available, including fishway studies; FERC's consultation and environmental review processes; fish management, restoration or natural resource plans; historical records; scientific and technical literature; scientific expertise available to and within the Services; and any other related information available to the Services.

Fishway prescriptions may address those elements of fishway construction, operation, and maintenance necessary to ensure effective fish passage and to maintain and restore all life stages over the term of the license. These elements

include location, flow amounts, gas saturation, water temperature, construction materials, fishway design, operation and construction schedules, performance standards, and operational studies, and post-licensing effectiveness measures and may include scaled drawings showing plan views, elevation views, water surface profile, and cross-section views as appropriate. If Services fishway designs exist for a specific species, they will be provided to the applicant or licensee early in the prescription process. Where appropriate, the Services may provide fish passage measures for hydropower projects during abandonment, decommissioning, or otherwise curtailing operation. The Services will endeavor to prescribe fishways to achieve identified fish passage goals using the best available technology in a practical and effective manner. When the Services determine that equally effective alternative means of meeting and achieving identified fish passage goals exist, they will use the alternative with the minimum cost.

When sufficient information is available, the Services will submit preliminary fishway prescriptions in response to FERC's notice that the project is "ready for environmental analysis" (REA). However, the Services are required by law to base prescriptions on substantial evidence in the FERC record. If information is insufficient at the time of the REA notice, the Services may exercise the FPA section 18 authority by reserving the authority to prescribe. If a prescription is likely, the Services may submit information on fish passage for FERC to include in its analysis. When the Services are not able to prescribe at the time of the REA notice, but anticipate submitting a prescription, the Services will notify FERC and other participants of their target date for submittal of their fishway prescription. Preliminary prescriptions will be provided as soon as sufficient information becomes available, or the Services may exercise section 18 authority through a reservation of authority. If the Services determine that uncertainty continues regarding the impacts of a hydropower project on fish passage, fishway prescriptions will be conservative and resolve the uncertainty in favor of assuring the safe, timely, and effective passage and protection of fish. Fishway prescriptions may include post-licensing evaluation and monitoring requirements to reduce uncertainty regarding effectiveness of fish passage.

At any time during the process when the evidence supports the conclusion that fish passage is not currently needed

or is not currently feasible, the Services will inform the applicant or licensee and FERC and may exercise section 18 by reserving authority to prescribe fishways in the future.

Once a preliminary fishway prescription is submitted to FERC, in a continuation of the consultation and coordination roles of the participants, any interested party may choose to provide new information related to the preliminary prescription to the Services. FERC's publication of its draft NEPA analysis provides a means for additional environmental information to be entered into FERC's record, which must be evaluated by the Services in the context of any preliminary prescriptions submitted. The Services will consider any new information, including new information provided in the draft NEPA document, and may review and modify their preliminary prescriptions as appropriate. Prior to FERC's release of the final NEPA analysis, the Services should either reaffirm the preliminary prescriptions for fishways or submit modified prescriptions for fishways for inclusion in any license or amendment issued by FERC. Furthermore, during the term of the license, the Services may modify a prescription in response to changes in circumstances and/or to new information.

Fishway prescriptions must be related to stated fish passage goals identified or adopted by the Services and could include goals identified by other interested parties in the context of national, regional, and watershed level planning. When watershed, river, or project-specific goals have not been identified, they may be inferred from related documents (i.e., regional goals from national goals). Goals may also be developed by the Services based on available information and on scientific expertise. Thus, relevant goals may be extrapolated from existing documents or be developed within the licensing context. Goals related to fish passage should be included in the administrative record.

Measures may be prescribed so that the Services can obtain information necessary to ensure the effectiveness of fish passage under the new license. These measures may be implemented either before or after construction and may include, but not be limited to, physical, hydraulic, biological, or other modeling; tests; monitoring evaluations; and inspections. These effectiveness measures are considered part of the fishway prescription.

It is not the goal of the Services to engineer the final design of the hydropower project. Accordingly, the Services may, leave the final

engineering details to the applicant or licensee and approve the engineering design proposed by the applicant or licensee to ensure that it adequately addresses the passage requirements of fish affected by the project. The Services will consider passage alternatives proposed by the applicant or licensee so long as passage requirements can be met to the satisfaction of the Services.

D. Documentation

The Services will file with FERC documentation of substantial evidence that supports the need for fishways, provides the basis for the fishway prescription, and demonstrates that the fishway prescribed is reasonably related to goals identified by the Services. This documentation will be in addition to the information already contained in FERC's administrative record. Such documentation may include, as appropriate, primary and original sources of information, including documents, reports, studies, evaluations, assessments, and other related information relied upon by the Services to develop fishway prescriptions; reasons for decisions regarding the need for fishways; alternatives considered; and any other information relied upon by the Services to develop fishway prescriptions. The Services will exercise best professional judgment in developing fishway conditions based on documentation in the record.

V. Reservation of Authority to Prescribe Fishways

Future fish passage needs, project design modifications, and management objectives, over the life of a license, cannot always be discerned or predicted when a hydropower project is licensed. Further, it is within the Services' discretion, as affirmed in *Wisconsin Public Service v. FERC*, 32 F. 3d 1165 (7th Cir. 1994), to either issue prescriptions during the licensing or amendment process or to reserve their authority. The Services will generally exercise section 18 of the FPA by reserving that authority for the purpose of maintaining the flexibility necessary to respond to new information prior to licensing and during the license term; e.g., fish passage needs, project modifications, management goals, environmental conditions, and technological innovations. When appropriate, the Services will exercise section 18 by reserving authority to prescribe fishways whether submitting a prescription or not. Because an exercise of section 18, through a reservation of authority to prescribe fishways, can be exercised at any time, such reservation

does not preclude the prescription of fishways prior to license issuance or throughout the term of the license when, and if, a fishway may become necessary. The reservation provides notice to the applicant or licensee of the need to be prepared to construct a fishway during the term of the license. A reservation may be activated when environmental conditions change or new information becomes available. When activated, a reservation to prescribe fishways may result in the formulation of a post-licensing prescription. For example, section 18 authority may be exercised by a reservation where there are no fish at present, but where fish will become present after passage is provided at downstream sites.

VI. Post-Licensing Modification of Fishway Prescriptions

The post-licensing modification of fishway prescriptions is a necessary mechanism to ensure effective fish passage after the license is issued. Fishway prescriptions may be modified by the Services, after license issuance, to address a number of factors, such as conditions of settlement or licensing; a change in local or regional conditions, technology, management emphasis, or ecological status; availability of new information; amendments to project design or operation; or a need for new or improved fishways at the project. Additionally, new fishways may be prescribed based on the above factors and on the license amended through the use of a license reopener provision.

Post-licensing modification of fishway prescriptions is also appropriate during the initial stages of fishway operation when the results of fishway evaluations indicate that additional prescriptive measures beyond those provided in the license are necessary to make the fishway more effective. Performance evaluations are a measure necessary to ensure the effectiveness of the facility, structure, device, or operation for passing fish. Once the fishway is operating effectively, future modifications will be based on an established need that is supported by substantial evidence, as determined by the Services.

Environmental changes may occur that require a modification of a prescription to maintain or restore the ability of a fishway to pass fish in a safe, timely, and effective manner. The development and implementation of comprehensive natural resource plans, including applicable state, regional, tribal, or Federal fishery management plans, may also warrant fishway prescription modification to meet new

or revised management goals. In such cases, the Services will work with the licensee to the extent possible to develop measures necessary to adapt the existing fishway to meet the passage needs of the plan's target resources before prescribing new facilities, structures, devices, operations, or measures. For all of these and other similar circumstances, the Services will meet with the licensee and other interested parties to identify the need for and specific type of modification required. The fishway prescription process is initiated post-licensing (i.e., when new information is available or when there is a license amendment), by the Services' filing a motion with FERC, with copies to the licensee and interested entities. The motion may be made pursuant to a reservation of authority, standard reopener, or license amendment proceeding. In all other respects, the prescription process is the same during both the pre- and the post-licensing periods.

VII. Intervention in the FERC Process

FERC's regulations allow any participant with a demonstrable interest in a licensing, post-licensing, or amendment proceeding to file a motion to intervene, and to seek status as a party to the licensing proceeding. In order to preserve their ability to fully participate in the process and to appeal any adverse final licensing decision, the Services should file a timely intervention in all proceedings in which they have an interest, in accordance with FERC's regulations and applicable Departmental procedures. However, party status is not required for the Services to provide fish passage prescriptions.

VIII. Relationship to the Endangered Species Act

This policy is intended to guide the Services in the exercise of their authorities under section 18 of the FPA. The requirements for conserving threatened and endangered species are separately set forth in the ESA and implementing regulations at 50 CFR part 402. Where fish passage for both listed and nonlisted species is involved, Services' personnel will fully coordinate fish passage efforts with endangered species efforts to provide consistent and unified fishway prescriptions for the safe, timely, and effective passage of fish. Fishway prescription formulation should be fully integrated with the ESA section 7 consultation process in FERC's licensing or during the license term.

IX. National Environmental Policy Act Compliance

The Services provide preliminary prescriptions to FERC for inclusion in FERC's NEPA analysis of the proposed project. This allows the prescriptions to be analyzed in the context of the entire project. After FERC completes the NEPA analysis, the Services then modify the prescriptions if necessary, based on the NEPA analysis, and provide them to FERC for inclusion in the final NEPA document and in the license.

X. Scope of the Policy

This policy applies to all activities of the Services related to the prescription of fishways at non-Federal hydroelectric projects licensed by FERC pursuant to the FPA. It does not expand the authorities of the Departments or the Services beyond those that currently exist and does not place additional requirements on anyone outside the Departments beyond those that already exist in the FPA and FERC's regulations at 18 CFR, Chapter I. This policy provides guidance for Services' personnel, but allows variations appropriate to individual circumstances.

XI. Authority for This Policy

The authority for this policy is section 18 of the Federal Power Act, (16 U.S.C. 811).

Dated: November 20, 2000.

Jamie Rappaport Clark,

*Director, U.S. Fish and Wildlife Service,
Department of the Interior.*

Dated: December 18, 2000.

Penelope Dalton,

*Assistant Administrator for Fisheries,
National Marine Fisheries Service.*

[FR Doc. 00-32723 Filed 12-21-00; 8:45 am]

BILLING CODES 3510-22-S; 4310-55-S

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Availability of Comprehensive Conservation Plan and Summary for Flint Hills National Wildlife Refuge, Hartford, KS

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of Availability.

SUMMARY: Pursuant to the Refuge Improvement Act of 1997, the U.S. Fish and Wildlife Service has published the Flint Hills National Wildlife Refuge Comprehensive Conservation Plan and Summary. This Plan describes how the

FWS intends to manage the Flint Hills NWR for the next 10-15 years.

ADDRESSES: A copy of the Plan or Summary may be obtained by writing to U.S. Fish and Wildlife Service, Flint Hills NWR, P.O. Box 128, Hartford, KS 66854 or download from <http://www.r6.fws.gov/larp/>.

FOR FURTHER INFORMATION CONTACT: Jerre Gamble, U.S. Fish and Wildlife Service, Flint Hills NWR, P.O. Box 128, Hartford, KS 66854; 316/392-5553.

SUPPLEMENTARY INFORMATION: Flint Hills National Wildlife Refuge straddles the Neosho River in eastern Kansas. The area is dominated by complex resource management issues revolving around the flood control function of John Redmond Reservoir. Activities associated with agriculture, flood control, and public recreation have placed increasing demands on the landscape and identified the need for more responsible utilization of land and water resources that support the remaining native ecosystem components.

Flint Hills National Wildlife Refuge will continue to conserve habitat for the diverse array of native plants and animals that rely upon the resources of the Refuge for survival. This Plan describes the conservation activities that the Fish and Wildlife Service intends to carry out on Flint Hills NWR.

Dated: December 18, 2000.

Ralph O. Morgenweck,

Regional Director, Denver, Colorado.

[FR Doc. 00-32759 Filed 12-21-00; 8:45 am]

BILLING CODE 4310-55-M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[WO-09310-091310-09PB-0901-0924 1A]

Extension of Approved Information Collection, OMB Approval Number 1004-090160

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, the Bureau of Land Management (BLM) announces its intention to request extension of an existing approval to collect certain information from lessees who submit a Geothermal Leasing Report. BLM uses the information to determine if a lessee qualifies for a lease extension. The implementing regulations are found at (43 CFR 3208).

DATES: You must submit your comments to BLM at the appropriate address below on or before February 20, 2001. BLM will not necessarily consider any comments received after the above date.

ADDRESSES: Comments may be mailed to: Regulatory Affairs Group (630), Bureau of Land Management, 1849 C Street NW., Room 401LS, Washington, DC 20240.

Comments may be sent via Internet to: WOCComment@blm.gov. Please include "ATTN: 1004-0160" and your name and return address in your Internet message.

Comments may be hand-delivered to the Bureau of Land Management, Administrative Record, Room 401, 1620 L Street, NW., Washington, DC.

Comments will be available for public review at the L Street address during regular business hours (7:45 a.m. to 4:15 p.m.), Monday through Friday.

FOR FURTHER INFORMATION CONTACT: You may contact Barbara Gamble on (202) 452-0338 (Commercial or FTS). Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service at 1-800-877-8330, 24 hours a day, seven days a week, to contact Ms. Gamble.

SUPPLEMENTARY INFORMATION: 5 CFR 1320.12(a) requires BLM to provide 60-day notice in the **Federal Register** concerning a collection of information contained in regulations in 43 CFR 3208 to solicit comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology. BLM will receive and analyze any comments sent in response to this notice and include them with its request for approval from the Office of Management and Budget under 44 U.S.C. 3501 *et seq.*

The Geothermal Steam Act of 1970 (30 U.S.C. 1001-1025) authorized the Secretary of the Interior to issue leases for geothermal development. The Geothermal Steam Act Amendments of 1988 (Pub. L. 100-443) supplemented and amended the Geothermal Steam Act

of 1970. BLM requires geothermal lessees to submit additional information under this law. The legislation allows for lease extensions when the Secretary of the Interior determines a lessee made a substantial investment to develop the geothermal resources. It will also allow leases to continue beyond the primary terms if there are wells capable of producing geothermal resources. The regulations at 43 CFR 3208 specifically address extended lease terms.

Lessees may request a lease extension beyond the primary term by: drilling, diligent efforts, production of byproducts, and unit commitment. Lessees provide the required information in a report to BLM. BLM uses the information to determine if a lessee qualifies to extend their lease.

Based on BLM's experience administering the activities described above, we estimate the public reporting burden for the information collected to average two (2) hours per response. The respondents include individuals, small businesses, and large corporations. The frequency of response is annual. The estimated number of responses per year is 75. The estimated total annual burden is 150 hours. BLM specifically requests your comments on its estimate of the amount of time that it takes to prepare a response.

BLM will summarize all responses to this notice and include them in the request for Office of Management and Budget approval. All comments will also become a matter of public record.

Dated: December 18, 2000.

Michael Schwartz,

BLM Information Collection Clearance Officer.

[FR Doc. 00-32655 Filed 12-21-00; 8:45 am]

BILLING CODE 4310-84-M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[WO-310-1310-PB-01-241A]

Extension of Approved Information Collection, OMB Approval Number 1004-0034

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, the Bureau of Land Management (BLM) announces its intention to request extension of an existing approval to collect certain information from those persons who wish to transfer interest in oil and gas or geothermal leases by

assignment of record title or transfer operating rights (sublease) in oil and gas or geothermal leases under the terms of the mineral leasing laws. The implementing regulations are found at (43 CFR 3106, 3135, and 3216).

DATES: You must submit your comments to BLM at the appropriate address below on or before February 20, 2001. BLM will not necessarily consider any comments received after the above date.

ADDRESSES: Comments may be mailed to: Regulatory Affairs Group (630), Bureau of Land Management, 1849 C Street NW., Room 401LS, Washington, DC 20240.

Comments may be sent via Internet to: WOCComments@blm.gov. Please include "ATTN: 1004-0034" and your name and return address in your Internet message.

Comments may be hand-delivered to the Bureau of Land Management, Administrative Record, Room 401, 1620 L Street, NW., Washington, DC.

Comments will be available for public review at the L Street address during regular business hours (7:45 a.m. to 4:15), Monday through Friday.

FOR FURTHER INFORMATION CONTACT: You may contact Barbara Gamble on (202) 452-0338 (Commercial or FTS). Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service at 1-800-877-8330, 24 hours a day, seven days a week, to contact Ms. Gamble.

SUPPLEMENTARY INFORMATION: 5 CFR 1320.12(a) requires BLM to provide 60-day notice in the **FEDERAL REGISTER** concerning a collection of information contained in regulations in 43 CFR 3106, 3135, and 3216 to solicit comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology. BLM will receive and analyze any comments sent in response to this notice and include them with its request for approval from the Office of Management and Budget under 44 U.S.C. 3510 *et seq.*

The Mineral Leasing Act of 1920 (30 U.S.C. 181 *et seq.*) and the Geothermal Steam Act of 1970 (30 U.S.C. 1001–1025) authorize the Secretary of the Interior to issue leases for development of Federal oil and gas and geothermal resources. The Act of August 7, 1947 (Mineral Leasing Act of Acquired Lands) authorizes the Secretary to lease lands acquired by the United States (30 U.S.C. 341–359). The Department of the Interior Appropriations Act of 1981 (42 U.S.C. 6508) provides for the competitive leasing of lands for oil and gas in the National Petroleum Reserve-Alaska (NPRA). The Attorney General's Opinion of April 2, 1941 (40 Opinion of Attorney General 41) provides the basis under which the Secretary issues certain leases for lands drained of mineral resources. The Federal Property and Administrative Services Act of 1949 (40 U.S.C. 471 *et seq.*) provides the authority for leasing lands acquired from the General Services Administration.

The regulations at 43 CFR 3106, 3135, and 3216 outline the procedures for assigned record title interest and transferring operating rights in a lease to explore for, develop, and produce oil and gas resources and geothermal resources.

The assignor/transferor provides the needed information to comply with the regulations in order to process the assignments of record title interest or transfer of operating rights (sublease) in a lease for oil and gas or geothermal resources. The assignor/transferor submits the required information to BLM for approval in accordance with 30 U.S.C. 187a and the regulations at 43 CFR 3106, 3135, and 3216.

BLM uses the information submitted by the assignor/transferor to identify the interest ownership that is assigned or transferred and the qualifications of the assignee/transferee. BLM determines if the assignee/transferee is qualified to obtain the interest sought and ensures the assignee/transferee does not exceed statutory acreage limitations.

Based on BLM's experience administering the activities described above, we estimate the public reporting burden for the information collected to average 30 minutes per response. The respondents include individuals, small businesses, and large corporations. The frequency of response is annual. The estimated number of response per year is 60,000. The estimated total annual burden is 30,000 hours. BLM specifically requests your comments on its estimate of the amount of time that it takes to prepare a response.

BLM will summarize all responses to this notice and include them in the

request for Office of Management and Budget approval. All comments will also become a matter of public record.

Dated: December 18, 2000.

Michael Schwartz,

BLM Information Collection Clearance Officer.

[FR Doc. 00–32656 Filed 12–21–00; 8:45 am]

BILLING CODE 4310–84–M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[UT–080–1430–PF]

Land Closure

AGENCY: Bureau of Land Management, Interior.

ACTION: Temporary Emergency Closure of public land in Uintah County, Utah.

SUMMARY: Notice is hereby given that the Vernal Field Office herewith re-issues a temporary emergency closure of public land in Uintah County, Utah, effective January 1, 2001. This order temporarily closes 1,320 acres of public land to public use and entry. This temporary closure area encompasses the following public land:

Salt Lake Meridian, Utah

T.10 S., R. 24 E.,

Sec. 22, E½, E½NW¼, SW¼NW¼, SW¼;

Sec. 23, W½;

Sec. 26, NW¼NW¼;

Sec. 27, NE¼, E½NW¼, NE¼SW¼, and N½SE¼.

The authorized officer, has determined that the underground methane generation occurring at the abandoned White River Oil Shale Mine is a safety hazard making the facility and surrounding area unsafe for human occupation or activity. The closure area effects the above described public land presently encumbered by the abandoned White River Oil Shale Mine, ancillary support facilities, and associated ventilation shafts. The closure prohibits all use, entry, or access onto the affected public lands; however, the access restriction may be waived under extraordinary circumstances where limited, short term, emergency access is warranted and appropriate clearances and authorization are obtained from the authorized officer.

Where emergency access is authorized by the authorized officer, it would be conditioned on the following provisions:

All persons entering and leaving the closure area shall be accompanied by personnel from the BLM's Vernal Field Office and only after said BLM staff

have determined that the area is safe for site visitation purposes.

All persons allowed emergency access into the closure area shall waive and release all direct and indirect claims that may occur against the United States for liability for any loss, damage, personal injury, or death that may occur as a result of their access to the closure area and will indemnify and hold harmless the United States. All such incidents shall immediately be reported to the BLM Field Office.

The purpose of this closure is to protect human life, ensure public safety, and to prevent human contact with a known hazardous situation. A map of the area affected by this closure is on file and may be viewed at the Vernal Field Office of the BLM.

EFFECTIVE DATE: The closure order is effective from January 1, 2001, through December 31, 2002, unless, prior thereto, it is rescinded or modified by the authorized officer.

SUPPLEMENTARY INFORMATION: This closure is under the authority of 43 CFR 8364.1. Persons violating this closure shall be subject to the penalties provided in 43 CFR 8360.0–7, including a fine not to exceed \$1,000.00 and/or imprisonment not to exceed one year.

FOR FURTHER INFORMATION CONTACT: The BLM Vernal Field office, 170 South 500 East, Vernal, Utah 84078, (435) 781–4400.

Dated: December 11, 2000.

David E. Howell,

Field Manager.

[FR Doc. 00–32641 Filed 12–21–00; 8:45 am]

BILLING CODE 4310–DQ–M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[WY–920–1310–01; WYW148518]

Notice of Proposed Reinstatement of Terminated; Oil and Gas Lease

Pursuant to the provisions of 30 U.S.C. 188(d) and (e), and 43 CFR 3108.2–3(a) and (b)(1), a petition for reinstatement of oil and gas lease WYW148518 for lands in Hot Springs County, Wyoming, was timely filed and was accompanied by all the required rentals accruing from the date of termination.

The lessee has agreed to the amended lease terms for rentals and royalties at rates of \$5.00 per acre, or fraction thereof, per year and 16⅔ percent, respectively.

The lessee has paid the required \$500 administrative fee and \$158 to reimburse the Department for the cost of

this **Federal Register** notice. The lessee has met all the requirements for reinstatement of the lease as set out in Section 31 (d) and (e) of the Mineral Lands Leasing Act of 1920 (30 U.S.C. 188), and the Bureau of Land Management is proposing to reinstate lease WYW148518 effective August 1, 2000, subject to the original terms and conditions of the lease and the increased rental and royalty rates cited above.

Mavis Love,

Acting Chief, Leasable Minerals Section.

[FR Doc. 00-32644 Filed 12-21-00; 8:45 am]

BILLING CODE 4310-22-M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[AZA 18465]

Public Land Order No. 7474; Extension of Public Land Order No. 6493; Arizona

AGENCY: Bureau of Land Management, Interior.

ACTION: Public land order.

SUMMARY: This order extends Public Land Order No. 6493 for an additional 20-year period. This extension is necessary to continue the protection of the Bureau of Prisons North Phoenix Facility.

EFFECTIVE DATE: December 20, 2003.

FOR FURTHER INFORMATION CONTACT: Jim Andersen, BLM Phoenix Field Office, 2015 West Deer Valley Road, Phoenix, Arizona 85027, 623-580-5570.

By virtue of the authority vested in the Secretary of the Interior by section 204 of the Federal Land Policy and Management Act of 1976, 43 U.S.C. 1714 (1994), it is ordered as follows:

1. Public Land Order No. 6493, which withdrew land for the protection of a portion of the Bureau of Prisons North Phoenix Facility, is hereby extended for an additional 20-year period following its date of expiration.

2. This withdrawal will expire 20 years from the effective date of this order unless, as a result of a review conducted before the expiration date pursuant to section 204(f) of the Federal Land Policy and Management Act of 1976, 43 U.S.C. 1714(f) (1994), the Secretary determines that the withdrawal shall be extended.

Dated: December 13, 2000.

Sylvia V. Baca,

Assistant Secretary of the Interior.

[FR Doc. 00-32643 Filed 12-21-00; 8:45 am]

BILLING CODE 4410-05-P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[CO-930-1430-ET; COC-25845]

Public Land Order No. 7473; Extension of Public Land Order No. 5811; Colorado

AGENCY: Bureau of Land Management, Interior.

ACTION: Public land order.

SUMMARY: This order extends Public Land Order No. 5811 for an additional 20-year period. This extension is necessary to continue the protection of the Bureau of Reclamation's McPhee Dam and Reservoir.

EFFECTIVE DATE: January 21, 2001.

FOR FURTHER INFORMATION CONTACT:

Doris E. Chelius, BLM Colorado State Office, 2850 Youngfield Street, Lakewood, Colorado 80215-7093, 303-239-3706.

By virtue of the authority vested in the Secretary of the Interior by section 204 of the Federal Land Policy and Management Act of 1976, 43 U.S.C. 1714 (1994), it is ordered as follows:

1. Public Land Order No. 5811, which withdrew National Forest System lands for protection of the McPhee Dam and Reservoir, Dolores Project, is hereby extended for an additional 20-year period following its date of expiration.

2. This withdrawal will expire 20 years from the effective date of this order unless, as a result of a review conducted prior to the expiration date pursuant to Section 204(f) of the Federal Land Policy and Management Act of 1976, 43 U.S.C. 1714(f) (1994), the Secretary determines that the withdrawal shall be extended.

Dated: December 8, 2000.

Sylvia V. Baca,

Assistant Secretary of the Interior.

[FR Doc. 00-32642 Filed 12-21-00; 8:45 am]

BILLING CODE 4310-JB-P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[SDM 44591]

Public Land Order No. 7477; Extension of Public Land Order No. 5793; South Dakota

AGENCY: Bureau of Land Management, Interior.

ACTION: Public land order.

SUMMARY: This order extends Public Land Order No. 5793 for an additional 20-year term. This extension is

necessary to continue the protection of the Forest Service Terry Peak Electronic Site.

EFFECTIVE DATE: December 24, 2000.

FOR FURTHER INFORMATION CONTACT:

Sandra Ward, BLM Montana State Office, P.O. Box 36800, Billings, Montana 59107, 406-896-5052.

By virtue of the authority vested in the Secretary of the Interior by Section 204 of the Federal Land Policy and Management Act of 1976, 43 U.S.C. 1714 (1994), it is ordered as follows:

1. Public Land Order No. 5793, which withdrew National Forest System land for protection of the Terry Peak Electronic Site, is hereby extended for an additional 20-year term following its date of expiration.

2. This withdrawal will expire 20 years from the effective date of this order, unless, as a result of a review conducted prior to the expiration date pursuant to Section 204(f) of the Federal Land Policy and Management Act of 1976, 43 U.S.C. 1714(f) (1994), the Secretary determines that the withdrawal shall be extended.

Dated: December 19, 2000.

Sylvia V. Baca,

Assistant Secretary of the Interior.

[FR Doc. 00-32835 Filed 12-21-00; 8:45 am]

BILLING CODE 3410-11-P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

(NV-930-1430-EU; N-66786)

Notice of Realty Action; Nevada

AGENCY: Bureau of Land Management, Interior.

ACTION: Direct Sale of Public Lands in Nye County, Nevada.

SUMMARY: The following described land near Beatty, Nye County, Nevada, has been examined and identified as suitable for disposal by direct sale, at the appraised fair market value, to James Key, resident of Beatty, Nevada. The sale is authorized under Section 203 and Section 209 of the Federal Land Policy and Management Act (FLPMA) of October 21, 1976 (43 U.S.C. 1713 and 1719):

Mount Diablo Meridian, Nevada

T. 12 S., R. 47 E.,

Section 8, NW $\frac{1}{4}$ SW $\frac{1}{4}$ NW $\frac{1}{4}$ SW $\frac{1}{4}$;

comprising 2.5 acres, more or less.

The land will not be offered for sale until at least 60 days after the date of publication of this notice in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT:

Charles Wright, Realty Specialist, Bureau of Land Management, Tonopah

Field Station, P.O. Box 911, 1553 South Main Street, Tonopah, NV 89049.

SUPPLEMENTARY INFORMATION: The land has been identified as suitable for disposal by the Tonopah Resource Management Plan. The land is not needed for any resource program and is not suitable for management by the Bureau or another Federal department or agency. An environmental assessment which analyzes potential impacts from this action has been prepared and is available for review at the address shown above.

The mineral estate, excepting saleable minerals, has been determined to have no known value. Therefore, the mineral estate, excepting saleable minerals, will be conveyed simultaneously with the surface estate in accordance with Section 209(b)(1) of Federal Land Policy and Management Act of 1976. Acceptance of the sale offer will constitute application for conveyance of the mineral interests. The sale proponent will be required to submit a \$50.00 non-refundable filing fee for conveyance of the mineral interests with the purchase price for the land. Failure to submit the non-refundable fee for the mineral estate within the time frame specified by the authorized officer will result in cancellation of the sale.

Upon publication of this Notice of Realty Action in the **Federal Register**, the lands will be segregated from all forms of appropriation under the public land laws, including the mining laws, but not the mineral leasing laws or disposals pursuant to Sections 203 and 209 of FLPMA. The segregation shall terminate upon issuance of a patent or other document of conveyance, upon publication in the **Federal Register** of a termination of segregation, or 270 days from date of this publication, which ever occurs first.

Patent, if issued, will be subject to the following third party rights: Excepting and Reserving to the United States:

1. Saleable minerals,
2. A right-of-way thereon for ditches or canals constructed by the authority of the United States. Act of August 30, 1980 (43 U.S.C. 945).

Subject to: All valid existing rights.

For a period of 45 days from the date of publication in the **Federal Register**, interested parties may submit comments to the Assistant Field Manager, Tonopah Field Station, P.O. Box 911, Tonopah, NV 89049. Any adverse comments will be evaluated by the State Director, who may sustain, vacate or modify this realty action and issue a final determination. In the absence of timely filed objections, this realty action will become a final determination of the Department of the Interior.

Dated: December 12, 2000.

W. Craig MacKinnon,

Assistant Field Manager.

[FR Doc. 00-32738 Filed 12-21-00; 8:45 am]

BILLING CODE 4310-HC-P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[NV-930-1430-ET; NVN-73931]

Notice of Proposed Withdrawal and Opportunity for Public Meeting; Nevada

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: The Bureau of Land Management proposes to withdraw 277.046 acres of public lands for a period of 20 years to protect the historic town of Rhyolite. This notice closes the lands for up to 2 years from surface entry and mining while various studies and analyses are made to make a final decision.

DATES: Comments and requests for meeting should be received on or before March 22, 2001.

ADDRESS: Comments and meeting requests should be sent to the Nevada State Director, BLM, 1340 Financial Blvd., P.O. Box 12000, Reno, Nevada 89520-0006.

FOR FURTHER INFORMATION CONTACT: Dennis J. Samuelson, BLM Nevada State Office, 775-861-6532.

SUPPLEMENTARY INFORMATION: On December 8, 2000, a petition was approved allowing the Bureau of Land Management to file an application to withdraw the following described public lands from settlement, sale, location, or entry under the general land laws, including the mining laws, subject to valid existing rights:

Mount Diablo Meridian

T. 12 S., R. 46 E.,
secs. 9 and 16 (within).

The areas described aggregate 277.046 acres in Nye County. For a more complete description, you may contact Dennis J. Samuelson at the phone number or address listed above.

The purpose of the proposed withdrawal is for the Bureau of Land Management to protect the historic town of Rhyolite, which contains numerous cultural resources. The most prominent resource is a train depot built in 1906. The lands will be managed for historic and recreation purposes. Rhyolite is located about 90 miles northwest of Las Vegas near the town of Beatty.

For a period of 90 days from the date of publication of this notice, all persons who wish to submit comments, suggestions, or objections in connection with the proposed withdrawal may present their views in writing to the Nevada State Director of the Bureau of Land Management.

Notice is hereby given that an opportunity for a public meeting is afforded in connection with the proposed withdrawal. All interested persons who desire a public meeting for the purpose of being heard on the proposed withdrawal must submit a written request to the Nevada State Director within 90 days from the date of publication of this notice. Upon determination by the authorized officer that a public meeting will be held, a notice of the time and place will be published in the **Federal Register** at least 30 days before the scheduled date of the meeting.

The application will be processed in accordance with the regulations set forth in 43 CFR Part 2300.

For a period of 2 years from the date of publication of this notice in the **Federal Register**, the lands will be segregated as specified above unless the application is denied or canceled or the withdrawal is approved prior to that date. Other uses which will be permitted during this segregative period are rights-of-way, leases, and permits.

Date: December 18, 2000.

Margaret L. Jensen,

Deputy State Director, Natural Resources, Lands, and Planning.

[FR Doc. 00-32760 Filed 12-21-00; 8:45 am]

BILLING CODE 4310-HC-P

DEPARTMENT OF THE INTERIOR

National Park Service

Record of Decision; Winter Use Plans for the Yellowstone and Grand Teton National Parks and John D. Rockefeller Jr., Memorial Parkway

Responsible Official:

Dated: November 22, 2000.

Karen Wade,

Intermountain Regional Director, National Park Service.

Record of Decision

Winter Use Plans for Yellowstone and Grand Teton National Parks and the John D. Rockefeller Jr., Memorial Parkway

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Record of Decision

Winter Use Plans for Yellowstone and Grand Teton National Parks and the John D. Rockefeller Jr., Memorial Parkway

The Decision

This decision made as a result of the Winter Use Plans Final Environmental Impact Statement (FEIS) for Yellowstone (YNP) and Grand Teton National Parks (GTNP) and the John D. Rockefeller Jr., Memorial Parkway (the Parkway) will guide winter use management in the three park units. The decision is to select a modified form of alternative G, as described and evaluated in the FEIS, with the changes to that alternative explained here. Elements of the decision are given in detail below as actions and assumptions

common to all 3 units, actions specific to Yellowstone, actions specific to Grand Teton and the Parkway, mitigation, and monitoring. The maps for alternative G and the description of each management zone provided in the FEIS, while not duplicated in this Record of Decision, are features of this decision.

In order to implement portions of this decision, the National Park Service (NPS) will propose to amend its regulations at 36 CFR 7.13(l), 7.21(a), and 7.22(g). Although this decision is final for the purposes of this planning project, those elements that will go through the rule making process may be modified based on further public comments.

Decision

The selected alternative emphasizes cleaner, quieter access to the parks using the technologies available today. Effective the winter of 2003–2004 and thereafter, it will allow oversnow motorized recreation access via NPS-managed snowcoach only, with limited exceptions for continued snowmobile access to other public and private lands adjacent to or within GTNP. Until then, interim actions will progressively reduce the impacts from snowmobile use in the parks.

This decision addresses the full range of issues regarding safety, natural resource impacts, and visitor experience and access. It addresses the issues in a way that will make it necessary for local economies to adapt, and for snowmobile users to access the parks using a different mode of transport.

Actions and Assumptions Common to All Units

Implementation

- Unless otherwise noted, the parks will implement all actions the winter following the Record of Decision (ROD) for the winter use plans and EIS. Actions requiring a change in regulations will be implemented once the new regulations are effective.

- If it can be demonstrated sufficiently for NPS to determine that an implemented action has affected or would substantially affect a concession operation prior to the expiration of its contract, the action will be implemented only through negotiation or when a new contract is awarded.

- NPS will develop a detailed snowcoach implementation plan in coordination with gateway communities, concessioners and winter permittees.

- NPS will coordinate with gateway communities, concessioners and winter

permittees and state tourism program resources on a new marketing strategy designed to facilitate winter visitation by snowcoach.

- Allow a planning and implementation period of 3 (three) years.

- In the winter of 2000–2001, snowmobile and snowplane use will continue under current regulations. This is a departure from alternative G. This change is made because the implementation of changes in snowmobile and snowplane use that require new regulations could not be made until the 2000–2001 season is nearly over. Waiting until 2001–2002 to set new limits on snowmobile and snowplane use will afford ample public notice of the new limits.

- In the winter of 2000–2001, actions that do not require regulations (such as increasing ranger patrols to reduce the disturbance of wildlife) will be undertaken to reduce the impacts from snowmobile use.

- In the winters of 2001–2003, existing commercial snowcoach operators will be encouraged to increase their fleet size, and snowmobile and other new operators will be encouraged to purchase or lease coaches and reduce snowmobile numbers.

- In 2001–2002, daily limits will be set on snowmobile and snowplane use so that daily use levels cannot increase above the average peak day use levels of recent years, as shown in table 1, below.

- In 2002–2003, daily limits will be set to limit total recreational snowmobile use to approximately 50% of the current average annual use levels at the South and West Entrances of YNP. Current snowmobile use levels will be maintained from the East and North Entrances of YNP. See table 1, below.

- In 2002–2003 for GTNP and the Parkway eliminate snowmobile use on the Teton Park Road, all motorized use on Jackson Lake, and all other recreational snowmobile use except for that on the CDST, Grassy Lake Road, and access routes to adjacent public lands, with limits shown in table 1, below.

- In 2003–2004 and thereafter, all oversnow motorized visitor travel in the parks will be by snowcoach, except for limited routes in GTNP that will remain open for snowmobile access to adjacent public or private lands and to private inholdings.

Regulation/Enforcement/Administration

- Several actions include possible road closures depending on the results of scientific studies. None of the actions preclude other closures for safety,

resource protection, or other reasons as identified in 36 CFR 1.5 or 2.18.

- At present no Environmental Protection Agency (EPA) standards exist for off-road vehicles. If the EPA adopts standards or measurement methods for vehicle emissions and sound applicable to winter use in the parks, they will be implemented in accordance with EPA regulations.

- Require all new oversnow vehicles purchased by the parks to conform to the best environmental standards available, and that other vehicles are retrofitted whenever possible with new technologies designed to lower sound and emission levels.

- Increase the field presence of park rangers during the interim period before full implementation of snowcoach access to monitor, anticipate, detect and mitigate resource and wildlife impacts and to increase visitor safety.

Resource Protection

- Continue scientific studies and monitoring regarding winter visitor use and park resources. Close selected areas of the park, including sections of roads, to visitor use if scientific studies indicate that human presence or activities have a detrimental effect on wildlife or other park resources that could not otherwise be mitigated. The appropriate level of environmental assessment under NEPA will be completed for all actions as required by CEQ regulations (40 CFR parts 1500–1508).

- Give a 1-year notice before any closure is implemented unless immediate closure is deemed necessary to avoid impairment of park resources or to protect public safety.

- Sand, or an equally environmentally neutral substance, will be used for traction on all plowed winter roads. Before spring opening, sand removal operations will continue on all plowed park roads.

- Investigate and implement options to reduce the palatability and accessibility to wildlife of the hydraulic fluid used in snow groomers.

- When snow depth warrants and at periodic intervals, routine plowing or grooming operations will include laying back roadside snowbanks that could be a barrier to wildlife exiting the road corridor.

Visitor Use and Access

- NPS will determine visitor use capacities based on studies that set indicators and standards for desired visitor experiences and resource conditions. The NPS will monitor indicators to maintain the conditions for each management prescription. If

necessary, techniques such as reservations, permits, and differential fees will be implemented. See zone descriptions, monitoring table, and Appendix H (Recreation Carrying Capacity).

- Continue to implement transition and action plans for accessibility and support the philosophy of universal access in the parks. The NPS will make reasonable efforts to ensure accessibility to buildings, facilities, programs, and services. The NPS will develop strategies to ensure that new and renovated facilities, programs and services (including those provided by concessioners) are designed, constructed, or offered in conformance with applicable policies, rules, regulations, and standards (including but not limited to the Architectural Barriers Act of 1968; the Americans with Disabilities Act of 1990 (ADA); the Uniform Federal Accessibility Standards of 1984 (UFAS); and the Guidelines for Outdoor Developed Areas of 1999).

- Architectural and Site Access and Programmatic Access: The NPS will evaluate existing buildings and existing and new programs, activities, and services (including telecommunications and media) to determine current accessibility and usability by disabled winter visitors. Action plans to remove barriers will be developed.

- This decision includes an affirmative commitment to implement strategies designed to provide a reasonable level of affordable access to winter park visitors.

- Backcountry nonmotorized use will continue to be allowed throughout the parks except where designated otherwise for resource protection purposes (shown as Zone 11 or area of designated trail use on alternative map).

- Other means of oversnow travel not foreseen in this Record of Decision must be specifically approved by the park superintendent.

- In the third year of the interim period (2002–2003), snowmobiles in YNP must be accompanied by an NPS permitted guide and travel in groups of no more than 11 (including the guide). The superintendent will be authorized to also require groups and guides in GTNP and the Parkway.

- In 2003–2004 and thereafter, permit only NPS-managed mass transit snowcoaches on designated oversnow roads, other than for allowable administrative, emergency or other snowmobile access as specified in other actions in this document.¹

¹ Note: The term “NPS managed” refers to permit management. In this case the mass transportation

- Through the permitting process phase out all oversnow vehicles that do not meet the best available environmental standards for oversnow mass transit travel. Currently, the mass transit oversnow vehicle that produces the lowest emissions is the conversion van mat track.² Any oversnow mass transit system in the parks must be low emission, quiet, safe, affordable, accessible, and comply with the requirements of EO 11644.

- Allow mass transit snowcoaches only when their sound levels are at or below 75 decibels as measured on the A-weighted scale at 50 feet at full throttle. Continue to work with snowcoach manufacturers and operators to meet a long-term goal to lower snowcoach sound levels to 70 decibels or lower.

- Prohibit late night oversnow travel from about 11 p.m. to 6 a.m. in 2000–2001, and thereafter from about 9 p.m. to 8 a.m., unless specifically authorized.

- Implement an information program on snow and trail conditions, points of interest, and available recreational opportunities. Through partnerships, establish park visitor contact opportunities in gateway communities and utilize state tourism program resources.

Actions Specific to Yellowstone National Park

- In Yellowstone, the NPS will continue to allow the plowing of Highway 191 and will continue to plow the road from Mammoth to Tower and Tower to the Northeast Entrance (Cooke City) throughout the winter.

- Grand Canyon of the Yellowstone and the McMin Bench bighorn sheep area will continue to be closed to winter use.

- Winter garbage storage facilities that are wildlife-proof will be constructed in the Old Faithful, Grant, Lake, and Canyon areas.

snowcoach system would be provided by private concessioners who operate under a permit from the NPS. Under the terms of the permit or concessions contract, the NPS may stipulate, among other items, the type of services to be offered, cost to the public, and number of visitors that may be served or transported. The NPS may require that the types of vehicles used meet certain environmental, accessibility and safety requirements. It is the responsibility of the NPS to monitor all services offered under permit to ensure that the public and the parks are being well served. These permits are generally offered for competitive bidding in limited numbers and are granted for a specific number of years.

² Estimates of emissions for conventional vans converted for oversnow travel indicate that the emissions increase once the conversion is made. For this reason adherence to EPA regulations for similar wheeled vans is neither appropriate nor required.

- Continue all existing groomed motorized routes (zone 3). Offer snowcoach service on the East Entrance Road if safety goals can be met. Management of avalanche danger on the East Entrance Road may mean unscheduled closures of the road to all travel.

- Provide nonmotorized opportunities (e.g., skiing and snowshoeing) (zones 8 and 9). Examples of existing roads or trails that will be groomed include Fountain Flats Road and portions of the East Entrance road.

- Where feasible, set parallel tracks on one or both sides of the snow roads to facilitate nonmotorized access.

- Increase interpretive opportunities related to the unique aspects of the winter environment by providing interpretive programs at destination areas and warming huts. Provide guided interpretive programs for organized groups on snowcoaches. Provide interpretive ski and snowshoe tours and programs such as near Tower, Canyon, Mammoth, Old Faithful, West Thumb, Madison, and West Entrance.

- Increase the size and number of warming huts and other day use facilities. Place warming huts and restrooms at popular ski trailheads (for example Tower), as support for motorized staging areas (for example Norris), and where the existing facility size is currently inadequate to handle to the dual function of warming hut and interpretive program staging area (for example, Canyon).

- Restrict nonmotorized uses in certain wildlife winter ranges and thermal areas to travel on designated routes or trails (zones 8 and 9).

- Implement the winter use season during the period from late November to mid-March.

- Reduce administrative snowmobile³ use from the 106 currently used and supplement with administrative snowcoaches, subject to available funding. When practicable, replace administrative snowmobiles with a type that meets the best available emission and sound limits.

- Continue allowing personal non-recreation use of snowmobiles by employees and their families living in the interior of Yellowstone; however, subject to available funding, provide administrative snowcoaches for their use and encourage them to replace their current snowmobiles with cleaner and quieter machines.

- Allow limited use of administrative snowmobiles by concessioners. Require cleaner and quieter technologies as they are developed (through permit and

contracts) and encourage the use of snowcoaches.

Actions Specific to Grand Teton National Park and the Parkway

- In Grand Teton and the Parkway, the following roadways will continue to be plowed:

- Highway 26/89/187 from the south boundary of the park to Moran

- Highway 89/287 from Moran to Colter Bay

- Highway 26/287 from Moran to the eastern park boundary

- Teton Park Road from Moose Junction to Taggart Lake Trailhead, and from Jackson Lake Junction to Signal Mountain Lodge; from Highway 89/287 along the Pacific Creek road to the park boundary; from Kelly to the eastern park boundary; from Gros Ventre Junction to Kelly to Shadow Mountain staging area; and the road to the eastern park boundary at Ditch Creek.

- Current winter closures will remain in effect on the Snake River floodplain, the Buffalo Fork River floodplain, the Uhl Hill area, Willow Flats, Kelly Hill, and Static Peak.

- Reasonable and direct access to adjacent public and private lands, or to privately owned lands within the park with permitted or historical motorized access, will continue via paved and plowed routes or via oversnow routes from GTNP (used by snowmobiles).⁴

- Provide opportunities for oversnow motorized trail use (zone 3) by snowcoaches only on the unplowed, groomed surface of the highway from Colter Bay to Flagg Ranch, in the future upon the meeting of certain conditions, and, effective 2003–2004 and thereafter, north into Yellowstone, and on the Grassy Lake Road.⁵

- Provide opportunities for nonmotorized ungroomed winter trail use (zone 9):

- On the Teton Park Road from Taggart Lake Trailhead to Signal Mountain.

- On Antelope Flats.

- Near Colter Bay and Two Ocean Lake.

- On the unplowed portion of the Moose-Wilson road.

- Continue destination and support facilities at Moose, Triangle X, Colter Bay, and Flagg Ranch, and add warming hut facilities along the Teton Park Road to provide visitor services and

interpretive opportunities that focus on nonmotorized uses (zone 1).

- Limit backcountry nonmotorized use to designated routes to address wildlife issues in certain wildlife winter ranges, or close certain areas to all use.

- Winterize facilities at Colter Bay to provide a suitable staging area for snowcoach access.⁶

- Effective 2002–2003, discontinue the motorized use of Jackson Lake's frozen surface (no snowplanes or snowmobiles).

- Increase interpretive opportunities related to the unique aspects of the winter environment by providing interpretive programs at destination areas and warming huts. Provide guided interpretive programs for organized groups on snowcoaches. Provide interpretive ski and snowshoe tours and programs at locations such as Moose, Colter Bay, and Flagg Ranch visitor services.

- Phase in administrative snowmobile types that meet the best available emission and sound limits. Administrative use of snowmobiles in Grand Teton is limited to law enforcement, utility and maintenance access, permitted scientific studies, search and rescue or other use as approved by the superintendent.⁷

Definitions

- Oversnow motor vehicles: self-propelled vehicles intended for travel on snow, driven by a track or tracks in contact with the snow that may be steered by skis or tracks in contact with the snow. This term includes both snowmobiles and snowcoaches.

- Snowmobiles: self-propelled vehicles intended for travel on snow, having a curb weight of not more than 1,000 pounds (450kg), driven by a track or tracks in contact with the snow, which may be steered by a ski or skis in contact with the snow.

- Snowplanes: self-propelled vehicles intended for oversnow travel, having a weight of not more than 1,000 pounds (450kg) mounted on skis in contact with the snow, and driven by a pusher-propeller.

- Snowcoaches: self-propelled, mass transit vehicles intended for travel on snow, having a curb weight of over 1,000 pounds (450kg), driven by a track or tracks and steered by skis or tracks, having a capacity of at least 8 passengers.

- The phrase gateway communities refers to the towns of Jackson and Cody,

⁴ 16 U.S.C. 406d–1, *et seq.*

⁵ Termination of plowing from Colter Bay to Flagg Ranch is contingent upon the winterization of facilities at Colter Bay and expiration and reissuance of a concession contract associated with Flagg Ranch. The present contract expires in 2009. See Actions and Assumptions Common to All Units, second bullet under Implementation.

⁶ This provision is contingent upon the termination of plowing from Colter Bay to Flagg Ranch.

⁷ EO 11644, sections (3) and (4).

³ EO 11644, sections (3) and (4).

Wyoming, and Gardiner and West Yellowstone, Montana.

- A designated route for nonmotorized recreation is defined as a marked or otherwise indicated oversnow travel way.

Mitigation

Mitigation beyond the actions described in the decision is necessary to reduce disclosed impacts to a level that meets legal requirements, or that is otherwise acceptable within the framework of regulations, executive orders or policies. The following measures are necessary to further mitigate impacts of this decision during the interim period before full implementation and thereafter.

Air Quality

- Park concessions will be required to mitigate the impacts of air pollution during the interim period by selling only bio-fuels and synthetic lubes inside the park.

Water Resources

- Best management practices will be used during the construction, reconstruction, or winter plowing of trails and roads to prevent unnecessary vegetation removal, erosion, and sedimentation.
- Separate new or reconstructed winter-motorized trails from drainages where practicable to mitigate the routing of snowpack contaminants into surface water.

- Any new or reconstructed winter use sanitary facilities will be constructed in locations and with advanced technologies that will protect water resources.

- A focused monitoring program will reduce the uncertainty of impacts from oversnow vehicles, and if necessary indicate best management practices that might be implemented.

Wildlife, Including Federally Protected Species and Species of Special Concern

- NPS personnel will patrol sensitive resource locations to ensure compliance with area closures.

- NPS personnel will increase patrols of locations where disturbance of wildlife by snowmobile use is most common, to reduce that disturbance.

- Monitoring of eagle populations to identify and protect nests will continue. The park will continue to support the objectives of the Greater Yellowstone Bald Eagle Management Plan.

- Monitoring of wolf populations will continue.

- Lynx surveys will be undertaken to document the distribution and abundance of lynx in the parks and their relationship to packed surfaces. The presence of other carnivores will be documented. The parks will abide by the recommendations of the Lynx Conservation Assessment Strategy.

- Continue to assess grizzly bear abundance, distribution, and habitat selection, including the location of dens. The information obtained will assist park managers in protecting important habitats and planning recreational activities that minimize disturbance to bears. Monitoring grizzly bear populations will continue in accordance with the Interagency Grizzly Bear Management Guidelines and the parks' bear management plans.

- Monitoring and protecting trumpeter swan habitats and nests will continue, including the closure of nest sites, when warranted, to public access from February 1 to September 15.

- Monitoring potential or known winter use conflicts will result in area closures if necessary to protect wildlife habitat.

- Conduct snow track surveys for carnivores (including lynx) on both groomed and ungroomed routes.

- Continue to monitor use of groomed, ungroomed, and plowed surfaces by bison and other ungulates.

Cultural Resources

- Should the discovery of human remains, funerary objects, sacred objects, or objects of cultural patrimony occur during construction, provisions outlined in the Native American Graves Protection and Repatriation Act of 1990 (25 USC 3001) will be followed.

- Trails and trailheads will be sited to avoid adversely impacting known cultural resources, including potential cultural landscapes. In addition, the use of natural materials and colors for all permanent signs erected will allow the signs to blend into their surroundings.

Interim Snowmobile Use Limits

During the winter of 2000–2001 snowmobile use will continue to be allowed under existing regulations. This deviates from the FEIS since regulations on use limits will not be finalized until near the end of that winter season or later. Making a change during that season would not provide enough notice to visitors, many of whom would have

already made plans to visit the parks before any limits could be finalized.

- During the winter of 2001–2002, snowmobile use will be capped as follows:

- Set daily snowmobile use numbers for all three park units at levels not to exceed the 7-year peak daily average. The visitor scenario developed for alternative A (see FEIS appendix G) shows snowmobile use distribution at YNP gateways, and by road segments in the three parks at both the current daily average and peak average snowmobile use levels over the past seven years. The scenario provides numbers that can be expressed as interim visitor use limits. Maximum daily limits at the entrances will be set at the average peak day snowmobile use (see Table 1 and footnote at the bottom of the following page).

- For snowplane use on Jackson Lake reissue permits to permit holders of record and do not issue any new permits. Limit snowmobile use on Jackson Lake to 30 per day.

- If monitoring indicates a trend of significant increase above average daily use as shown in Table 1, NPS will consider adjusting the cap downward at other than traditional peak use periods pursuant to, and as authorized under, 36 CFR 1.5 and 2.18.

- In 2002–2003 set daily snowmobile entrance limits to reduce total recreational snowmobile use to levels that will result in approximately 50% of the current average annual use level at the South and West Entrances of YNP. Current snowmobile use levels will be maintained from the East and North Entrances of YNP.

- In 2002–2003 for the Parkway, in addition to limiting use between Flagg Ranch and the South Entrance to YNP, limit snowmobile use on the Grassy Lake Road and the CDST in the Parkway to current use levels.

- In 2002–2003 for GTNP eliminate snowmobile use on the Teton Park Road, all motorized use on Jackson Lake, and all other recreational use by snowmobiles except for that on the CDST and access routes to adjacent public lands. Limit snowmobile use on the CDST in GTNP to current use levels.

- In 2003–2004 and thereafter, all oversnow motorized visitor travel in the parks will be by snowcoach except for limited routes in GTNP that will remain open for snowmobile access.

TABLE 1.—INTERIM CAPS ON SNOWMOBILES IN YELLOWSTONE (YNP), ROCKEFELLER PARKWAY (JDRMP) AND GRAND TETON (GTNP)

Road segments	Historic average daily use	2001–2002 Peak day limits	2002–2003 Daily limits
YNP North Entrance	41	60	60
YNP West Entrance	555	1030	278
YNP East Entrance	37	100	65
JDRMP Flagg Ranch to YNP South Entrance	176	330	90
JDRMP Grassy Lake Road	25	40	25
JDRMP Flagg Ranch to GTNP Moran Junction	25	70	25
GTNP Jackson Lake	30	30	0
GTNP Teton Park Road	11	20	0
GTNP Moose-Wilson Road	3	10	0

*Implementation of this limit is to ensure that use does not exceed the historic averages for use on the busiest peak days and the level of impact associated with it. Use fluctuates daily, increasing especially during certain holiday periods. Use caps should act to allow such fluctuations, since this is the nature of business and visitation. This is why the peak use day represents a cap, to allow the business pattern to continue. It *is not* the intent of this cap to allow peak use numbers to occur every day. If this were to occur then levels would be exceeded overall, and additional impacts would be incurred. It *is* the intent of this cap to replicate the pattern and amount of use that has been established over an average of seven years.

Monitoring

In order to assess the long-term effects of management actions on park resources and values resource inventory, monitoring and adaptive management are incorporated into this decision. The key resources and values potentially impacted by winter recreation use in the three park units are air quality, wildlife, sound,⁸ water resources, safety, and visitor experience. Attachment A outlines specific indicators for monitoring these resources and values. The indicators will be monitored to ensure protection of natural resources and park values and evaluate management success. The selected alternative also includes adaptive management provisions. It provides for systematic feedback to park management and allows for adjustment of activities to mitigate unplanned or undesirable outcomes. Procedures, indicators, standards and potential management actions for adaptive

management are also presented in Attachment A.

Monitoring programs will be coordinated among the parks. The programs will function and be coordinated through the planning staffs of the parks. The development of annual plans and reports will be coordinated through the planning units, and the planning units will be responsible for delivering those products. Actual monitoring responsibilities for park personnel will be assigned through annual plans.

Monitoring programs will be conducted on a sampling basis for the purpose of effective use of funds and personnel. It is expected that initial monitoring will be intensive, both in geographic and temporal extent, so that correlations can be made and results can be extrapolated. It is also expected that monitoring over time will become less intensive and arrive at a low intensity, maintenance level. Sampling schedules can vary from year to year, focusing on different areas within the park units.

U.S. EPA expressed concerns about the actions that would be taken if NPS does not have sufficient funds to monitor winter use in accordance with the adaptive management part of this decision. Actions affecting park values for which there are no defined standards, such as odor, sound or visitor satisfaction, are subject to an adaptive management approach. If continuing problems are indicated relative to such impacts, but there are not sufficient funds for focused monitoring and evaluation of those problems, emergency management actions will be implemented to eliminate the impact pending the attainment of funds.

Rationale for the Decision

This section provides the reasons for selecting FEIS alternative G as the decision and the basis for winter use plans in the three park units. In arriving at this decision, I have considered the detailed analysis of effects in the FEIS

for a range of alternative plans that would govern winter use. I have considered how each alternative responds to the purpose and need for action, to improve existing conditions in the parks and move them toward a desired condition that is implicit in NPS mandates. In doing so, I considered the impacts for each alternative program and weighed them against affirmative direction for protecting park resources and values, and their enjoyment by future generations, from adverse impacts or impairment. I also considered the degree to which each alternative would enhance the condition of resources or values and their enjoyment. Other considerations include socioeconomic impacts, effects on lands adjacent to the three parks, the plans or desires articulated by local communities and nonfederal governments, and the full body of public comments on the draft EIS. All these considerations are presented below as they contribute to the decision.

The fundamental basis for the decision is the direction provided in laws, regulations, executive orders and policies (mandates) that relate to human uses of the parks and their effect on park resources and values. This basis is overlain by the analysis of effects on park resources and values disclosed in the FEIS. Then, conclusions or findings are made about the alternatives and their effects in relation to the key mandates regarding adverse impacts and impairment. Other considerations are incorporated into the discussion.

Basis for the Decision

Law

The fundamental purpose of the national park system established by the Organic Act and reaffirmed by the General Authorities Act, as amended, begins with a mandate to conserve park resources and values. This mandate is independent of the separate prohibition on impairment and applies all the time, with respect to all park resources and

⁸ NPS Director's Order #47 provides guidance for inventory and monitoring procedures necessary to preserve the natural soundscape. NPS-77 provides guidance for monitoring and inventory of other natural resources elements.

values, even when there is no risk that any park resources or values may be impaired. NPS managers must always seek ways to avoid, or to minimize to the greatest degree practicable, adverse impacts on park resources and values. The laws give the NPS the discretion to allow some impacts to park resources and values when appropriate and necessary to fulfill the purposes of a park as long as that impact does not constitute impairment.

The Organic Act mandate includes providing for the enjoyment of park resources and values by the people of the United States. The mandate applies not just to the people who visit the parks—but to all the people—including those who derive inspiration and knowledge from afar. NPS policies acknowledge that providing opportunities for public enjoyment is a fundamental part of the NPS mission. While the policies permit recreation and other activities, including NPS management activities, they may be allowed only when they will not cause an impairment or derogation of a park's resources, values or purposes. Recognizing that the enjoyment of the national parks by future generations can be assured only if the quality of park resources and values is left unimpaired, Congress has provided that when there is a conflict between conserving resources and values and providing for enjoyment of them, conservation is to be the primary concern.⁹

Regulation

Snowmobiling (specifically) may be allowed only where it is consistent with the park's natural, cultural, scenic and aesthetic values, safety considerations, park management objectives, and will not disturb wildlife or damage park resources.¹⁰

Executive Orders

Areas and trails for off road vehicle use shall be located in areas of the national park system only if the agency head determines that off road vehicle use in such locations will not adversely effect their natural, aesthetic or scenic values. Use will be controlled or directed to protect the resources, promote safety, and minimize conflicts among various users of those lands. Also, the agency head shall monitor the effects of such use that may be authorized, and upon that information

they shall from time to time amend or rescind designations, or take other actions to eliminate adverse impacts.¹¹ If the agency determines that the use of off-road vehicles (including snowmobiles) will cause or is causing considerable adverse effects on the soil, vegetation, wildlife, wildlife habitat, such areas shall immediately be closed to that use.¹²

Interpretation of Policy

Impairment is an impact that, in the professional judgment of the responsible NPS manager, would harm the integrity of park resources or values, including the opportunities that otherwise would be present for the enjoyment of those resources or values. Impairment may occur from visitor use or park management activities.¹³

NPS Director's Order # 55 define the terms "resources and values" as the park's scenery, natural and historic objects, and wildlife, including, to the extent present in the park: The ecological, biological and physical processes that created the park and that continue to act upon it; scenic features; natural visibility (both in daytime and at night); natural landscapes; natural soundscapes¹⁴ and smells; water and air resources; soil; geological resources; paleontological resources; archeological resources; cultural landscapes; ethnographic resources; historic and prehistoric sites, structures, and objects; museum collections; and native plants and animals. The park's resources and values also include the opportunity for enjoyment of these resources, to the extent that can be done without impairing them. The term also includes the park's role in contributing to the national dignity, the high public value and integrity, and the superlative environmental quality of the national park system, and the benefit and inspiration provided to the American people by the national park and any additional specific purposes for which a park was established. An impact is more likely to constitute an impairment to the

extent that it affects a resource or value whose conservation is:

- Necessary to fulfill specific purposes identified in the establishing legislation;
- Key to the cultural or natural integrity of the park or opportunities to enjoy the park; or
- Identified as a goal in relevant NPS planning documents.

The 1988 NPS Management Policies state that the National Park Service will seek to perpetuate the best possible air quality in parks because clean air is critical to visitor enjoyment, human health, scenic vistas, and the preservation of natural systems and cultural resources. The policies also recognize that many natural resources, including water and wildlife, are sensitive to air pollution. Additionally, NPS must err on the side of protecting air quality and related values if there is doubt as to the impacts on park resources of existing or potential air pollution.¹⁵ NPS also has recognized that it must preserve the natural quiet and the natural sounds associated with the physical and biological resources of the parks. Managers must monitor sounds and take actions to prevent or minimize unnatural sounds that adversely affect park resources or values and visitors' enjoyment of them.

The 1988 NPS management policies¹⁶ also recognize that the NPS Organic Act directs the agency to provide for the public enjoyment of parks while leaving resources unimpaired for future generations. The policies mandate that the use of parks will be resource-based and nonconsumptive of resources. To the extent practicable, the NPS will encourage people to come to the parks and to pursue inspirational, educational, and recreational activities related to the resources found in the parks. NPS must manage visitor use and, as necessary, regulate the amount and kind, and the time and place, of visitor activities.

NPS must encourage recreational activities that are consistent with applicable legislation, that promote visitor enjoyment of park resources through a direct association or relation to those resources so long as those uses are consistent with the protection of the resources and are compatible with other visitor uses. NPS must manage recreational use to protect park resources, provide for public enjoyment, promote public safety, and minimize conflicts with other visitor activities and park uses. Finally, unless the activity is required by statute, NPS will not allow

¹¹ EO 11644, Use of Off-Road Vehicles on Public Lands, *Federal Register*, Vol 37, page 2877, No. 27—Wed. February 9, 1972.

¹² EO 11989, Off Road Vehicles on Public Lands, *Federal Register*, Vol 42, page 26959 No: 101—Wed. May 25, 1977.

¹³ Directors Order #55, September 8, 2000, as amended November 17, 2000.

¹⁴ NPS Director's Order #47 articulates operational policies requiring the protection, maintenance or restoration of the natural soundscape resource in a condition unimpaired by inappropriate noise sources. Inappropriate noise is that generated by activities at a level described as excessive, which impacts the park's natural soundscapes and jeopardizes the natural resources or the purposes for which the park was created.

⁹ The Redwood Act of March 27, 1978 serves as the basis for any judicial resolution of competing private and public values and interests in the national park system, and affirms the primary consideration of conserving, unimpaired, park resources and values.

¹⁰ 36 CFR 2.18 Snowmobiles.

¹⁵ 1988 NPS Management Policies, Chapter 4

¹⁶ 1988 NPS Management Policies, Chapter 8

a recreational activity in a park if it would involve or result in:

- Inconsistency with the park's enabling legislation or proclamation, or derogation of the values or purposes for which the park was established
- Unacceptable impacts on visitor enjoyment due to interference or conflict with other visitor use activities
- Consumptive use of park resources
- Unacceptable impacts on park resources or natural processes
- Unacceptable levels of danger to the welfare or safety of the public, including participants

Public use of a park is an important reason for the creating and sustaining the national park system. In developing the winter use plan and environmental impact statement, the goal of the parks was to provide for a winter use experience to a wide range of people, not just to the most physically fit. Given the mandate of the Organic Act, to preserve and provide for public enjoyment, some level of adverse impact from visitor use during the winter is acceptable, if the parks mitigate the impacts to the greatest extent practicable. Should future monitoring disclose that the impacts are too much for the resources to sustain, it will be appropriate to further restrict winter visitor use in the parks.

How Environmental Issues Were Considered and Addressed

Considering present winter use activities, the key management concerns and objectives relating to park resources and values are: Air quality, wildlife (especially ungulates), natural soundscapes, and opportunities for visitor experience (of these resources and values, including scenic quality and aesthetics). Related concerns that are key elements in the desired condition are the safety of employees and visitors, and access for purposes of park enjoyment. Finally, there is an issue regarding how local, private commercial industries have developed to serve visitors and facilitate their enjoyment of the parks.

Natural Resources

The analysis of natural resource/environmental consequences for a range of alternatives shows clearly that there are overall adverse impacts associated with snowmobile use in the parks, even when some areas are closed to that use. Snowmobile use at current levels adversely affects wildlife, air quality, and natural soundscapes and natural odors. Further, it adversely impacts the enjoyment of those values and resources by other visitors. The impact on people who may visit the three parks once or

twice in a lifetime, and who seek the resources and values for which the parks were created, may be adversely and irretrievably affected.

Elimination of these impacts is most easily and effectively accomplished by eliminating snowmobile use. Holding use at current levels under all alternatives but G would allow documented adverse impacts of snowmobiles to continue. The level of adverse impact varies by resource or value, and by alternative, but it is demonstrated to be more than negligible and often moderate when considered cumulatively over the three park units. Locally, the impact can be major. The effect on resources and values is demonstrated to impact the enjoyment of those resources by other visitors. Mitigation of the impacts of snowmobiles, as proposed in the different alternatives, is insufficient to reduce the impacts to a level deemed acceptable within the constraints of the law, regulations, executive orders and policies presented as the basis for this decision. Reduction of numbers of snowmobiles is problematic because carrying capacity studies are left to the future, and adverse impacts would continue until capacities are determined and effectively implemented.

Other winter uses and means of access also produce impacts. Cross country skiing and other nonmotorized forms of recreation are shown to impact wildlife. Since there are areas that can be identified as critical to bison and other ungulates, mitigation as proposed in some alternatives effectively reduces or eliminates the impairment. Snowplane use, though limited to Jackson Lake, has a dominant and unmitigated impact on the natural soundscape.

The use of snowcoaches on groomed roads is demonstrated to impact wildlife, air quality, and natural soundscapes. However, mass transit snowcoach use effectively mitigates the closure of parks to snowmobiles and results in much less traffic while allowing winter access for current levels of visitation. Snowcoaches would impact resources or values, or the enjoyment of them (at the current level of visitation) at least a magnitude lower than with snowmobile access. Adverse impacts of an NPS managed snowcoach system on wildlife, as in alternative G, would occur at low and mitigable levels.

Factors Other Than Environmental Consequences Considered in Making the Decision

Safety and Access

Safety issues are related to access issues. Modes of access and volumes of traffic are primary factors. Presently unsafe conditions can be improved, as proposed in several alternatives, by separating different uses and modes of transport, by eliminating wheeled vehicle use in places, and by eliminating large volumes of oversnow motorized use especially where ungulates use groomed surfaces. Safety would be most improved where a number of these measures are combined, as in alternatives F and G. All alternatives hypothesize impacts on the basis of motorized oversnow access at current use levels. However, there are different mixes of snowcoach, snowplane, and snowmobile use, distributed differently through the range of alternatives. In some areas, snowmobiles operate on groomed trails in the same locale as nonmotorized visitors, wheeled vehicles and large ungulates. Therefore, there is a risk that continued snowmobile use would result in accidents and is unsafe. In some places, the volume of wheeled vehicle traffic during the winter—much of which is associated with snowmobile staging—results in a higher rate of accidents. This represents a situation that must be remedied. The selected alternative eliminates the source of most safety concerns, snowmobile use, as well as wheeled vehicle use on a plowed road that currently has a high winter accident rate (Highway 89/287 from Colter Bay to Flagg Ranch). Discontinued plowing of the route from Colter Bay to Flagg Ranch would also convert Flagg Ranch to an oversnow destination. This would provide a new opportunity of that nature, similar to that available at Old Faithful in Yellowstone's interior. Opportunities for developing winter recreation around Flagg Ranch are abundant. There is a perception that not plowing the road would make a snowcoach trip from Colter Bay to Old Faithful too long. Flagg Ranch, as a destination, allows people the opportunity to break this trip up if they are unwilling or unable to make the trip to Old Faithful in one day.

Economic Impacts on Local Communities

The impacts of any alternative on economies beyond the gateway communities are generally negligible. Gateway communities are affected in different alternatives by entrance closure or area closure (D and F), or

closure to snowmobiles and change in allowable modes of motorized access (B, C and G). Economically, West Yellowstone is most affected through the range of alternatives because that community is most directly tied to access via snowmobile. Not coincidentally, the West Entrance to Old Faithful is the most adversely impacted oversnow route in the three-unit area.

Consistency With Land Use Plans, Policies or Controls for Adjacent Lands

Impacts on adjacent lands for all alternatives are described on pages 434–474 in the FEIS. There are concerns about how any reduction in snowmobile use within the three parks would translate into increased use on national forest lands in particular. The Forest Service, a cooperating agency, indicates that alternative G could result in conditions that would necessitate amendments to forest plans because snowmobile use on those lands is at the highest tolerance level permissible. My determination is that use on national forests is likely not to increase.¹⁷ Further, the forests have provided no convincing evidence or monitoring data to support their concerns, or to support that the need to revisit their forest plans does not already exist. I consider that the period of three years being allowed for a transition to snowcoaches only in the parks will facilitate the monitoring of recreational snowmobile use on public lands (national forests) in the Greater Yellowstone Area. I agree that such monitoring is necessary to develop a baseline for gauging the impacts of future winter management changes on public lands, and resources therein. Therefore, this is part of the rationale for allowing a three-year phase in period.

Potentially affected States and counties were involved as cooperating agencies in the preparation of this EIS (see pages 16–18 in the FEIS). Through the process, these entities identified no issues concerning conflicts with any land use plans, policies or controls that may exist. Any such impacts are inferred in the analysis (FEIS pages 434–435). Concerns expressed by the cooperators are twofold. On the one hand, they are concerned about increased use on adjacent lands resulting from the parks' decision, and how it would affect other public lands, wildlife habitat, and currently groomed snowmobile trail systems. On the other hand, they are concerned that the decision would devastate local

economies by drastically reducing snowmobile use and visitation to the area. These positions are in conflict. My assessment is: first, that snowmobile use is likely to decrease, or at least not increase, on adjacent lands; and second, that snowcoach access to the parks will invigorate local entrepreneurs in marketing a special (albeit different) park experience. As explained elsewhere, the effect of alternative G on local economies is expected to be of short-term duration—mitigated by provisions for implementation over time and allowing communities and businesses to adapt.

Public Comments on the Draft EIS

Comments on the draft EIS are discussed explicitly in the public participation section of this record of decision. The vast majority of the comments did not substantively address the merits of the EIS analysis. Many comments assisted NPS in clarifying or otherwise improving the disclosure of impacts in the FEIS (as documented in FEIS Volume III). Most comments (94%) expressed some preference for winter use management that resembled some alternative evaluated in the draft EIS. I wish to make clear that, although it is not the primary rationale for this decision, the public expression of preference is certainly a factor that I considered. The public's preference in the large body of comment was evenly divided between those who clearly wished for continued snowmobile use and those who felt that snowmobiles should not be allowed in the parks. Four percent of those who commented indicated there should be no motorized use or grooming of winter routes in the parks. The overwhelming negative reaction to the preferred alternative B in the draft EIS, which would have plowed the road from West Yellowstone to Old Faithful, was a factor in considering a new preferred alternative for the final EIS.

Findings

Park Values and Resources

The use of snowmobiles and snowplanes at present levels harms the integrity of the resources and values of these three parks, and so constitutes an impairment of the resources and values, which is not permissible under the NPS Organic Act. In YNP, the impairment is the result of the impacts from snowmobile use on air quality, wildlife, the natural soundscape, and opportunities for enjoyment of the park by visitors. In GTNP, the impairment is the result of the impacts from snowmobile and snowplane use on the

natural soundscape and opportunities for enjoyment of the park by visitors. In the Parkway, the impairment is the result of impacts from snowmobile use on air quality, the natural soundscape, and opportunities for enjoyment of the park.

Under the NPS Organic Act, the NPS may not allow the impairment of park resources and values, and when there is an impairment, the NPS must eliminate it. The combination of actions provided for in this Record of Decision will eliminate the impairment in GTNP following the winter of 2001–2002, and in YNP and the Parkway following the winter of 2002.

We have also determined that the snowmobile use now occurring is inconsistent with the requirements of the Clean Air Act (in the case of YNP and the Parkway), Executive Orders 11644 and 11989, the NPS's general snowmobile regulations, and NPS management objectives for the parks. We have determined that the snowplane use occurring in GTNP is inconsistent with Executive Orders 11644 and 11989 and NPS management objectives for the parks.

We have determined that the snowcoach use that will occur in YNP and the Parkway under this decision, and the snowmobile use that will continue in GTNP in the winter of 2002–2003 and thereafter is consistent with the requirements of Executive Orders 11644 and 11989 and the NPS's general snowmobile regulations.

There is no current means of mitigation, aside from a reduction of numbers unsupported by a carrying capacity analysis, that assures recreation snowmobile use impacts could be reduced, predictably and soon, to a level that does not impair and adversely impact these resources and values.

Snowmobile use for official administrative or emergency purposes in the three park units is specifically allowed under the regulations and executive orders cited herein as the basis for the decision. Incidental amounts of snowmobile use in GTNP for purposes of winter access to inheld private lands or to adjacent public lands as provided under the establishment legislation for the park.¹⁸ These are not recreation uses, per se, that are the subject of analysis in the FEIS.

Clean, quiet and odorless snowmobiles are not available at present. Even with technical advances in snowmobiles, the impacts of snowmobile use on wildlife, especially ungulates using groomed routes,

¹⁷ I believe the analysis indicating that decreased use in the parks would result in decreased use generally in the Greater Yellowstone Area, thereby reducing use on forests not increasing it, is sound.

¹⁸ EO 11644, sections (3) and (4), and 16 USC 406d–1, *et seq.*

constitutes disturbance and harassment at a time when individual animals are particularly challenged for survival. The continued use of snowmobiles as provided in the alternatives studied other than alternative G is found to be inconsistent with the health and integrity of resources existing in the three park units. Continued use hinders the enjoyment of resources and values for which the parks were created, most notably natural soundscapes, clean and clear air, and undisturbed wildlife in a natural setting.

The social and economic impacts of the elimination of most snowmobile use in the parks can be mitigated to a high degree by providing oversnow access using mass transit snowcoaches. Considering the analysis of alternatives, there is a clear magnitude of difference between the impacts of snowmobiles and the impacts of snowcoaches on natural resource values and the opportunities to enjoy them. This rationale supports the selection of alternative G.

The use of groomed routes by snowcoaches adversely affects wildlife, air quality, natural soundscapes, and the opportunity to enjoy those values, as disclosed in the FEIS, although the adverse effects are negligible to minor. These impacts are found not to impair those values and opportunities. This is due to the overall decrease in impacts to a level described as negligible—with greatly decreased volumes of traffic and consequent decreases in odor, noise, and pollutants. The area within the three park units that would be available for use without audible motorized sound would be maximized using snowcoach access. An NPS managed mass transit snowcoach system would assertively implement available technologies for further reducing the amount of sound and pollution created. It would assertively implement schedules and strategies and controls for minimizing impacts on wildlife due to use of groomed surfaces. Additionally, because operators of snowcoaches will be familiar with park roadways and trained in appropriate techniques for mitigating the effects of vehicle-wildlife encounters the potential for wildlife harassment will be minimized.

Skiing and other nonmotorized uses adversely affect wildlife, particularly bison, elk, moose, and bighorn sheep. Backcountry use, in particular, stresses these ungulates at a time when their energy reserves are low. In areas adjacent to high use nonmotorized routes animals may adapt to regular passage by humans using a predictable route. Nonmotorized trail use therefore has fewer adverse impacts than does

unrestricted backcountry use. Therefore by limiting nonmotorized use in certain winter habitats to designated routes, adverse impacts of nonmotorized use are suitably reduced. Where the impacts of nonmotorized travel on wildlife cannot be suitably mitigated through route restrictions critical winter range will be closed. With this mitigation, limited nonmotorized use is found to be consistent with park resources and values, and it facilitates their enjoyment. FEIS alternative G closes certain important winter wildlife habitat to nonmotorized use, and limits use in other areas to designated trails and routes only.

Safety and Access

The analysis shows that impacts on safety of visitors and employees are associated with snowmobile use. It is found that current use by snowmobiles represents a risk to health and safety. This risk is mitigated to the highest degree in alternative G. Risks associated with NPS managed snowcoach systems are negligible, since there would be greater controls over speed, time of operation, driver training and experience, and the volume of traffic on the route. In addition, this system offers access to the public that is equivalent in numbers to current use. In doing so, the parks would be accessible to a larger population of young, elderly, and disabled visitors.

Economic Impacts on Local Communities

It has been found that snowmobile use as currently constituted, and as evaluated in the range of alternatives, adversely impacts and impairs park resources and values. Therefore, the use must be discontinued in order to meet the primary mandates, regulations and policies of the national park service. This has clear economic impacts on all the local, gateway communities, permittees and concessions that are highly dependent upon winter snowmobile use in the parks. However, the greatest impact on these communities would be closing the parks to winter motorized access entirely. Alternative G offers an opportunity for the same level of access that currently exists, while improving opportunities for people who cannot or choose not to ride snowmobiles. It is found that the cessation in the future of plowing a portion of the southern route into YNP, in addition to improving safety, would create additional opportunities for people to enjoy a destination winter area (Flagg Ranch) using oversnow transport.

Due to economic impacts (as disclosed in the FEIS), measures are incorporated into the implementation features of alternative G to allow communities, permittees and concessioners time to adapt. Considering the economic impacts, three years are to be allowed for conversion to an NPS managed snowcoach system, and existing concession contracts will be honored until they expire. During the first year, snowmobile use will be continue under existing regulations. During the second year of implementation, snowmobile use will be subject to daily limits based on historic peak day use, to avoid the occurrence of days with even higher use than in the past. Then, one more year of snowmobile use, at approximately 50% of current levels, will be allowed. This affords snowmobile operators three years to take advantage of existing technology for snowcoaches, to realize the investment they presently have in snowmobiles, and to market new opportunities. NPS will produce an implementation plan as soon as possible to develop the details of snowcoach transport in the parks. This plan will be developed in coordination with gateway communities, concessioners and permittees in order to insure successful implementation of the alternative. NPS will also work with these entities to develop and implement a new marketing strategy for winter recreation in the parks.

Additional measures will be used to reduce impacts to the degree possible during the interim period. This mitigation includes, but is not limited to, the following measures (see also the actions and mitigation sections of the decision, above).

During the interim period, snowmobile and snowplane use will be monitored and managed in a manner that prevents or mitigates local impacts to the greatest extent practicable;

Ranger patrols will be increased to facilitate monitoring as well as detection and on-the-spot handling of impacts particularly for wildlife disturbance.

Park concessions will be required to mitigate impacts on air quality by selling only bio-fuels and synthetic lubes inside the park;

Snowmobile tour guides shall receive additional training in appropriate methods of avoiding wildlife disturbance, and park personnel will assertively provide similar information to all other users. Prohibit late night oversnow travel.

In the third year of the phase-in period, all recreation snowmobile users in YNP must be accompanied by a permitted guide and travel in groups of

no more than 11 (including the guide). The superintendent will be authorized to also require groups and guides in GTNP and the Parkway.

A phase-in period of three years is necessary to allow the creation and implementation of a functional mass transit system using snowcoaches.

Measures Taken To Avoid Environmental Harm

The focus of the EIS analysis is to improve environmental conditions relative to those which exist due to current use and management. Alternative G best improves environmental conditions, as demonstrated in the FEIS and this decision rationale. Therefore, the features of selected alternative G and the mitigation that applies with this decision are construed as measures taken to avoid environmental harm. If future monitoring, as provided in this decision, indicates that impacts are too great to sustain additional use, or that impairment occurs, it will be appropriate to implement further management changes. Monitoring plans will describe standards or thresholds of impact, and management actions that will be taken if standards are not met. See the monitoring section of the decision, above.

Public Involvement

Scoping

The NPS accepted public scoping comments from April 14 to July 18, 1998. Scoping brochures were mailed to about 6,000 interested parties, and 12 public meetings were held throughout the GYA and in Idaho, Montana, and Wyoming. In addition to local area and regional meetings, the NPS held four national meetings in Salt Lake City, Denver, Minneapolis, and Washington D.C. About 2,000 comment letters were received (about 1,200 of these were form letters), from which about 15,000 discrete comments were obtained. Scoping respondents included businesses; private and nonprofit organizations; local, state and federal agencies; and the public at large. Comments were received from 46 states and several foreign countries.

Summary of Public Scoping Comment

Comments received during scoping cover a full range of topics including issues, concerns, analysis questions, procedural questions, general opinions, and requests. Comments were sorted into the categories shown in Table 2, pages 22–24 in the FEIS.

The NPS addressed all comments received in one of two ways: (1) Either they were analyzed in detail through the

development of an alternative or as a possible impact of winter use; or (2) they were not analyzed further based on the rationale presented in FEIS Volume II, Appendix A. The NPS classified comments as major issues or concerns to be analyzed in detail based on relevance to the decision to be made. The following section, Major Issues, describes in greater detail those comment categories considered relevant. Issues or Concerns Not Addressed in the Plans/EIS describes specific types of comments not carried forward for in-depth analysis, and the rationale for their dismissal.

Major Issues

This section summarizes the major issues that relate to the purpose and need for action for the future of winter use in the three NPS units. These issues parallel the existing conditions identified in the FEIS in the purpose and need for action. While common concerns exist among the issues, they are categorized for purposes of analysis and alternative formulation. Because the decision regarding the future of winter use in the GYA is largely programmatic, relevant issues are those that bear on: (1) Winter programs that might be necessary to address existing circumstances and achieve desired conditions; and (2) the effects of those programs. An issue is defined as a point of contention about the specific possible environmental effect of a specific management action or program. Generally, comments on the DEIS about the details of implementing a program are not considered major issues. Implementation details will be important during future site-specific analyses under the new plan.

Another opportunity for public involvement is the ability to comment on the DEIS. No new major issues were identified as a result of public comments on the DEIS. FEIS Volume III contains the analysis of public comments on the DEIS, and responses to the comments. Major issues are described below.

Visitor Use and Access

Various user groups contend that the national parks offer either too much or not enough of various types of use. Some people are concerned that the parks do not offer an adequate range of winter experiences and will not be able to respond to future winter recreation demand. Others suggested that winter experiences should include dogsledding, off-road motorized play areas, and increases in both groomed motorized and nonmotorized trails. Other people voiced concerns about too

much winter use, suggesting that YNP should be closed in part or altogether, for the winter season. Because of the amount of use relative to the available facilities, both ski and snowmobile use sometimes occurs on the same groomed surface. This adds to the perception of too much use, and leads to other issues relating to visitor experience and safety. Many people contend that motorized use has greatly affected opportunities for nonmotorized use in the surrounding GYA, displacing cross-country skiing and other nonmotorized recreation to the parks. Another aspect of the issue relates to the affordability of winter access, and access for disabled, and old and young visitors. Some argue for increased availability of motorized access (via snowmobile in particular) to serve these access needs. Another issue is the high cost of winter access to the parks.

Visitor Experience

Expectations for quality winter recreation experiences are different for different user groups. This raises contention between groups for which quiet, solitude, and clean air needs conflict with the impacts of snowmobiles, especially when facilities for these different groups are in close proximity to each other. Nonmotorized users are easily affected or displaced by the sight, sound, and odor of snowmobiles. While skiing generally does not affect the quality of the snowmobiling experience, there are safety issues associated with slower traffic on groomed surfaces used by higher speed vehicles. In addition the quality of the visitor experience can be affected by the number of available support facilities (such as parking lots or rest rooms), the extent to which facilities are crowded, and the availability of information.

Human Health and Safety

Four primary health and safety issues were identified regarding winter visitor use:

- The effect of motorized vehicular emissions and noise on employees who are required to travel or work in areas with high traffic levels. Visitors may be subjected to some of the same impacts.
- Speed limits and the frequency of motor vehicle accidents and fatalities, and the number of nighttime collisions involving wildlife that often result in severe injury or fatality to both animals and people.
- Avalanche hazards.
- Safety risks where different modes of winter transport are co-located or in close proximity, like the CDST where

wheeled-vehicles and snowmobiles share the highway right-of-way.

Social and Economic Issues

Many comments reflected the effect of changes in parks management actions on local communities. Local businesses provide services to visitors near both parks, and many local economies rely, in part, on revenues from parks visitors in the winter. Concern was voiced that eliminating oversnow travel and snowmobiles in particular or closing an entrance to a park during the winter could have a detrimental effect on local economies. Other commenters stated that concern for parks' resources should be elevated above economics.

Natural Resources

Impacts of winter use on natural resources revolve around three major issues.

- The impact of groomed surfaces and their use on wildlife: Over the last several years, bison have been removed from the population because they have migrated from YNP to state and private lands during the winter. Some people commented on the effect that backcountry skiing might have on wildlife, particularly the displacement of large ungulates from important winter range.

- Air quality: The effect of snowmobile emissions on air quality was identified as a concern with respect to health, natural resources, and aesthetic and wilderness values. For example, on high snowmobile use days in YNP, the visual evidence and odor of snowmobile exhaust is apparent in some areas. The effect of hydrocarbons, carbon monoxide, and particulate matter emitted by snowmobiles on water quality was also a concern.

- Oversnow vehicle sound: The sound levels of snowmobiles and snowcoaches were raised as issues with regard to aesthetics and wilderness values. For example, on some days it is difficult for most visitors to travel to an area in YNP where snowmachines cannot be heard. For this reason some people question whether the use of snowmobiles and snowcoaches is appropriate in the national parks. Other people state that the sound of snowmachines has no impact on their ability to enjoy the parks.

Issues or Concerns Not Addressed in the Plans/EIS

Scoping issues and concerns that were not addressed in the EIS are listed below. The rationale for their dismissal may be found in the FEIS on pages 26–28. Essentially the reason for dismissal is that the issue is being dealt with in

another analysis, is beyond the scope of the purpose and need for action, or is a matter that is governed by procedural laws (like the National Environmental Policy Act—NEPA).

- Privatization
- Summer/Winter Use Comparisons
- Wildlife Carrying Capacities
- Land Use
- Economic Effects: Costs
- EIS Process
- Cooperating Agencies
- NEPA and NPS Policy
- Scientific Methods and Data

Federal Register Notices

A notice of intent to prepare an EIS was published in the **Federal Register** on April 15, 1998, officially beginning the scoping process. A notice of availability for the Winter Use Plan and Draft Environmental Impact Statement (EIS) for Yellowstone and Grand Teton National Parks and the John D. Rockefeller Jr., Memorial Parkway appeared in the **Federal Register**, August 15, 1999. The notice indicated that the public comment due date was November 15. The comment period was extended twice, once to December 1, 1999, and again to December 15, 1999. Notices of these deadline extensions were published in the **Federal Register**. The notice of availability for the FEIS was published on October 20, 2000.

Distribution of the Draft Environmental Impact Statement

In August 1999, postcards were mailed to 6000 persons notifying them of the impending release of the DEIS. Approximately 4,000 draft documents and summaries were mailed to interested parties during September 1999. In addition, documents were mailed to agencies, businesses, organizations, and public officials who had either requested the document or were generally interested in the management of winter use in the parks.

Public Meetings/Hearings

Sixteen public meetings using an open house format were held early in the scoping period ranging from April through July of 1998. Meetings were held in each of the five gateway communities to the three park units. Other meetings were held within the region at Dubois and Casper, Wyoming, Billings and Bozeman, Montana, and Boise, Ashton and Pocatello, Idaho. Meetings outside the region were held at Denver, Colorado, Minneapolis, Minnesota, Salt Lake City, Utah, and Washington, D.C. Public hearings to solicit public comment on the DEIS were held during the month of October 1999 in the following cities: Idaho Falls,

Idaho; West Yellowstone and Livingston, Montana; Cody and Jackson, Wyoming; and Denver, Colorado. The proceedings of each hearing were transcribed and entered into the record. An average of 45 persons spoke at each hearing.

Comments on the Draft Environmental Impact Statement

Over 48,600 pieces of correspondence were received in response to the DEIS. Correspondence consisted of individual letters, form letters, e-mails, telephone calls, and hearing presentations. This body of comment is summarized, categorized, indexed and responded to in Volume III (parts one, two, and three) of the FEIS. Part one includes the summary, individual letters and specific responses to the contents of the letters. Part two includes the variety of form letters received (separate letters having the same content) and specific responses to their content. Part three contains the results of compiling all comments from all sources, categorizing and summarizing them, and then providing a response to each. This approach was considered necessary owing to the extreme volume of public comments on the DEIS. Following is a brief analysis of recurrent themes in the body of comment, and how NPS responds to them.

Many commenters expressed consternation about the lack of a “no snowmobiling” alternative in the DEIS, and suggested that impact descriptions and data to support the EIS and the preferred alternative were not detailed enough. NPS responds first, that a “no snowmobiling” alternative was provided in the DEIS—alternative G. Secondly, in some cases the NPS has added information to support the analysis of impacts in the FEIS. Additionally, NPS is engaged in programmatic planning, rather than project-specific planning; therefore analysis and data collection have been conducted on a reconnaissance level. Further, where data is lacking or unavailable even at that level, CEQ regulations provide for the decision process to continue based on best available data and professional application of credible methods.

Many people stated they could not support any of the DEIS alternative “mixes.” A large number of comments levied criticism on the preferred alternative—to the point that constructive comments on the other alternatives were greatly lacking. Three additional “alternatives” were proposed: Revised Alternative E (in various forms provided by cooperating agencies and the Blue Ribbon Coalition),

the Citizens' Solution (provided by a consortium of conservation groups), and the Natural Regulation Alternative (provided by The Fund for Animals).¹⁹ All such comments were read as the decisions that people would like to see the NPS make, based upon their opinions about impacts and their interpretations about laws.

The body of comment included little substantive information beyond that disclosed in the DEIS, and did not demonstrate that an alternative (feature) did not belong in the range of choices available for the decision-maker. Given the ability of a decision-maker to mix features from the FEIS range of alternatives, much of the criticism in the public comment does not apply to the analysis. Regarding the great amount of comment on the preferred alternative, and perceived lack of justification for it, the NPS responds by saying that such criticism is more appropriately applied to the decision. In fact, the NPS changed the preferred alternative between draft and final EIS whereupon most of these comments no longer apply.

Some commenters said that the desired conditions or objectives were too general, and that there is no demonstrated need for management change. In effect, such comments missed the real issues that are conveyed by statements of existing conditions. The NPS responds by explaining that the EIS is programmatic, leading to a plan, which is general in nature. In addition issues regarding resource impacts, health and safety, and visitor experience are documented sufficiently by the NPS to indicate the need for major management changes supported by a new plan.

Given the scope of analysis, the NPS developed alternatives (alternative plans) as possible ways to proceed from the current condition toward the desired condition. The NPS maintains that public access during the winter is an appropriate objective to be achieved. Accommodating a variety of recreational uses is also valid. In each case, activities must be evaluated in terms of impacts on parks' resources and values, health and safety, and visitor enjoyment. Alternatives that vary the location, amount and proximity of uses are needed to assess the relative impact or

change from the current condition. The EIS expresses impacts or changes in terms that allow people to understand how each alternative satisfies the purpose and need for action. It is unreasonable to expect that all alternatives would address all aspects of the purpose and need equally, or that all alternatives worthy of consideration would have no impacts. In the final analysis, the NPS concludes that the purpose and need for action articulated in the EIS is appropriate, and that the range of alternatives considered in detail is adequate. See Comparison of Alternatives at the end of this decision document.

Public Response to the FEIS

The FEIS was published and available to the public in hardcopy and on the internet on October 10, 2000. Summaries of the FEIS were mailed to about 46,500 interested parties, and about 400 copies of the FEIS were mailed at that time. The public was able to provide comments up until October 31. Due to the potential public controversy of the selection of alternative G as the preferred alternative in the FEIS, the former Assistant Secretary for Fish and Wildlife and Parks agreed to solicit public comment on that document. About 10,970 comment documents were received, including letters, e-mails, and postcards. Comments were read and evaluated regarding their content. A comment summary is attached to this decision (Attachment B). Generally, there were more respondents favoring elimination of snowmobiles from the parks than those who support continued snowmobiling. State and local governments and most business interests who responded favor continued snowmobiling.

Consultation

Cooperating Agencies

The details of cooperation with other agencies are provided on pages 16–17 and Appendix A of the FEIS. In summary, State and county governments surrounding the GYA requested and were granted cooperating agency status (40 CFR 1501.6) in December 1997 and January 1998. The NPS requested that the US Forest Service become a cooperating agency because of possible impacts on surrounding national forests from changes in the parks' winter use management; and the USFS acceded. Agreements were developed to assign formal roles in the EIS process and establish expectations. The NPS held its first meeting with the cooperating

agencies on February 13, 1998. Appendix A in the FEIS (Volume II) further discusses coordination with cooperating agencies.

Through the EIS process, NPS made it clear that veto or decision-making power does not accompany cooperating agency status. As the lead agency charged with carrying out the NEPA process under Sec. 102(2)(c) of NEPA, the NPS retains sole decision-making authority over the EIS and its process.

There were a number of comments on the DEIS relating to the designation of cooperating agencies. Many people objected to the inclusion of the counties in particular, feeling that their involvement biased the decision-making process and the EIS; others felt that the NPS did not involve or listen to the cooperating agencies. Most cooperators stated that there was insufficient time or information to provide adequate input to the NPS, and that the NPS had not met the terms of the signed memoranda of agreement. Conversely, many of the cooperating agencies commented that they had provided good information that the NPS did not consider or incorporate. A table that illustrates the extent to which the NPS interacted with cooperating agencies is contained in Appendix A of the FEIS.

The NPS believes that much of the criticism from cooperating agencies stems from the time frame for producing this EIS, which is noted in the cooperating agreements, a lack of experience, and a fundamentally different perspective on the issues. Few federal agencies have experience dealing with such a large number of cooperating agencies on a single NEPA project. With the exception of the USFS and the State of Montana, few of the cooperating agencies have experience producing environmental impact statements, and the analyses necessary in their areas of special expertise.^{20 21} NPS believes it met all of its responsibilities under the cooperating agreements to the best of its ability under the highly constraining time frame.

American Indian Tribes

The details of consultation with American Indian Tribes are provided in the FEIS on pages 18–20. To summarize: NPS is committed to recognizing the past and present existence of American Indians in the region, and the traces of their use as an important part of the

¹⁹ Most features of Revised Alternative E and The Citizens' Solution were covered within the DEIS range of alternatives. Certain features were either considered to be implementation details or outside the scope of analysis. The Natural Regulation Alternative, by advocating no motorized access or groomed routes, was considered outside the scope of analysis—although some alternatives close sections of the parks to motorized use, and adaptive management could conceivably result in other sections being closed over time.

²⁰ The CEQ definition of special expertise is: "statutory responsibility, agency mission, or related program experience." (40 CFR 1508.26)

²¹ Montana has a state law governing environmental policy: Montana Environmental Policy Act.

cultural environment to be preserved and interpreted. NPS initiated consultation along with scoping in May 1998 in accordance with the Presidential Memorandum of April 29, 1994, "Government-to-Government Relations with Native American Tribal Governments" and in compliance with a variety of laws, federal regulations, and agency management policies and directives. Eight tribes were identified as being traditionally affiliated with the GYA.

By April 1999, an additional 13 contemporary tribes had been recognized by YNP and GTNP as traditionally affiliated with the GYA. The NPS notified the 21 affiliated tribes of an affiliated tribal consultation meeting to be held at YNP on May 20, at which the Plans/EIS would be one of the planning projects and issues discussed. On April 23, NPS faxed invitation letters to the tribal consultation meeting, and four days later the NPS mailed copies of the draft alternatives to each tribe. During the week of May 3, the NPS made follow-up telephone calls to each of the tribes, to confirm receipt of the draft alternatives and encourage participation in the affiliated tribal consultation meeting on May 20.

At that meeting, tribal representatives voiced concerns that oversnow motorized vehicles, the grooming of road and trail surfaces, and the movement of people would negatively impact YNP's bison population. The affiliated tribes received copies of the DEIS for review and comment in mid-September 1999, and were notified of six public hearings on the draft plans in late-September 1999. On October 6, 1999, members of the Assiniboine and Sioux (Fort Peck), Cheyenne River Sioux, Confederated Salish and Kootenai, Crow, Lac Courte Oreilles, Nez Perce, Rosebud Sioux, the Winnebago Tribe of Nebraska, and organizations met with Yellowstone and Grand Teton staff to discuss the Winter Use Plans as part of fall 1999 government-to-government tribal consultation meetings.

The NPS will continue to consult with representatives of affiliated tribes as actions resulting from this plan are implemented. The goal of consultation is to insure that the affiliated tribes' interests and concerns are adequately addressed, as well as to develop and accomplish future programs in a way that respects the beliefs, traditions, and other cultural values of the American Indian tribes who have ancestral ties to the area.

State Historic Preservation Offices

In October 1995, a programmatic agreement was developed among the National Conference of State Historic Preservation Offices (SHPO), the Advisory Council on Historic Preservation (Council) and the NPS. In accordance with the agreement and pursuant to Section 106 of the National Historic Preservation Act (16 U.S.C. 470(f)), consultation with the Wyoming, Montana, and Idaho SHPOs and the Council was initiated in May 1998. The NPS sent copies of the scoping brochure (May 1998) and the draft preliminary winter use alternatives (December 1998) to the SHPOs and the Council. In accordance with their request, the NPS continued to consult with the Wyoming, Montana, and Idaho SHPOs and the Council regarding actions described in the Winter Use Plans/EIS that may affect cultural resources (FEIS Appendix E). The NPS mailed copies of the Draft EIS to each SHPO and the Council for review and comment. Before completion of the FEIS, the NPS contacted the SHPOs of all three states directly, and all offices stated that they had no comments on the DEIS and saw no need for further consultation.

U.S. Fish and Wildlife Service

The settlement agreement under which the winter use plan and EIS were produced also required the NPS to prepare a biological assessment (BA) and request formal consultation with the USFWS pursuant to section 7(a)(2) of the ESA, 16 U.S.C. 1536(a)(2) and its implementing regulations. To comply, on February 16, 2000 the NPS requested from the USFWS an updated list of all federally protected threatened, endangered, proposed, or candidate species that might occur in the affected area (FEIS Appendix D). Because winter use is highly controversial, and the NPS was aware of the potential for considerable post-draft changes, it elected not to initiate consultation at the time the DEIS was issued. Instead, a BA was prepared for the FEIS preferred alternative, and subsequently submitted to USFWS on July 5, 2000.²² On October 25, 2000, USFWS provided a letter concurring with NPS' determination in the biological assessment that implementation of the winter use plans as proposed is not likely to affect threatened or endangered species or migratory birds in the action area. The letter notes the coordination between

²² Actions taken in accordance with *Endangered Species Consultation Handbook: Procedures for Conducting Consultation and Conference Activities under Section 7 of the Endangered Species Act*, March 1998.

NPS and USFS through the Greater Yellowstone Coordinating Committee which resulted in a commitment to monitor possible but unanticipated impacts on grizzly bears as a result of the action.

Alternatives Considered

Alternative Development

Alternative development is described in detail on pages 31–32 and in Appendix A of the FEIS. The alternatives for the Winter Use Plans and Environmental Impact Statement for Yellowstone National Park (YNP), Grand Teton National Park (GTNP) and the John D. Rockefeller, Jr., Memorial Parkway (the Parkway) were formulated in response to the major issues and concerns raised through public and internal scoping. In addition to the scoping process, the National Park Service (NPS) and the cooperating agencies met in Idaho Falls, Idaho, for 3 days during October 1998 to formulate initial concepts for alternatives. Later, similar workshops were conducted with the staffs in both parks. For a complete discussion of the concepts generated during the workshops see FEIS Appendix A.

The NPS planning team evaluated the concepts in terms of their responsiveness to the major issues and concerns, the decision to be made, and the purpose and need for the Winter Use Plans. The concepts were also evaluated against their adherence to current law, park management guidelines, and NPS mandates and policies. Lastly, each concept was evaluated for its economic and technical feasibility. The concepts that best met the above criteria were packaged into the range of alternatives discussed below. Each alternative proposed considers a different means of achieving the desired condition of the parks in the winter while minimizing impacts to park resources.

Scope of Analysis in the FEIS

The scope of analysis determines the range of alternatives to be considered. The analysis in the EIS is limited to recreation during the wintertime (about December 15 through March 15, annually). Geographically, the analysis is limited to recreation management within the boundaries of the three national park units.²³ Recreational use considerations and supporting facilities

²³ As a matter of process under CEQ regulations, the impacts of park management that are known or suspected to occur at other times and places must be disclosed in the EIS. In this EIS, economic impacts outside park boundaries are disclosed in the socioeconomic impacts section. Physical and resource effects are disclosed in the sections on adjacent lands and cumulative impacts.

are limited to those that are technically possible at the present time or are feasible for development and implementation. The range of alternatives presents options for motorized and nonmotorized winter recreational use in the three park units considering reasonably expected technological improvements in emissions and sound of snowmachines. One alternative evaluates the impacts of current winter use (per the settlement agreement and CEQ regulations). In this instance, "no action" is interpreted as current management, which is appropriate for programmatic planning.²⁴

Alternatives

Alternative A (No Action)

This alternative reflects current use and management practices in the parks and meets the requirement for including a no action alternative in an EIS.²⁵ Alternative A is a baseline for analysis and reflects existing conditions. Other alternatives are intended to improve the existing condition in one or more major issue areas. Issues associated with alternative A include visitor access difficulties, visitor experience conflicts, unsafe conditions, and resource impacts.

Alternative B

This alternative provides for a moderate range of affordable and appropriate winter visitor experiences. Key changes in recreational opportunities include: Plowing the road from West Yellowstone to Old Faithful to allow mass transit access by wheeled vehicles, moving the CDST to a year-round path from Moran to Flagg Ranch, and phasing out snowmobile use on Jackson Lake. Over the next 10 years, an advisory committee would make recommendations on phasing and

implementing sound and emission standards for air quality and motor vehicle sound issues. By winter 2008(2009, strict emission and sound requirements would be required by all vehicles entering the parks. In addition this alternative emphasizes an adaptive approach to park resource management, which would allow the results of new and ongoing research and monitoring to be incorporated as it becomes available. Adaptive management increases the Park Service's ability to solve visitor access and experience issues and resource issues over time. Using the criteria stated within Executive Order (EO) 11644 (as amended) and its implementing regulation (36 CFR 2.18), monitoring results demonstrating disturbance to wildlife or damage to park resources would be cause to implement actions for mitigating these conditions (for example, closure to winter visitor use or trail restrictions).

Alternative C

This alternative provides for maximum winter visitor opportunities for a range of park experiences, with emphasis on motorized recreation, while mitigating some natural resource impacts and safety concerns. Key changes in recreational opportunities include: plowing the road from West Yellowstone to Old Faithful to allow access by wheeled vehicles, providing a widened highway corridor to accommodate the CDST, and providing additional groomed trails for both motorized and nonmotorized uses. This alternative directly addresses issues that arose during scoping about potential impacts of management change on local economies. It shows how the range of winter opportunities could be preserved, applying mitigation primarily in the areas of air quality and sound impacts.

Alternative D

This alternative emphasizes opportunities for visitor access to the unique winter aspects of the parks (for example, geysers, geothermal areas, wildlife, and scenic vistas), and protection of those qualities and natural resources by phasing in cleaner and quieter modes of travel. It focuses winter visitor activities near destination areas and gateway communities. Key changes in recreational opportunities include: eliminating motorized oversnow access to Yellowstone through its East Entrance, limiting snowmobile use in Grand Teton and the Parkway to the CDST and the Grassy Lake Road, eliminating wheeled-vehicle access from Colter Bay to Flagg Ranch to accommodate oversnow vehicles on the

groomed highway surface, and eliminating snowmobile use on Jackson Lake. Emphasizing uses in different areas of the park minimizes conflicts between nonmotorized and motorized users, and addresses issues about visitor access and experience. Support facilities would have minimal amenities. In this alternative, visitor access routes and timing would be modified to provide safer conditions. Over time, issues regarding impacts on natural resources would be addressed, particularly in Grand Teton and on the east side of Yellowstone.

Alternative E

This alternative emphasizes the protection of wildlife and other natural resources while allowing park visitors access to a range of winter recreation experiences. It uses an adaptive planning approach that allows the results of new and ongoing research and monitoring to be incorporated. Key changes to current recreational opportunities are: eliminating motorized oversnow access in Grand Teton and the Parkway except for use on the Grassy Lake Road and north of Flagg Ranch into Yellowstone, and eliminating all winter motorized use on Jackson Lake.

This alternative addresses the full range of winter use issues in Yellowstone over time, but the current condition would prevail in the short term. Using the criteria stated in EO 11644 (as amended) and its implementing regulation (36 CFR 2.18), monitoring results demonstrating disturbance to wildlife or damage to park resources would be cause to implement actions for mitigating these conditions (for example, closure to snowmobile use). Alternative E calls for instituting an advisory committee to make recommendations about emission and sound standards. Local, county, state, and federal agencies as well as representatives from the snowmobile industry and environmental groups would participate on this committee. In Grand Teton and the Parkway, the full range of issues are addressed more immediately by limiting oversnow motorized use to the north end of the park, thus separating uses and eliminating most resource and visitor experience conflicts relating to snowmobile use.

Alternative F

Alternative F emphasizes wildlife protection. Key changes in recreational opportunities include: eliminating all winter access to Yellowstone's interior through its North and West Entrances, eliminating motorized oversnow access in Grand Teton and the Parkway except

²⁴ Many commenters on the DEIS stated that the "no action" alternative must be "no snowmobiling", and that the court settlement showed that to be the appropriate course of action. The park service's interpretation of "no action" means no change in general management direction from the present. The settlement agreement did not include any concessions to claims by The Fund for Animals, nor did it remove any options within the park service's discretion for park management from the range of alternatives to be considered. In approving the settlement agreement, the court asserted that a comprehensive winter use EIS (in accordance with CEQ regulations) would be written.

²⁵ CEQ 40 Most Asked Questions, question number 3. Where an existing program is being evaluated, "no action" is "no change in management." "No action" may be thought of as continuing with the present course of action until the action is changed. CEQ states that in such instances, "to construct an alternative based on no management at all would be a useless academic exercise."

for use on the Grassy Lake Road and north of Flagg Ranch into Yellowstone, and eliminating all winter motorized use on Jackson Lake. For YNP this alternative addresses issues regarding protection of wildlife resources by focusing winter visitor activities near scenic areas in the eastern and southern portions of YNP. These areas are generally outside important winter range for large ungulate wildlife species. In Grand Teton and the Parkway, the full range of issues is addressed by limiting oversnow motorized use to the north end of the park, thus separating uses and eliminating most resource and visitor experience conflicts relating to snowmobile use.

Alternative G (The FEIS Preferred Alternative)

This alternative emphasizes cleaner, quieter access to the parks using the technologies available today. It would allow oversnow access on all routes currently available via NPS-managed snowcoach only. Other key changes in recreational opportunities include: eliminating winter plowing on the Colter Bay to Flagg Ranch route, making

Flagg Ranch a destination via oversnow transport, and eliminating all winter motorized use on Jackson Lake. This alternative addresses the full range of issues regarding safety, natural resource impacts, and visitor experience and access. It addresses the issues in a way that would make it necessary for local economies to adapt, and for visitors wanting motorized oversnow access to the parks to use snowcoaches rather than snowmobiles.

Comparison of Alternatives

A comparison of alternative actions and the effects of the alternatives may be found in the FEIS beginning on page 66 (Tables 11 and 12). The following rating process, using the FEIS data, is designed to illustrate—in a relative fashion—how each alternative meets the purpose and need for action. The purpose and need elements are equivalent to the impact topics assessed in the EIS. The rating scale is defined below.

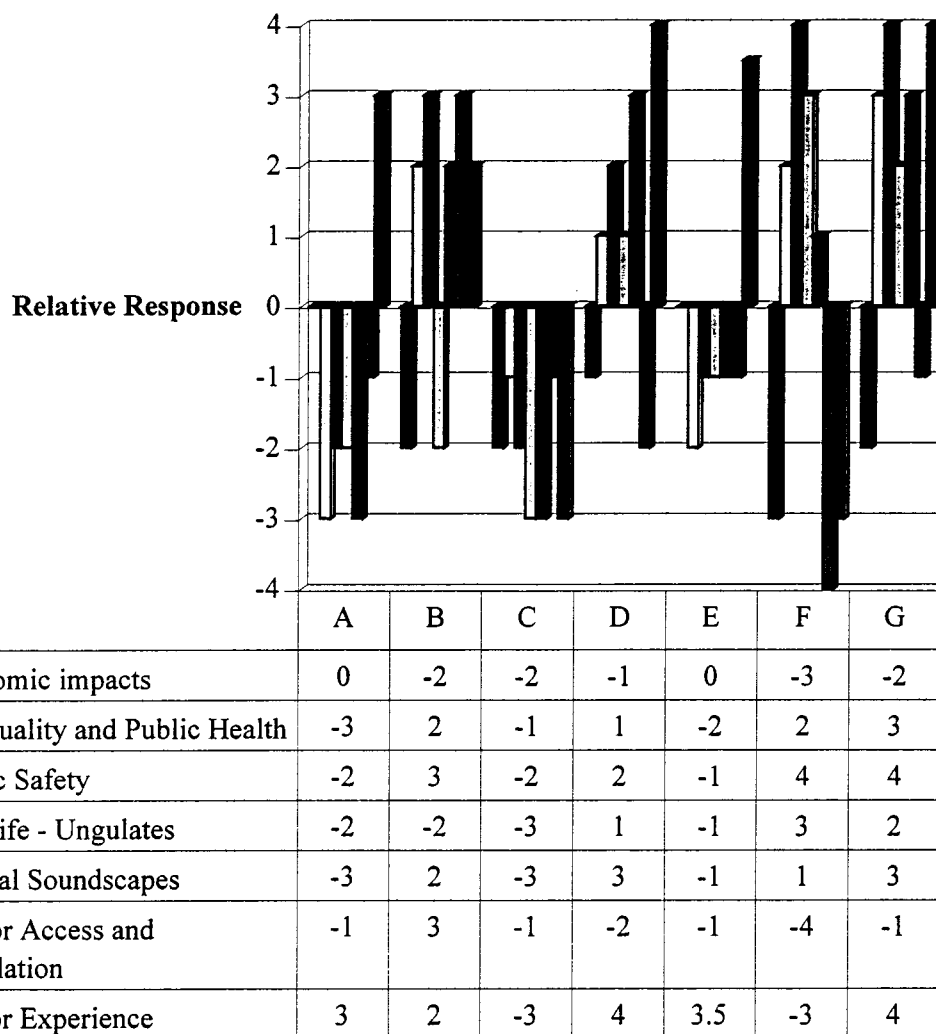
Rating	Definition
+4	Major beneficial impact
+3	Moderate beneficial impact

Rating	Definition
+2	Minor beneficial impact
+1	Identifiable but negligible beneficial impact
0	Neutral level—no adverse impact, no beneficial impact
–1	Identifiable but negligible adverse impact
–2	Minor adverse impact
–3	Moderate adverse impact
–4	Major adverse impact

With reference to the summarized impacts by alternative in the FEIS Chapter II (Table 12), a rating was assigned to each cell; *e.g.*, where a major beneficial impact was disclosed, a +4 was assigned to that block. This represents a composite rating, and it should be noted that the detailed effects analysis represented by the rating is found in Chapter IV of the FEIS. The impact topics were weighted equally in this rating. All impact topics for all alternatives were rated in this fashion and then tabulated accordingly. A chart tabulating the ratings for major impact topics, or purpose and need elements, is shown below.

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Alternatives' Responses to Major Issues



This chart illustrates effects relative to a neutral environmental baseline reflecting an assessment of no identifiable adverse or beneficial effect.²⁶ In the EIS, the defined environmental baseline is the existing condition, or alternative A (no action).

²⁶ For such illustrations, the selection of a rating scale has many possible permutations. In this case, a scale showing positive and negative values was selected in order to better visualize the adverse impacts as opposed to the beneficial impacts of each alternative. An added feature of this scale is that it illustrates the existing condition, represented by Alternative A, as a condition to be improved in terms of "purpose and need" elements.

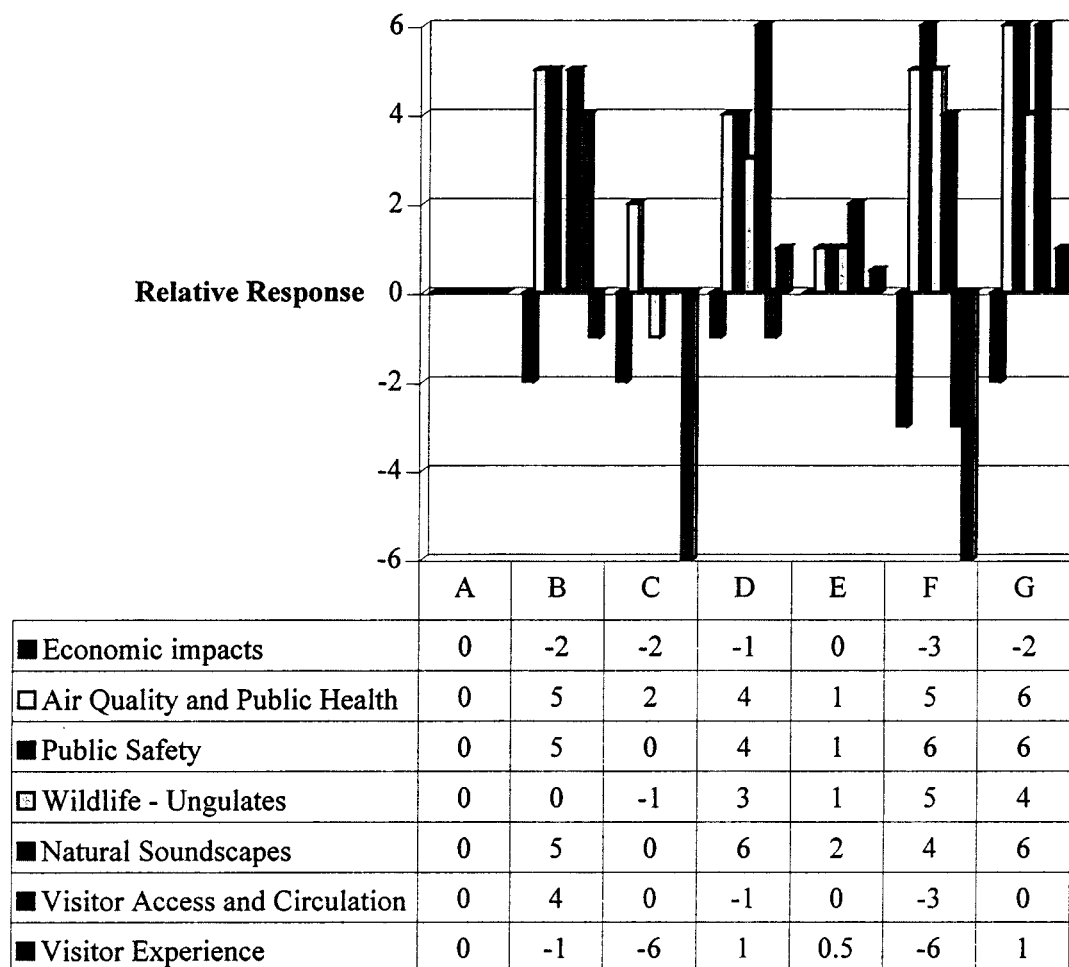
Therefore, another data set and chart were generated to normalize the ratings relative to alternative A. That is, for each impact topic, the difference between the ratings for alternative A and the analogous ratings for each other alternative was gauged. For example, alternative A has a rating of +3 for visitor experience and F has a rating of -3 for the same element; the relative difference (or the scale difference) between the two is -6.²⁷ The resulting

²⁷ This explains why the chart shows values up to +/- 6, when the rating scale for effects is +/- 4.

chart, below, shows alternative A as having no effects relative to the existing condition, and the other alternatives as having positive or negative effects compared to that base. The chart is an illustration of the extent to which each alternative meets the purpose and need for action, moving management from the existing to the desired condition.

The "effects" scale does not apply to the second chart; it is the relative change from alternative A that is now illustrated.

Alternatives' Responses to Major Issues Compared to Alternative A



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The purpose and need for action, as expressed in Chapter I of the FEIS, is illustrated fundamentally by describing the desired condition for the park units and comparing it to the existing condition. The descriptions are made in terms that relate to park resources and values, so that there is a direct relationship with mandates, regulations, executive orders and policies that direct NPS in managing resources and values. The relationship of existing condition to desired condition is developed through the most important resources and values within the context of winter use, as determined in the FEIS.

The intent of actions proposed in the alternatives is to change management so that parks move from their existing condition toward the desired condition. Since various important resource elements make up the existing/desired condition relationship, it is expected

that different alternatives designed to emphasize different concerns will respond differently to the overall purpose and need for action. As illustrated in the above chart, this is the case for winter use alternatives in the three park units.

The above comparison chart illustrates the following generalizations. The existing condition is represented effectively by alternative A. Comparing other alternatives to alternative A, it is clear that all but alternative C respond positively, overall, to the purpose and need for action. Alternative E would improve the condition of all resources and values (and the opportunity to enjoy them), compared to alternative A, but the improvement overall would be of a fairly low magnitude while retaining the economic status quo. In alternative G impacts on all resources/values would be greatly decreased over

existing conditions, and decreased overall to a greater extent than in any other alternative. This improvement would come primarily at the cost of economic impacts to local communities, also shown in the above chart. Balancing the positive and negative changes from the existing condition, alternatives D, B and F rank in that order below alternative G. All would adversely impact one or two of the four gateway communities while improving resource conditions. Alternative F would greatly improve resource conditions, while incurring long-term adverse impacts on opportunities to enjoy park resources and values, and on the winter economies of West Yellowstone and Gardiner, Montana.

In showing the generalized and relative comparisons, the chart does not reflect analysis details. For example, although alternative F greatly improves

resource conditions overall, there would still be disturbance to wildlife associated with snowmobile use at certain times and certain places. Analysis details such as this apply to all alternatives. The reader is referred to Table 12 and Chapter IV in the FEIS, where the detailed analyses are summarized and presented respectively.

Environmentally Preferred Alternative

Based on reduced impacts to human health and safety, air quality, visitor access, the natural soundscape and wildlife the NPS has identified alternative G as the environmentally preferred alternative. The U.S. Environmental Protection Agency, in its comments on both the Draft and Final EISs, similarly identifies this alternative as its environmentally preferred action.

Information Contact

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Attachment A—Monitoring and Adaptive Management Plans

Standards, Methods, and Intensity by Management Zone

Monitoring and Adaptive Management

Introduction

General resource inventory (and monitoring) and adaptive management are two approaches to assure the implementation and success of management actions. General resource inventory and monitoring in accordance with the National Park Service (NPS) 77 Resource Management Guidelines (NPS 1991) is a necessary part of the decision that proceeds from the Winter Use Final EIS (See Appendix I). Adaptive management is also a component of this decision.

The two approaches are distinguished by the degree of uncertainty regarding the impacts to park values. Adaptive management is an appropriate approach when important information pertaining to natural resource and visitor use management is lacking, and there is a need to take immediate management action rather than to wait for additional information to be collected. It is a process of implementing management decisions as scientifically driven

experiments that test predictions and assumptions in management plans, and using the resulting information to improve the plans. General resource monitoring is appropriate where standards exist either in laws, regulations or general management plans. Techniques must be available to measure conditions for effective comparison with the standard.

Additionally, the National Parks Omnibus Act of 1998 requires a program of inventory and monitoring of National Park System resources to establish baseline information and to provide information on long-term trends of the condition of national park system resources (16 U.S.C. 5934). The service also must use the results of scientific research, including monitoring and inventory, in making decisions about the management of parks (16 U.S.C. 5936).

The Winter Use EIS identifies information needs related to winter use as it may impact critical park values: air quality, natural quiet, wildlife, aquatic resources, and visitor experience. Both adaptive management and monitoring require standards, or thresholds, to establish baselines upon which to assess degradation to monitored park values. The initial identification of indicators, standards, methods and management responses that relate to critical values is located in FEIS appendix I. This is the basis for developing monitoring plans under authority of this decision.

Coordination and Responsibility Requirements

Monitoring programs will be coordinated between Yellowstone and Grand Teton National Parks. The programs will function and be coordinated through the planning staffs of both parks. The development of annual plans and reports will be coordinated through the planning units, and the planning units will be responsible for delivering those products to management. Other park divisions will coordinate with planning, and provide resources for performing monitoring tasks.

Adaptive Management Program

The essential first step when formulating an adaptive management strategy for the affected environment is to articulate the critical uncertainties, particularly where some information is known about a specific resource but conclusive evidence is currently unavailable. Based on current knowledge, a management scenario is then designed to test specific hypotheses relating to the critical uncertainties. Monitoring and

evaluation strategies are then employed to evaluate outcomes relative to acceptable thresholds, and assist in the development of management alternatives. Monitoring within the framework of adaptive management is critical because of the uncertainty of predictions based on limited information. It provides systematic feedback for management, and allows adjustment of activities to mitigate unplanned or undesirable outcomes.

A critical step in adaptive management involves the National Environmental Policy Act (NEPA). Each time a new management proposal is evaluated the analysis must be documented by performing the appropriate level of NEPA compliance. Some actions, such as permanent road closures to protect wildlife or the construction of new facilities may require an additional site-specific NEPA analysis, which includes public scoping. Some actions might be administrative in nature, or be implementable through application of a NEPA categorical exclusion (Ref: NPS 12).

The adaptive management process is shown schematically in Figure 1. Tables follow that prescribe monitoring standards, methods and proposed management actions for critical resources in each winter management zone. These are tables 12 through 22.

Monitoring Program

General resource monitoring applies when adequate information exists to make informed management decisions. It is the process of collecting information to evaluate if the objectives of a management plan are being realized. General monitoring techniques (as opposed to monitoring conducted within the adaptive management framework) will be employed to assess impacts to public health and safety; geothermal features; water quality; threatened and endangered species; trumpeter swans and some aspects of visitor experience, including access and circulation. NPS-77, Natural Resources Management Guideline, will be used initially as a guide to monitoring specific resource areas. As new techniques are developed, or as commonly accepted procedures become available, monitoring protocols will change.

Tables follow that prescribe monitoring standards, methods and possible management actions for critical resources in each winter management zone. These are tables 1 through 11.

Annual Monitoring and Adaptive Management Plans

The overall objective for monitoring and adaptive management is to assess the long-term effects of management actions on park resources and values. Specific objectives accrue to each winter management zone (FEIS Table xx and Figures xx and xx). With reference to the following tables, for each management zone and for each resource of concern, monitoring indicators are presented. For each indicator, a standard either exists or is hypothesized (for adaptive management). Also, for each indicator a monitoring method and intensity is prescribed. Finally, management actions are indicated if the standards should be exceeded.

Monitoring and adaptive management plans will be developed annually during workplanning and budget processes for the coming year. Plans will be developed through the planning staffs of both park units. Monitoring will be conducted on a sampling basis for the purpose of effective use of funds and personnel. The guiding principle for monitoring is to collect purposeful data—even if the amount is limited—rather than collecting a great deal of data that cannot be used statistically to arrive at valid conclusions. Therefore, monitoring plans will be brief and will cover the following items:

- The zones to be sampled, along with the indicators, standards, and methods to be used.
- Specific locations for monitoring, and the planned intensity—frequency of monitoring.
- A schedule (times) for data collection and submittal.
- The division or individual that is responsible for monitoring and reporting.

It is expected that initial monitoring will be intensive, both in geographic and temporal extent, so that correlations can be made and results can be extrapolated. It is also expected that monitoring over time will become less intensive and arrive at a low intensity, maintenance level. Sampling schedules can vary from year to year, focusing on different areas within the park units. Monitoring plans will continue to be coordinated between Yellowstone and Grand Teton so that common methods are used, efficiency is achieved, and results are comparable. Annual monitoring reports will be written and publicized through the planning units of the two parks.

Annual Monitoring and Adaptive Management Reports

Feedback for management is implicit in monitoring and adaptive management programs. In order for feedback to occur,

data must be collected effectively in accordance with a plan. Data must be captured in an accessible information system, capable of evaluation and statistical manipulation. Then, evaluations must be put in meaningful terms for management. The requirement of a formal report is essential to meet this need. The report should be published to a standard that is appropriate for public consumption.

Annual monitoring reports will be brief, and will meet the following requirements:

- Sum up the information collected during the year.
- Express conclusions relating to each management zone and indicator that was monitored.
- Extrapolate the conclusions to other areas, when possible and appropriate.
- State the need for applying management actions based on monitoring.
- Make recommendations for changes in monitoring locations, protocols, techniques or thresholds that should be considered in the monitoring plan for the following year.

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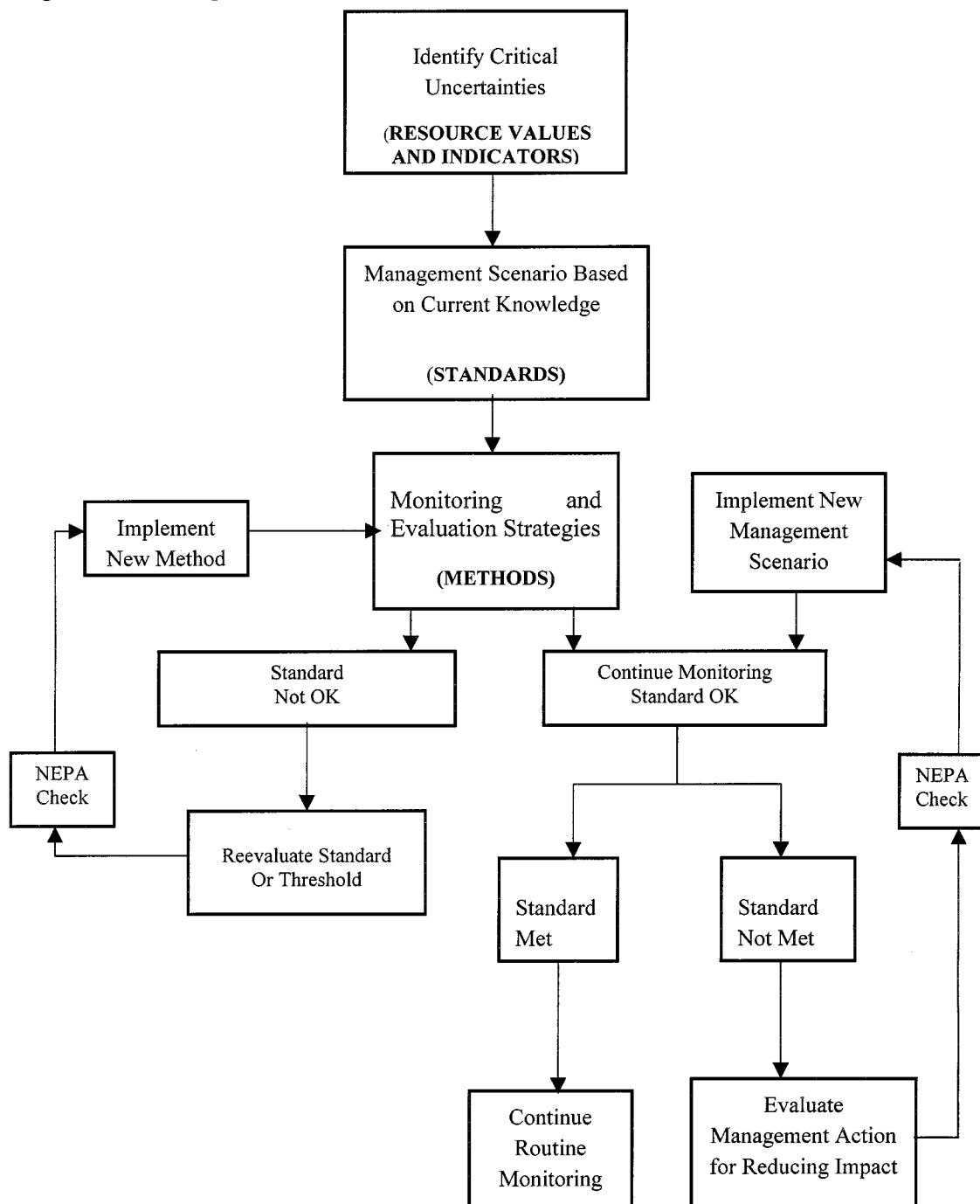
Figure 1. The Adaptive Management Process.

Table 1. Monitoring Standards, Methods, Intensity by Management Zone, Yellowstone and Grand Teton National Parks and the John D. Rockefeller, Jr., Memorial Parkway Winter Use Plan.

Management Zone → Resource Value	I Destination or Support Area				
	Indicator	Preliminary Standard	Method	Monitoring Intensity*	Management Actions
Air Quality and Public Health	Visibility	State and federal air quality standards	Time lapse video Fixed site sampling of particulate matter (PM _{2.5} and PM ₁₀)	High	Establish vehicle carrying capacity reduce vehicle numbers Review annually
	Park workers and visitors exposure to CO, particulate matter, aldehydes, and VOCs	State and federal air quality standards	Fixed site sampling of PM and carbon monoxide, and VOCs	High	Establish vehicle carrying capacity reduce vehicle numbers Review annually
Wildlife	Bird and mammal habitation re; effectiveness of garbage facilities	Garbage unavailable to wildlife	Personal samples for exposure to aldehydes, VOCs, carbon monoxide, and particulate matter Photo surveys, and observation	High	Reduce exposure to emissions Reduce emissions Review annually
Water/Snowpack	Water quality: pH, hydrogen, ammonium, calcium, sulfate, nitrate, and VOCs	State and federal water quality standards	Surface water sampling Snowpack sampling	Moderate	Increase or improve garbage security Increase garbage storage Review annually Determination and application of best management practices Reduce emissions and vehicle numbers Review annually
Safety	Vehicle accidents and incidents	Continual improvement three-year sliding average	Incident descriptions and GIS mapping	High	Sign and reduce speed limits in areas of recurring incidents Increase law enforcement and information programs in areas of concern Review monthly
Geothermal Features	Human-caused damage to geothermal areas	No degradation of geothermal resources	Remote sensing and visual observation	High	Increase enforcement and monitoring Implement additional information programs Restrict travel Review monthly
Visitor Experience	Waiting lines	Visitors wait no more than 5 minutes to access restrooms and park information	Observation	Moderate	Increase facilities where possible Increase information programs Review annually
	Perceptions of crowding at attraction sites	Visitors are able to see, smell, and hear the natural environment at popular attraction sites such as Old Faithful or Jackson Lake	Visitor survey	High	Establish carrying capacities Review Every other year
	Visitor satisfaction with opportunities to experience park values (wildlife viewing, scenery, and clean air), affordable services, and access to information	Visitors are highly satisfied with their park experience	Visitor survey	High	Establish carrying capacities Review Every other year

*High = Daily to weekly or in accordance with standard protocol for parameter; Moderate = Monthly to seasonally and during peak days or use periods; Low = Annually during peak use periods or at the end of the season.

Record of Decision for Winter Use

Monitoring and Adaptive Management

Table 2. Monitoring Standards, Methods, Intensity by Management Zone, Yellowstone and Grand Teton National Parks and the John D. Rockefeller, Jr., Memorial Parkway Winter Use Plan.

Management Zone →		Plowed Road					Monitoring Intensity*	Management Actions
Resource Value	Indicator	Preliminary Standard	Method					
Air Quality (Public Health)	Visibility	No degradation. State and Federal air quality standards	Photo survey Fixed site sampling of PM	Moderate				Establish vehicle carrying capacity Review annually
	Park workers and visitors exposure to CO, particulate matter, aldehydes, and VOCs	State air quality standards	Fixed site sampling of PM, Carbon Monoxide Personal samples for exposure to aldehydes, VOCs, and particulate matter	Moderate				Establish vehicle carrying capacity Review annually
Wildlife	Vehicle caused wildlife mortality	No effect to population	Incident reports, roadside surveys, and visual observations	High				Sign and reduce speed limits in areas of recurring incidents Review monthly
	Wildlife trapped by snow berms in road corridor	No effect on population						Increase number of exit berms – reevaluate location of existing exits Review weekly
Sound	Distance and time human-caused sound is audible	CFR for vehicle sound	Audibility logging	High				Increase enforcement Review annually
Water/Snowpack	Water quality: pH, Hydrogen, Ammonium, Calcium, Sulfate, Nitrate and VOC's	State and Federal water quality standards	surface water sampling Snowpack sampling	Moderate				Establish vehicle carrying capacity Determination and application of best management practices Review annually
Safety	Motor vehicle accidents Motorized vs. nonmotorized visitor conflict	Continuous improvement three-year sliding average	Incident reports and GIS	High				Sign and reduce speed limits in areas of recurring incidents Increase law enforcement in areas of concern Review monthly
Visitor Experience	Encounter rates	Not to exceed 250 vehicles per hour for more than 1 hour per day. Visitors are able to see, smell, and hear the natural environment at roadside pullouts and interpretive trails Visitors are highly satisfied (+90%) with their park experience	Visitor survey	High				Establish carrying capacities/reduce visitor numbers Review every other year
	Visitor satisfaction levels with opportunities to experience park values and opportunities to view wildlife, scenery, and experience clean air and solitude		Visitor survey	High				Establish carrying capacities/reduce visitor numbers Review every other year

*High = Daily to weekly or in accordance with standard protocol for parameter; Moderate = Monthly to seasonally and during peak days or use periods; Low = Annually during peak use periods or at the end of the season.

Record of Decision for Winter Use

Monitoring and Adaptive Management

Table 3. Monitoring Standards, Methods, Intensity by Management Zone, Yellowstone and Grand Teton National Parks and the John D. Rockefeller, Jr., Memorial Parkway Winter Use Plan.

Management Zone →	3 Groomed Motorized Route Clean and Quiet				
	Resource Value	Indicator	Preliminary Standard	Method	Monitoring Intensity*
Air Quality (Public Health)	Visibility		No degradation. Area free of any visible sign of human-caused pollutants at least 95% of each 24-hour period	Photo survey Fixed site sampling of PM ₁₀	Moderate
	Park workers and visitors exposure to CO, particulate matter, aldehydes, and VOCs		State and federal air quality standards	Fixed site sampling of PM and carbon monoxide	Moderate
				Personal samples for exposure to aldehydes, VOCs, and particulate matter Establish exposure measurements for snowcoaches	
Wildlife	Wildlife mortalities caused by oversnow vehicles		No effect on population	Incident reports and roadside surveys, photo surveys, and visual observations	Low
	Wildlife harassment or displacement due to vehicle sound or movements		No effect on population	Incident reports and photo surveys	High
	Bison use of groomed surfaces		No effect on population	Photo surveys, air surveys, and telemetry	High
	Lynx habitat effectiveness		No effect on population	Carnivore and snowshoe hare track surveys	
Sound	Distance and time human-caused sound is audible		CFR for vehicle sound	Audibility logging	Moderate
Water/Snowpack	Water quality: pH, Hydrogen, Ammonium, Calcium, Sulfate, Nitrate, and VOCs		State and Federal water quality standards Snowpack sampling	Spring runoff surface water sampling Snowpack sampling	High
Safety	Oversnow vehicle accidents		Continuous improvement three-year sliding average	Incident reports and GIS	High
Visitor Experience	Encounter rates		Not to exceed 250 vehicles per hour for more than 1 hour per day. Visitors are able to see, smell, and hear the natural environment at roadside pullouts and interpretive trails	Visitor survey	High
	Smoothness of groomed surface		No worse than fair 20% of a 24-hour period	Visual observation	
	Visitor satisfaction levels with opportunities to experience park values and opportunities to view wildlife, scenery, and experience clean air and solitude.		Visitors are highly satisfied (+90%) with their park experience	Visitor survey	High

* High = Daily to weekly or in accordance with standard protocol for parameter; Moderate = Monthly to seasonally and during peak days or use periods; Low = Annually during peak use periods or at the end of the season.

Record of Decision for Winter Use

Monitoring and Adaptive Management

Table 4. Monitoring Standards, Methods, Intensity by Management Zone, Yellowstone and Grand Teton National Parks and the John D. Rockefeller, Jr., Memorial Parkway Winter Use Plan.

Management Zone →		4 Groomed Motorized Route				
Resource Value	Indicator	Preliminary Standard	Method	Monitoring Intensity*	Management Actions	
Air Quality (Public Health)	Visibility	No degradation. Area free of any visible sign of human-caused pollutants at least 95% of each 24-hour period	Photo survey and time lapse video Fixed site sampling of particulate matter (PM _{2.5} and PM ₁₀)	High	Establish vehicle carrying capacities/reduce vehicle numbers Implement new technologies Review annually	
	Park workers and visitors exposure to CO, particulate matter, aldehydes, and VOCs	State air quality standards	Fixed site sampling of PM, Carbon Monoxide	High	Establish vehicle carrying capacities/reduce vehicle numbers Implement new technologies Review annually	
			Personal samples for exposure to aldehydes, VOCs, and particulate matter Establish exposure measurements for snowcoaches			
Wildlife	Wildlife mortalities caused by oversnow vehicles	No effect on population	Incident reports and roadside surveys, photo surveys, and visual observations	Low	Sign and reduce speed limits in areas of recurring incidents Review monthly	
	Wildlife harassment	No effect on population	Incident reports and photo surveys	High	Increase law enforcement Review annually	
Sound	Bison use of groomed surfaces	No effect on population	Photo and air surveys	High	Mitigate effects or close roads to grooming Review annually	
	Lynx habitat effectiveness	No effect on population	Carnivore and snowshoe hare track surveys	High		
Water/ Snowpack	Distance and time human-caused sound is audible	CFR for vehicle sound	Audibility logging	High	Increase enforcement Review annually	
	Water quality: pH, Hydrogen, Ammonium, Calcium, Sulfate, Nitrate, and VOCs	State and Federal water quality standards	Spring runoff surface water sampling Snowpack sampling	High	Determination and application of best management practices Reduce emissions Implement or require new technologies Review annually	
Safety	Oversnow vehicle accidents	Continuous improvement three-year sliding scale	Incident reports and GIS	High	Sign and reduce speed limits in areas of recurring incidents. Increase law enforcement in areas of concern.	
Visitor Experience	Encounter rates	Visitors are able to see, smell, and hear the natural environment at roadside pullouts and interpretive trails	Visitor survey	High	Establish carrying capacities/reduce visitor numbers Review every other year	
	Smoothness of groomed surface	No worse than fair 20% of a 24-hour period	Visual observation		Improve or increase grooming Reduce visitor numbers Review annually	
	Visitor satisfaction levels with opportunities to experience park values and opportunities to view wildlife, scenery, and experience clean air and solitude.	Visitors are highly satisfied (+90%) with their park experience	Visitor survey	High	Establish carrying capacities/reduce visitor numbers Review every other year	

*High = Daily to weekly or in accordance with standard protocol for parameter; Moderate = Monthly to seasonally and during peak days or use periods; Low = Annually during peak use periods or at the end of the season

Record of Decision for Winter Use

Monitoring and Adaptive Management

Table 5. Monitoring Standards, Methods, Intensity by Management Zone, Yellowstone and Grand Teton National Parks and the John D. Rockefeller, Jr., Memorial Parkway Winter Use Plan.

5 Groomed Motorized Trail Clean and Quiet						
Management Zone →	Resource Value	Indicator	Preliminary Standard	Method	Monitoring Intensity*	Management Actions
Air Quality (Public Health)	Visibility		No degradation. Area free of any visible sign of human-caused pollutants	Photo survey	Low	Establish vehicle carrying capacity/reduce vehicle numbers Review annually
	Park workers and visitors exposure to CO, particulate matter, aldehydes, and VOCs		State air quality standards	Fixed site sampling of particulate matter (PM _{2.5} and PM ₁₀) Personal samples for exposure to aldehydes, VOCs, and carbon monoxide	Low	Establish vehicle carrying capacity/reduce vehicle numbers Review annually
				Incident reports and roadside surveys, photo surveys, and visual observations	Low	Sign and reduce speed limits in areas of recurring incidents Review monthly
Wildlife	Wildlife mortalities caused by oversnow vehicles		No effect on population	Incident reports and photo surveys	High	Increase law enforcement Review annually
	Wildlife harassment		No effect on population	Photo and air surveys	Low	Close trail Review annually
	Bison use of groomed surfaces		No effect on population	Carnivore and snowshoe hare track surveys	High	Increase law enforcement Review annually
Sound	Lynx habitat effectiveness		CFR for vehicle sound	Audibility logging	High	Determination and application of best management practices Reduce vehicle numbers Implement or require new technologies Review annually
Water/Snowpack	Distance and time human-caused sound is audible		State and Federal water quality standards	Spring runoff surface water sampling	High	Sign and reduce speed limits in areas of recurring incidents. Increase law enforcement in areas of concern. Review monthly
	Surface water sampling of pH, Hydrogen, Ammonium, Calcium, Sulfate, Nitrate, and VOCs		Continuous improvement three-year sliding scale	Incident reports and GIS	High	Establish carrying capacity/reduce visitor numbers Review every other year
Safety	Oversnow vehicle accidents Conflicts between motorized and nonmotorized use		Not to exceed 16 to 20 parties per day 80% of the time. Visitors are able to see, smell, and hear the natural environment at roadside pullouts and interpretive trails	Visitor survey	Low	Improve or increase grooming Reduce vehicle numbers Review annually
Visitor Experience	Encounter rates		No worse than fair 30% of the winter season	Visual observation	High	Reduce visitor numbers Review every other year
	Smoothness of groomed surface		Visitors are highly satisfied (190%) with their park experience	Visitor survey	High	Reduce visitor numbers Review every other year

*High = Daily to weekly or in accordance with standard protocol for parameter; Moderate = Monthly to seasonally and during peak days or use periods; Low = Annually during peak use periods or at the end of the season.

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Monitoring and Adaptive Management

Table 6. Monitoring Standards, Methods, Intensity by Management Zone, Yellowstone and Grand Teton National Parks and the John D. Rockefeller, Jr., Memorial Parkway Winter Use Plan.

6 Groomed Motorized Trail					
Management Zone →	Resource Value	Indicator	Preliminary Standard	Method	Monitoring Intensity*
Air Quality (Public Health)	Visibility		No degradation. Area free of any visible sign of human-caused pollutants	Photo survey	Low
	Park workers and visitors exposure to CO, particulate matter, aldehydes, and VOCs		State air quality standards	Fixed site sampling of particulate matter (PM _{2.5} and PM ₁₀) Carbon Monoxide Personal samples for exposure to aldehydes, VOCs, and particulate matter	Low
Wildlife	Wildlife mortalities caused by oversnow vehicles		No effect on population	Incident reports and roadside surveys, photo surveys, and visual observations	Low
	Wildlife harassment		No effect on population	Incident reports and photo surveys	Low
	Bison use of groomed surfaces		No effect on population	Photo and air surveys	Low
	Lynx habitat effectiveness		No effect on population	Carnivore and snowshoe hare track surveys Audibility logging	High
Sound	Distance and time human-caused sound is audible		CPR for vehicle sound		High
Water/Snowpack	Surface water sampling of pH, Hydrogen, Ammonium, Calcium, Sulfate, Nitrate, and VOCs		State and Federal water quality standards	Spring runoff surface water sampling	Low
Safety	Oversnow vehicle accidents Conflicts between motorized and nonmotorized use		Continuous improvement three-year sliding scale	Incident reports and GIS	High
Visitor Experience	Encounter rates		Not to exceed 16 to 20 parties per day 80% of the time. Visitors are able to see, smell, and hear the natural environment at roadside pullouts and interpretive trails	Visitor survey	High
	Smoothness of groomed surface		No worse than fair 30% of the winter season	Visual observation	Low
	Visitor satisfaction levels with opportunities to experience park values and opportunities to view wildlife, scenery, and experience clean air and solitude.		Visitors are highly satisfied (>90%) with their park experience	Visitor survey	High

*High = Daily to weekly or in accordance with standard protocol for parameter; Moderate = Monthly to seasonally and during peak days or use periods; Low = Annually during peak use periods or at the end of the season.

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Monitoring and Adaptive Management

Table 7. Monitoring Standards, Methods, Intensity by Management Zone, Yellowstone and Grand Teton National Parks and the John D. Rockefeller, Jr., Memorial Parkway Winter Use Plan.

Management Zone → Resource Value	Un groomed Motorized Trail				
	Indicator	Preliminary Standard	Method	Monitoring Intensity*	Management Actions
Air Quality (Public Health)	Visibility	No degradation. Area free of any visible sign of human-caused pollutants	Photo survey and time lapse video Fixed site sampling of particulate matter (PM _{2.5} and PM ₁₀)	Low	Establish vehicle carrying capacity /reduce vehicle numbers Review annually
	Park workers and visitors exposure to CO, particulate matter, aldehydes, and VOCs	State air quality standards	Fixed site sampling of particulate matter (PM _{2.5} and PM ₁₀) Carbon Monoxide Personal samples for exposure to aldehydes, VOCs, and particulate matter	Low	Establish vehicle carrying capacity /reduce vehicle numbers Review annually
Wildlife	Wildlife mortalities caused by oversnow vehicles	No effect on population	Incident reports and roadside surveys, photo surveys, and visual observations	Low	Sign and reduce speed limits in areas of recurring incidents Review monthly
	Wildlife harassment	No effect on population	Incident reports and photo surveys	Low	Increase law enforcement Review annually
	Lynx habitat effectiveness	No effect on population	Carnivore and snowshoe hare track surveys	High	Close trail Review annually
Sound	Distance and time human-caused sound is audible	CFR for vehicle sound	Audibility logging	High	Increase law enforcement Review annually
Water/ Snowpack	Surface water sampling of pH, Hydrogen, Ammonium, Calcium, Sulfate, Nitrate, and VOCs	State and Federal water quality standards	Spring runoff surface water sampling	Low	Determination and application of best management practices Reduce vehicle numbers Implement or require new technologies Review annually
Safety	Oversnow vehicle accidents Conflicts between motorized and nonmotorized use	Continuous improvement three-year sliding scale	Incident reports and GIS	Low	Sign and reduce speed limits in areas of recurring incidents. Increase law enforcement in areas of concern Review monthly
Visitor Experience	Encounter rates	Not to exceed 16 to 20 parties per day 80% of the time. Visitors are able to see, smell, and hear the natural environment at roadside pullouts and interpretive trails	Visitor survey	Low	Establish carrying capacity/reduce visitor numbers Review every other year
	Visitor satisfaction levels with opportunities to experience park values and opportunities to view wildlife, scenery, and experience clean air and solitude	Visitors are highly satisfied (490%) with their park experience	Visitor survey	Low	Establish carrying capacities/reduce visitor numbers Review every other year

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Monitoring and Adaptive Management

Table 8. Monitoring Standards, Methods, Intensity by Management Zone, Yellowstone and Grand Teton National Parks and the John D. Rockefeller, Jr., Memorial Parkway Winter Use Plan.

8 Groomed Nonmotorized Trail					
Management Zone →	Indicator	Preliminary Standard	Method	Monitoring Intensity*	Management Actions
Air Quality (Public Health)	Visibility	No degradation. Area free of any visible sign of human-caused pollutants	Photo survey	Low	Establish vehicle carrying capacity/ reduce vehicle numbers Review annually
	Park workers and visitors exposure to CO, particulate matter, aldehydes, and VOCs	State air quality standards	Fixed site sampling of particulate matter (PM _{2.5} and PM ₁₀) Carbon Monoxide Personal samples for exposure to aldehydes, VOCs, and particulate matter	Low	Establish vehicle carrying capacity/ reduce vehicle numbers Review annually
Wildlife	Wildlife harassment	No effect on population	Incident reports and photo surveys	Low	Increase law enforcement and information programs Review annually
	Lynx habitat effectiveness	No effect on population	Carnivore and snowshoe hare track surveys	High	Close trail Review annually
Sound	Distance and time human-caused sound is audible	CFR for vehicle sound	Audibility logging	High	Increase law enforcement Review annually
Water/ Snowpack	Surface water sampling of pH, Hydrogen, Ammonium, Calcium, Sulfate, Nitrate, and VOCs	State and Federal water quality standards	Spring runoff surface water sampling	Low	Determination and application of best management practices Reduce vehicle numbers Implement or require new technologies Review annually
Safety	Conflicts between motorized and nonmotorized use Search and rescue Human and wildlife conflicts	Continuous improvement three-year sliding scale	Incident reports and GIS	Low	Increase law enforcement and information programs in areas of concern Review monthly
Visitor Experience	Encounter rates	Not to exceed 10 to 15 parties per day over 70% of the use season. Visitors are able to see, smell, and hear the natural environment at roadside pullouts and interpretive trails	Visitor survey	Low	Establish carrying capacity/ reduce visitor numbers Review every other year
	Smoothness of groomed surface	No worse than fair 30% of the winter season	Visual observation	Low	Improve or increase grooming Reduce vehicle numbers Review annually
	Visitor satisfaction levels with opportunities to experience park values and opportunities to view wildlife, scenery, and experience clean air and solitude.	Visitors are highly satisfied (+90%) with their park experience	Visitor survey	Low	Establish carrying capacities/ reduce visitor numbers Review every other year

*High = Daily to weekly or in accordance with standard protocol for parameter; Moderate = Monthly to seasonally and during peak days or use periods; Low = Annually during peak use periods or at the end of the season.

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Monitoring and Adaptive Management

Table 9. Monitoring Standards, Methods, Intensity by Management Zone, Yellowstone and Grand Teton National Parks and the John D. Rockefeller, Jr., Memorial Parkway Winter Use Plan.

9 Ungroomed Nonmotorized Trail or Area					
Management Zone →	Resource Value	Indicator	Preliminary Standard	Method	Monitoring Intensity*
Air Quality (Public Health)	Visibility		No degradation. Area free of any visible sign of human-caused pollutants	Photo survey and time lapse video Fixed site sampling of particulate matter (PM _{2.5} and PM ₁₀)	Moderate
	Wildlife harassment		No effect on population	Incident reports and photo surveys	Moderate
Wildlife	Human and grizzly bear conflicts during pre- or post denning period		No incidents	Mapping of denning areas	High
	Lynx habitat effectiveness		No effect on population	Carnivore and snowshoe hare track surveys	High
Sound	Distance and time human-caused sound is audible		CFR for vehicle sound	Audibility logging	High
	Surface water sampling of pH, Hydrogen, Ammonium, Calcium, Sulfate, Nitrate, and VOC's		State and Federal water quality standards	Spring runoff surface water sampling	Low
Water/Snowpack	Conflicts between motorized and nonmotorized use		Continuous improvement three-year sliding scale	Incident reports and GIS	High
	Search and rescue				
Safety	Human and wildlife conflicts				
	Encounter rates		Not to exceed 10 to 15 parties per day over 70% of the use season. Visitors are able to see, smell, and hear the natural environment at roadside pullouts and interpretive trails	Visitor survey	Low
Visitor Experience	Visitor satisfaction levels with opportunities to experience park values and opportunities to view wildlife, scenery, and experience clean air and solitude		Visitors are highly satisfied (+90%) with their park experience	Visitor survey	Low

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Monitoring and Adaptive Management

Table 10. Monitoring Standards, Methods, Intensity by Management Zone, Yellowstone and Grand Teton National Parks and the John D. Rockefeller, Jr., Memorial Parkway Winter Use Plan.

10 Backcountry Nonmotorized Trail or Area					
Management Zone →	Resource Value	Indicator	Preliminary Standard	Method	Monitoring Intensity*
Air Quality (Public Health)	Visibility		No degradation. Area free of any visible sign of human-caused pollutants	Photo survey and time lapse video Fixed site sampling of particulate matter (PM _{2.5} and PM ₁₀)	Moderate
	Wildlife	Wildlife harassment	No effect on population	Incident reports and photo surveys, and observation	Moderate
Sound	Human and grizzly bear conflicts during pre- or post denning period		No incidents	Mapping of denning areas Incident reports	High
	Lynx habitat effectiveness		No effect on population	Carnivore and snowshoe hare track surveys Audibility logging	High
Water/Snowpack	Distance and time human-caused sound is audible		CFR for vehicle sound		High
	Surface water sampling of pH, Hydrogen, Ammonium, Calcium, Sulfate, Nitrate, and VOCs		State and Federal water quality standards	Spring runoff surface water sampling Snowpack sampling	Moderate
Safety	Search and rescue		Continuous improvement three-year sliding scale	Incident reports and GIS	High
	Human and wildlife conflicts				High
Visitor Experience	Encounter rates		Not to exceed 5 to 10 parties per day over 80% of the use season. Visitors are able to see, smell, and hear the natural environment and experience quiet and solitude	Visitor survey	Low
	Visitor satisfaction levels with opportunities to experience park values and opportunities to view wildlife, scenery, and experience clean air and solitude		Visitors are highly satisfied (>90%) with their park experience	Visitor survey	Low

*High = Daily to weekly or in accordance with standard protocol for parameter; Moderate = Monthly to seasonally and during peak days or use periods; Low = Annually during peak use periods or at the end of the season.

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Monitoring and Adaptive Management

Table 11. Monitoring Standards, Methods, Intensity by Management Zone, Yellowstone and Grand Teton National Parks and the John D. Rockefeller, Jr., Memorial Parkway Winter Use Plan.

II Sensitive Resource Area					
Management Zone →	Resource Value	Indicator	Preliminary Standard	Method	Monitoring Intensity*
Air Quality (Public Health)	Wildlife	Visibility/Success of closure	No degradation	Photo survey and time lapse video Fixed site sampling of particulate matter (PM _{2.5} and PM ₁₀)	Moderate
		Wildlife harassment	No incidents	Incident reports and photo surveys, and observation	Moderate
Water/ Snowpack	Safety	Human and grizzly bear conflicts during pre- or post denning period/ closure	No incidents	Mapping of denning areas Incident reports	High
		Lynx habitat effectiveness	No effect on population	Carnivore and snowshoe hare track surveys	High
Water/ Snowpack	Safety	Surface water sampling of pH, Hydrogen, Ammonium, Calcium, Sulfate, Nitrate, and VOC ₃	State and Federal water quality standards	Spring runoff surface water sampling Snowpack sampling	Moderate
		Search and rescue Human and wildlife conflicts	No incidents	Incident reports and GIS	High
Management Actions					
Evaluate success of closure Review annually					
Evaluate success of closure Review annually					
Evaluate success of closure Review annually					
Evaluate success of closure Review annually					

*High = Daily to weekly or in accordance with standard protocol for parameter; Moderate = Monthly to seasonally and during peak days or use periods; Low = Annually during peak use periods or at the end of the season.

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Monitoring and Adaptive Management

Table 12. Adaptive Management Indicators, Standards, and Methods by Management Zone, Yellowstone and Grand Teton National Parks and the John D. Rockefeller, Jr., Memorial Parkway Winter Use Plan.

Management Zone → Resource Value	I Destination or Support Area				
	Indicator	Standard	Preliminary Method	Monitoring Intensity*	Management Actions
Air Quality	Odor	Area free of odor of human-caused pollutants not less than 90% of a given 24-hour period	Park visitor survey	High	Implement or require new technologies Reduce vehicle numbers/ reduce carrying capacity
	Visibility	No degradation. Area free of any visible sign of human-caused pollutants not less than 95% of a each 24-hour period Particulate matter not to exceed	Photo survey and time lapse video Fixed site sampling of particulate matter (PM _{2.5} and PM ₁₀)	High	Implement or require new technologies Reduce vehicle numbers/ reduce carrying capacity
Sound	Distance and time human-caused sound is audible	% time vehicles audible at attraction sites not to exceed 50%	Audibility logging	High	Implement or require new technologies Reduce vehicle numbers/ reduce carrying capacity
Water/ Snowpack	Water quality: pH, Hydrogen, Ammonium, Calcium, Sulfate, Nitrate, and VOC's	State and federal water quality standards	Spring runoff surface water sampling Snowpack sampling	Moderate	Determination and application of best management practices Implement or require new technologies Reduce vehicle numbers/ reduce carrying capacity
Visitor Experience	Perceptions of crowding at attraction sites	Visitors are able to see, smell, and hear the natural environment at popular attraction sites such as Old Faithful or Jackson lake	Visitor survey and Encounter rates	High	Establish carrying capacity Reduce visitor numbers
	Visitor satisfaction with opportunities to experience park values (wildlife viewing, scenery and clean air) affordable services and access to information.	Visitors are highly satisfied with their park experience	Visitor survey	High	Establish carrying capacity Reduce visitor numbers

*High = Daily to weekly or in accordance with standard protocol for parameter; Moderate = Monthly to seasonally and during peak days or use periods; Low = Annually during peak use periods or at the end of the season.

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Monitoring and Adaptive Management

Table 13. Adaptive Management Indicators, Standards, and Methods by Management Zone, Yellowstone and Grand Teton National Parks and the John D. Rockefeller, Jr., Memorial Parkway Winter Use Plan.

Management Zone →	2 Plowed Road				
	Resource Value	Indicator	Preliminary Standard	Method	Monitoring Intensity*
Air Quality (Public Health)	Odor		Area free of any noticeable odor of human-caused pollutants at least 90% of each 24-hour period	Park visitor survey	Moderate
	Visibility		No degradation. Area free of any visible sign of human-caused pollutants at least 95% of each 24-hour period	Photo survey and time lapse video Fixed site sampling of particulate matter (PM _{2.5} and PM ₁₀)	Moderate
Wildlife	Vehicle caused wildlife mortality		No significant adverse effects	Incident reports, roadside surveys, GIS, and visual observations	High
	Bison movements on plowed roads		No significant adverse effects	Continue bison monitoring flights and photo surveys	High
	Wildlife harassment or displacement due to vehicle sound or movements		No significant adverse effects	Incident reports and photo surveys	High
	Wildlife trapped by snow berms in road corridor		No significant adverse effects	Incident reports, roadside surveys, and visual observations	High
Sound	Distance and time human-caused sound is audible		Time vehicles audible at 100' distance not to exceed 50 %	Audibility logging	High
	Water quality: pH, Hydrogen, Ammonium, Calcium, Sulfate, Nitrate, and VOCs		State and federal water quality standards	Spring runoff surface water sampling Snowpack sampling	Moderate
Visitor Experience	Perceptions of crowding		Visitors are able to see, smell, and hear the natural environment at roadside pullouts and interpretive trails	Visitor survey Encounter rates	High
	Visitor satisfaction levels with opportunities to experience park values and opportunities to view wildlife, scenery, and experience clean air and solitude.		Visitors are highly satisfied (190%) with their park experience	Visitor survey	High

*High = Daily to weekly or in accordance with standard protocol for parameter; Moderate = Monthly to seasonally and during peak days or use periods; Low = Annually during peak use periods or at the end of the season.

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Monitoring and Adaptive Management

Table 14. Adaptive Management Indicators, Standards and Methods by Management Zone, Yellowstone and Grand Teton National Parks and the John D. Rockefeller, Jr., Memorial Parkway Winter Use Plan.

3 Groomed Motorized Route Clean and Quiet				
Management Zone →	Resource Value	Indicator	Preliminary Standard	Method
Air Quality (Public Health)	Odor		Area free of any noticeable odor of human-caused pollutants at least 90% of each 24-hour period	Park visitor survey
	Visibility		No degradation. Area free of any visible sign of human-caused pollutants at least 95% of each 24-hour period	Photo survey and time lapse video Fixed site sampling of particulate matter (PM _{2.5} and PM ₁₀)
Wildlife	Wildlife mortalities caused by oversnow vehicles		No significant adverse effects	Incident reports, roadside surveys, photo surveys, and visual observations
	Wildlife harassment or displacement due to vehicle sound or movements		No significant adverse effects	Incident reports, photo surveys, and visual observation
	Bison use of groomed surfaces		No significant adverse effects	Photo surveys, air surveys, and telemetry
	Lynx habitat effectiveness		No significant adverse effects	Carnivore and snowshoe hare track surveys
Sound	Distance and time human-caused sound is audible		Time vehicles audible at 100' distance not to exceed 50 %	Audibility logging
	Water quality: pH, Hydrogen, Ammonium, Calcium, Sulfate, Nitrate, and VOCs		State and federal water quality standards	Spring runoff surface water sampling Snowpack sampling
Visitor Experience	Perceptions of crowding		Visitors are able to see, smell, and hear the natural environment at roadside pullouts and interpretive trails	Visitor survey Encounter rates
	Smoothness of groomed surface		No worse than fair 20% of a 24-hour period	Visual observation
	Visitor satisfaction levels with opportunities to experience park values and opportunities to view wildlife, scenery, and experience clean air and solitude.		Visitors are highly satisfied (190%) with their park experience	Visitor survey

*High = Daily to weekly or in accordance with standard protocol for parameter; Moderate = Monthly to seasonally and during peak days or use periods; Low = Annually during peak use periods or at the end of the season.
 †Mogul study to determine temperature and vehicle numbers for this management action is ongoing (Alger and Civalney 2000).

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Monitoring and Adaptive Management

Table 15. Adaptive Management Indicators, Standards and Methods and by Management Zone, Yellowstone and Grand Teton National Parks and the John D. Rockefeller, Jr., Memorial Parkway Winter Use Plan.

4 Groomed Motorized Route					
Management Zone →	Resource Value	Indicator	Preliminary Standard	Method	Monitoring Intensity*
Air Quality (Public Health)	Visibility		No degradation. Area free of any visible sign of human-caused pollutants at least 95% of each 24-hour period	Photo survey and time lapse video Fixed site sampling of particulate matter (PM _{2.5} and PM ₁₀)	High
	Odor		Area free of any noticeable odor of human-caused pollutants at least 95% of each 24-hour period	Visitor survey	Moderate
Wildlife	Wildlife mortalities caused by oversnow vehicles		No significant adverse effects	Incident reports and roadside surveys, photo surveys, and visual observations	Low
	Wildlife harassment or displacement due to vehicle sound or movements		No significant adverse effects	Incident reports and photo surveys	High
	Bison use of groomed surfaces		No significant adverse effects	Photo and air surveys	High
Sound	Lynx habitat effectiveness		No significant adverse effects	Carnivore and snowshoe hare track surveys	High
	Distance and time human-caused sound is audible		Time vehicles audible at 100' distance not to exceed 50 %	Audibility logging	High
Water/Snowpack	Water quality: pH, Hydrogen, Ammonium, Calcium, Sulfate, Nitrate, and VOCs		State and federal water quality standards	Spring runoff surface water sampling Snowpack sampling	High
Visitor Experience	Perceptions of crowding		Visitors are able to see, smell, and hear the natural environment at roadside pullouts and interpretive trails	Visitor survey Encounter rates	High
	Smoothness of groomed surface		No worse than fair 20% of a 24-hour period	Visual observation	
	Visitor satisfaction levels with opportunities to experience park values and opportunities to view wildlife, scenery, and experience clean air and solitude		Visitors are highly satisfied (+90%) with their park experience	Visitor survey	High

*High = Daily to weekly or in accordance with standard protocol for parameter; Moderate = Monthly to seasonally and during peak days or use periods; Low = Annually during peak use periods or at the end of the season.
 †Mogul study to determine temperature and vehicle numbers for this management action is ongoing (Alger and Gwalthney 2000).

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Monitoring and Adaptive Management

Table 16. Adaptive Management Indicators, Standards and Methods by Management Zone, Yellowstone and Grand Teton National Parks and the John D. Rockefeller, Jr., Memorial Parkway Winter Use Plan.

Management Zone →	5 Groomed Motorized Trail Clean and Quiet				
	Resource Value	Indicator	Preliminary Standard	Method	Monitoring Intensity*
Air Quality (Public Health)	Odor		Area free of any noticeable odor of human-caused pollutants	Park visitor survey	Low
	Visibility		No degradation. Area free of any visible sign of human-caused pollutants	Photo survey and time lapse video Fixed site sampling of particulate matter (PM _{2.5} and PM ₁₀)	Low
Wildlife	Wildlife harassment or displacement from habitat as a result of vehicle sound or movements		No significant adverse effects	Incident reports and photo surveys, and visual observations	High
	Bison use of groomed surfaces		No significant adverse effects	Photo and air surveys	Low
Sound	Lynx habitat effectiveness		No significant adverse effects	Carnivore and snowshoe hare track surveys	High
	Distance and time human-caused sound is audible		Time vehicles audible at 100' distance not to exceed 25 %	Audibility logging	High
Water Quality/Snowpack	Water quality: pH, Hydrogen, Ammonium, Calcium, Sulfate, Nitrate, and VOC's		State and federal water quality standards	Spring runoff surface water sampling Snowpack sampling	High
	Perceptions of crowding		Visitors are able to see, smell, and hear the natural environment at roadside pullouts and interpretive trails. Moderate levels of solitude and quiet available	Visitor survey Encounter rates	High
Visitor Experience	Smoothness of groomed surface		No worse than fair 30% of the winter season	Visual observation	Low
	Visitor satisfaction levels with opportunities to experience park values and opportunities to view wildlife, scenery, and experience clean air and solitude.		Visitors are highly satisfied (+90%) with their park experience	Visitor survey	High

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¹Mogul study to determine temperature and vehicle numbers for this management action is ongoing (Alger and Gwaltney 2000).

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Monitoring and Adaptive Management

Table 17. Adaptive Management Indicators, Standards and Methods by Management Zone, Yellowstone and Grand Teton National Parks and the John D. Rockefeller, Jr., Memorial Parkway Winter Use Plan.

Groomed Motorized Trail					
Management Zone →	Resource Value	Indicator	Preliminary Standard	Method	Monitoring Intensity*
Air Quality (Public Health)	Odor		Area free of any noticeable odor of human-caused pollutants	Park visitor survey	Low
	Visibility		No degradation. Area free of any visible sign of human-caused pollutants	Photo survey and time lapse video Fixed site sampling of particulate matter (PM _{2.5} and PM ₁₀)	Low
Wildlife	Wildlife harassment or displacement from habitat as a result of vehicle sound or movements		No significant adverse effects	Incident reports and photo surveys, and visual observation	Moderate
					Sign and reduce speed limits in areas of recurring incidents Increase law enforcement and information programs Close areas to use
Sound	Bison use of groomed surfaces		No significant adverse effects	Photo and air surveys	Low
	Lynx habitat effectiveness		No significant adverse effects	Carnivore and snowshoe hare track surveys	High
Water/ Snowpack	Distance and time human-caused sound is audible		Time vehicles audible at 100' distance not to exceed 25 %	Audibility logging	High
	Surface water sampling of pH, Hydrogen, Ammonium, Calcium, Sulfate, Nitrate, and VOCs		State and federal water quality standards	Spring runoff surface water sampling Snowpack sampling	Low
Visitor Experience	Perceptions of crowding		Visitors are able to see, smell, and hear the natural environment at roadside pullouts and interpretive trails. Moderate levels of solitude and quiet available	Visitor survey Encounter rates	High
	Smoothness of groomed surface		No worse than fair 30% of the winter season	Visual observation	Low
	Visitor satisfaction levels with opportunities to experience park values and opportunities to view wildlife, scenery, and experience clean air and solitude		Visitors are highly satisfied (190%) with their park experience	Visitor survey	High
					Increase grooming Reduce vehicle numbers when threshold temperature is reached ¹ Establish visitor carrying capacities Reduce visitor numbers

*High = Daily to weekly or in accordance with standard protocol for parameter; Moderate = Monthly to seasonally and during peak days or use periods; Low = Annually during peak use periods or at the end of the season.

¹Mogul study to determine temperature and vehicle numbers for this management action is ongoing (Alger and Gwalthney 2000).

Record of Decision for Winter Use

Monitoring and Adaptive Management

Table 18. Adaptive Management Indicators, Standards and Methods by Management Zone, Yellowstone and Grand Teton National Parks and the John D. Rockefeller, Jr., Memorial Parkway Winter Use Plan.

Management Zone →	7 Ungroomed Motorized Trail				
	Resource Value	Indicator	Preliminary Standard	Method	Monitoring Intensity*
Air Quality (Public Health)	Odor		Area free of any noticeable odor of human-caused pollutants	Park visitor survey	Low
	Visibility		No degradation. Area free of any visible sign of human-caused pollutants	Photo survey and time lapse video Fixed site sampling of particulate matter (PM _{1.5} and PM ₁₀)	Low
Wildlife	Wildlife harassment or displacement from habitat as a result of vehicle sound or movements		No significant adverse effects	Incident reports and photo surveys, and visual observation	Moderate
	Lynx habitat effectiveness		No significant adverse effects	Carnivore and snowshoe hare track surveys	High
Sound	Distance and time human-caused sound is audible		Time vehicles audible at 100' distance not to exceed 25 %	Audibility logging	High
Water/ Snowpack	Surface water sampling of pH, Hydrogen, Ammonium, Calcium, Sulfate, Nitrate, and VOC's		State and federal water quality standards	Spring runoff surface water sampling Snowpack sampling	Low
	Perceptions of crowding		Visitors are able to see, smell, and hear the natural environment at roadside pullouts and interpretive trails. Moderate levels of solitude and quiet available	Visitor survey Encounter rates	High
Visitor Experience	Visitor satisfaction levels with opportunities to experience park values and opportunities to view wildlife, scenery, and experience clean air and solitude		Visitors are highly satisfied (+90%) with their park experience	Visitor survey	High

*High = Daily to weekly or in accordance with standard protocol for parameter; Moderate = Monthly to seasonally and during peak days or use periods; Low = Annually during peak use periods or at the end of the season.

Record of Decision for Winter Use

Monitoring and Adaptive Management

Table 19. Adaptive Management Indicators, Standards, and Methods by Management Zone, Yellowstone and Grand Teton National Parks and the John D. Rockefeller, Jr., Memorial Parkway Winter Use Plan.

8 Groomed Nonmotorized Trail					
Management Zone →	Resource Value	Indicator	Preliminary Standard	Method	Monitoring Intensity*
Air Quality (Public Health)	Odor		Area free of any noticeable odor of human-caused pollutants	Park visitor survey	Low
	Visibility		No degradation. Area free of any visible sign of human-caused pollutants	Photo survey and time lapse video Fixed site sampling of particulate matter (PM _{2.5} and PM ₁₀)	Low
Wildlife	Wildlife harassment or displacement from habitat as a result of visitor activity or movements		No significant adverse effects	Incident reports and photo surveys	High
	Lynx habitat effectiveness		No significant adverse effects	Carnivore and snowshoe hare track surveys	High
Sound	Distance and time human-caused sound is audible		Time vehicles audible at 500' distant from trailhead or motorized route not to exceed 10 % during daylight hours (8AM-4PM)	Audibility logging	High
Visitor Experience	Perceptions of crowding		Visitors are able to see, smell, and hear the natural environment and to experience quiet and solitude	Visitor survey Encounter rates	High
	Visitor satisfaction levels with opportunities to experience park values and opportunities to view wildlife, scenery, and experience clean air and solitude		Visitors are highly satisfied (+90%) with their park experience	Visitor survey	High
					Implement or require new technologies Reduce emissions and carrying capacity
					Implement or require new technologies Reduce emissions and carrying capacity
					Increase law enforcement and visitor information Use of designated trails only Close areas to use
					Eliminate grooming operations Mitigate effects or close trail
					Implement new technologies Reduce sound emissions or reduce vehicle numbers
					Establish visitor carrying capacities Reduce visitor numbers
					Establish visitor carrying capacities Reduce visitor numbers

*High = Daily to weekly or in accordance with standard protocol for parameter; Moderate = Monthly to seasonally and during peak days or use periods; Low = Annually during peak use periods or at the end of the season.

Record of Decision for Winter Use

Monitoring and Adaptive Management

Table 20. Adaptive Management Indicators, Standards and Methods by Management Zone, Yellowstone and Grand Teton National Parks and the John D. Rockefeller, Jr., Memorial Parkway Winter Use Plan.

9 Un groomed Nonmotorized Trail or Area					
Management Zone →	Resource Value	Indicator	Preliminary Standard	Method	Monitoring Intensity*
Air Quality (Public Health)	Odor		Area free of any noticeable odor of human-caused pollutants	Park visitor survey	Low
	Visibility		No degradation. Area free of any visible sign of human-caused pollutants	Photo survey and time lapse video Fixed site sampling of particulate matter (PM _{2.5} and PM ₁₀)	Low
Wildlife	Human bear conflicts during pre- and post denning periods		No significant adverse effects	Mapping of denning areas	Moderate
	Wildlife harassment or displacement from habitat as a result of visitor activity or movements		No significant adverse effects	Incident reports and photo surveys	High
	Lynx habitat effectiveness		No significant adverse effects	Carnivore and snowshoe hare track surveys	High
Sound	Distance and time human-caused sound is audible		Time vehicles audible at 500' distant from trailhead or motorized route not to exceed 10 % during daylight hours (8AM-4PM).	Audibility logging	High
	Perceptions of crowding		Visitors are able to see, smell, and hear the natural environment. Frequent opportunities to experience quiet and solitude are available	Visitor survey Encounter rates	High
Visitor Experience	Visitor satisfaction levels with opportunities to experience park values and opportunities to view wildlife, scenery, and experience clean air and solitude		Visitors are highly satisfied (90%) with their park experience	Visitor survey	High

*High = Daily to weekly or in accordance with standard protocol for parameter; Moderate = Monthly to seasonally and during peak days or use periods; Low = Annually during peak use periods or at the end of the season.

Record of Decision for Winter Use

Monitoring and Adaptive Management

Table 21. Adaptive Management Indicators, Standards, and Methods by Management Zone, Yellowstone and Grand Teton National Parks and the John D. Rockefeller, Jr., Memorial Parkway Winter Use Plan.

Management Zone →	Backcountry Nonmotorized Trail or Area				
	Resource Value	Indicator	Preliminary Standard	Method	Monitoring Intensity*
Air Quality (Public Health)	Odor		Area free of any noticeable odor of human-caused pollutants	Park visitor survey	Low
	Visibility		No degradation. Area free of any visible sign of human-caused pollutants	Photo survey and time lapse video Fixed site sampling of particulate matter (PM _{2.5} and PM ₁₀)	Moderate
Wildlife	Human bear conflicts during pre- and post denning periods		No significant adverse effects	Mapping of denning areas	High
	Wildlife harassment or displacement from habitat as a result of visitor activity or movements		No significant adverse effects	Incident reports and photo surveys	High
	Lynx habitat effectiveness		No significant adverse effects	Carnivore and snowshoe hare track surveys	High
Water Quality/Snowpack	Water quality: pH, hydrogen, ammonium, calcium, sulfate, nitrate, and VOCs		State and federal water quality standards	Spring runoff surface water sampling Snowpack sampling	Moderate
Sound	Distance and time human-caused sound is audible		Time vehicles audible at 500' distant from trailhead or motorized route not to exceed 10 % during daylight hours (8AM-4PM). Vehicles not audible beyond 1000' from TH or motorized route.	Audibility logging	Moderate
Visitor Experience	Perceptions of crowding		Visitors are able to see, smell, and hear the natural environment. Frequent opportunities to experience quiet and solitude are available	Visitor survey Encounter rates	Moderate
	Visitor satisfaction levels with opportunities to experience park values and opportunities to view wildlife, scenery, and experience clean air and solitude		Visitors are highly satisfied (+90%) with their park experience	Visitor survey	Moderate

*High = Daily to weekly or in accordance with standard protocol for parameter; Moderate = Monthly to seasonally and during peak days or use periods; Low = Annually during peak use periods or at the end of the season.

Record of Decision for Winter Use

Monitoring and Adaptive Management

Table 22. Adaptive Management Indicators, Standards, Methods by Management Zone, Yellowstone and Grand Teton National Parks and the John D. Rockefeller, Jr., Parkway Winter Use Plan.

Management Zone →	11 Sensitive Resource Area				
Resource Value	Indicator	Preliminary Standard	Method	Monitoring Intensity*	Management Actions
Air Quality (Public Health)	Visibility	No degradation.	Photo survey and time lapse video Fixed site sampling of particulate matter (PM _{2.5} and PM ₁₀)	Moderate	Evaluate success of closure
Wildlife	Wildlife harassment or displacement from habitat as a result of visitor activity or movements	No incidents	Incident reports and photo surveys	High	Evaluate success of closure
	Human / grizzly bear conflicts during pre or post denning periods	No incidents	Mapping of denning areas	High	Evaluate success of closure
	Lynx habitat effectiveness	No adverse effects	Carnivore and snowshoe hare track surveys	High	Evaluate success of closure
*High = Daily to weekly or in accordance with standard protocol for parameter; Moderate = Monthly to seasonally and during peak days or use periods;					

Attachment B—Summary of Public Comments on the FEIS**Summary of Public Comment on the FEIS****Introduction**

After the FEIS was published on October 10, 2000 the public was invited to comment up until October 31. The total body of comment divides into two basic types. First, the content of most of the documents fell into categories of repeated topics, statements and rationale that were not explicit to the FEIS analysis. NPS read all pieces of mail and coded the statements that were made in each. A summary of this body of comment is provided in a table with accompanying conclusions. In this category, there were about 10,880 responses in the form of letters, postcards and e-mails. Of these, 6,717 were form letters and 4,163 were not.

A second set of letters and e-mails, numbering 55, is distinguished by more discussion specific to the FEIS and the process that produced it. They generally provide greater amounts of detail and rationale for their statements. This set of correspondence includes the cooperating agencies, other federal, tribal, state or local agencies (or their representatives), concessioners, advocacy groups, and a number of individuals. Most had commented earlier on the Draft EIS. These letters were read and summarized point by point for the decision maker, to whom copies of the letters were also submitted. This attachment contains a general summary of the letters, by group type.

Summary of Coded Comments

Comment letters were coded in order to determine the following information:

- Support for or against a specific alternative
- Support for or against individual components of a specific alternative
- Support for or against a specific mode of recreational oversnow travel
- Flaws in the analysis presented in the FEIS
- Pertinent new information or data that was omitted from the FEIS
- New alternatives that were not analyzed in the FEIS

Categories of comments and the number received are listed in the following table. The comments are listed with the most often received comments descending to the least often received comments. An individual document may contain from one to many separate comments.

Count	Classification
6446	I support elimination of snowmobiles in the three park units.
5491	I support Alternative G.
5424	The NPS has the responsibility under its mandate to protect resources.
4724	Snowcoaches are a good means of allowing access while eliminating effects on wildlife and visitor experience.
3324	I support the use of snowmobiles in the parks.
2392	The analysis is flawed, science is bad; numbers that Sierra Club gave you . . . are biased; etc.
2177	The snowmobile industry is trying hard to meet needs for cleaner, quieter snowmobiles.
1735	Snowmobilers have a right to personal access to the park.
1480	Snowmobiles don't impact resources, or have minimal impact.
1413	Snowmobiles have significant impacts on air quality and the natural soundscape.
1361	Support for specific alternative Revised E.
1182	Snowmobiles have significant impacts on wildlife.
890	Snowmobiles have significant impacts on the winter visitor experience.
867	I believe that banning snowmobiles is an overkill reaction to problems associated with current snowmobile technology.
663	Support for specific EIS alternative A.
653	Alternative G will have devastating economic impacts.
567	People should be allowed to visit the parks using any means of access they wish.
381	Summer/winter comparisons . . . i.e., buses versus snowmobiles, emissions, crowding, wildlife impacts.
323	The parks are for all the people, not just the "elite."
225	Alternative G discriminates against snowmobilers; if snowmobiling is eliminated, skiing should be eliminated too.
225	No Comment.
184	I would like to see a phase-in of clean and quiet snowmobiles.
142	Economic impacts of eliminating snowmobile use are overstated.
111	No Road Grooming.
96	Support for specific EIS alternative C.
94	I support clean, quiet and more environmentally friendly snowmobiles or snowcoaches.
91	Support for specific EIS alternative F.
65	People who are walking and skiing disturb wildlife more than people who ride on machines.
59	Support for specific EIS alternative E.
52	The analysis is good(for whatever reason).
45	The snowmobile industry is not responsive to needed technological changes for environmental protection.
35	Support for specific EIS alternative B.
18	No Vehicles.
16	Pro-snowplane—Snowplanes don't impact resources.
12	Support for specific EIS alternative D.
9	Support for specific alternative Natural Regulation Alternative.
8	NEPA process is flawed and not enough time to comment on FEIS.
7	Duplicates.
5	There is no feasibility analysis for snowcoach operation, snowcoaches will make the park inaccessible.
2	NPS is not responsive to people who snowmobile or snowplane.
2	There should be a multiple-use alternative.
1	NPS should not use military ordinance for avalanche control.
1	NPS ignored reasonable suggestions from the cooperating agencies.
1	NPS' selection was not driven by facts or need for action.

One type of comment that was not included in the overall document count were e-mails received from an internet polling site named "vote.com." The e-mails that were received were the result of an ongoing poll about snowmobile use. People responding to the poll were asked to vote a "yes" or "no" to the question "Should snowmobiles be banned from Yellowstone Park?" Adjacent to the "yes" vote was the statement, "People could still take winter tours in cleaner, quieter snow coaches." Adjacent to the "no" vote was the statement, "Banning recreational snowmobile users from the park would hurt local businesses." The results were 619 "yes" votes and 1970 "no" votes. There was some conflicting information concerning the privacy policy statement of "Vote.com." The site states that the vote is confidential, but the results received included the e-mail address of each person voting. A comment was also received expressing concern about the "Vote.com" comments.

Summary of Individual Letter Contents

Federal Government, Tribal Governments

Comments on the FEIS were received from: U.S. Environmental Protection Agency, U.S. Bureau of Reclamation, The Shoshone-Bannock Tribes, Senator Michael B. Enzi of Wyoming, and from Donald A. Manzullo of the U.S. House of Representatives' Committee on Small Business.

EPA has no environmental objections to the FEIS preferred alternative. EPA finds that the FEIS adequately discloses the impacts of all alternatives, and is improved from the DEIS by adequately responding to comments from EPA, other agencies and the public.

The tribes recommend the implementation of Alternative F, citing the description of the alternative as rationale. They further state that the trust obligations owed by the U.S. to American Indian tribes outweighs any commitment to snowmobilers or other recreationists, or to the states of Wyoming, Montana and Idaho. They feel that government to government consultation was inadequate.

U.S. Bureau of Reclamation expresses concerns about the ongoing business, research, data collection and administrative travel necessary for BOR to carry out its duties within the parks. They indicate the FEIS is unclear about the options BOR has for necessary travel, since most of the routes used by the agency are designated for snowcoach travel only, and that the agency must travel in the parks to collect data necessary in forecasting

snowmelt, and reservoir function including flood control. Winter access is necessary to meet agency responsibilities.

U.S. Senate, Senator Michael B. Enzi of Wyoming expresses deep concerns about how NPS has mishandled the opportunity to provide clear direction and a vision for management. He states that NPS has chosen to proceed with a politically biased, predetermined conclusion that excludes the community and places the parks out of reach for most Americans in the winter. Senator Enzi states that snowcoach access only is infeasible for several reasons, and that it is evident the snowmobile industry has available technology to comply with any NPS noise or emission standards NPS might impose. He also states that NPS violated NEPA and several other laws in this process.

Donald A. Manzullo, U.S. House of Representatives, Committee on Small Business references testimony from the July 13, 2000 hearing before the House Small Business Tax, Finance & Exports Subcommittee (The Impact of Banning Snowmobiles Inside National Parks on Small Business, Serial No. 106-68). He states that NPS has ignored the main thrust of the concerns expressed during the DEIS public comment period by reiterating support for alternative G. He feels that a snowcoach only system will not work and that the economic impacts from this alternative are large.

State Government, Agencies

Comments were received from the governors of the States of Idaho, Montana and Wyoming, and from State Senator Colin Simpson of Wyoming. All three states were cooperating agencies in the effort.

Governor Kempthorne of Idaho attaches to his letter a note from Carl Wilgus, cooperating agency representative from the State of Idaho, stating that the NPS has ignored, discounted or minimized the good faith input from the State of Idaho. Mr. Wilgus states that the NPS has repeatedly missed deadlines and then unreasonably expected the cooperating agencies to comply with unreasonable deadlines. He states the NPS prematurely selected a preferred alternative before reviewing all of the public comment on the DEIS. Among the Governor's comments are the following. The revised alternative E submitted by the cooperating agencies was not adequately considered by the NPS. The cooperating agencies were denied representation on the identification (sic) team. The choice of alternative G is not grounded in either

scientific fact or public support. The elimination of snowmobiles will only create greater congestion and safety problems in other popular locations outside the parks. The loss of the personal freedom to ride snowmobiles into the parks is an irreversible and irretrievable commitment of resources. The economic analysis presented in the DEIS is flawed because the NPS failed to recognize the "Law of Dimensioning Returns" (sic) (that the revenue generated in the winter allows local businesses to stay open, covers the cost of operations and keeps the community alive.) None of the alternatives presented in the FEIS are acceptable to the State of Idaho. The State of Idaho strongly supports revised alternative E.

The Honorable Colin B. Simpson, Wyoming State Legislature states that by eliminating the preferred access for 60% of current visitors, NPS is clearly acting in the biased interest of a minority of its clients. He indicates the ban is unreasonable and unsubstantiated, and agrees with the letter from Park County Commissioners (WY). Among other statements in the letter are: adaptive management provisions could deny access to the park without due consideration of benefits and enjoyment; negative economic impact on gateway communities; and the FEIS is flawed by not addressing economic feasibility of snowcoaches.

Governor Marc Racicot of Montana would like thorough consideration of the Montana Preferred Alternative that was submitted during the comment period on the DEIS. Governor Racicot was not satisfied with the NPS response to Montana's alternative that was published in the FEIS. In addition, the Governor expresses the following: the lack of effort to reach a broader consensus (by NPS); request for a complete evaluation of the Montana alternative to be conducted and provided to them; request that the NPS include flexibility in Record of Decision regarding cleaner and quieter snowmobile technology; and request that the NPS include flexibility with regard to snowcoach only travel to plan for the possibility that the proposal will not work.

Governor Jim Geringer of Wyoming is extremely disappointed in the NPS's failure to fully comply with the procedures outlined in the National Environmental Policy Act (NEPA). He states the FEIS contains many information gaps, which are the result of an unrealistic timeframe and a flawed NEPA process. Wyoming does not support alternative G and indicates that the analysis presented in the FEIS does not support that alternative as a final

decision. Other concerns noted include: the state was not adequately consulted and its information was ignored; cleaner quieter snowmobiles have an appropriate role to play in the parks; NPS has failed to conduct a feasibility study of a mass transportation system to service all entrances; and the Record of Decision should include some type of escape clause or back-up plan to guarantee public access in the event snowcoaches fail to provide reliable service from all entrances. The Governor indicates support for adaptive management including the utilization of cleaner and quieter snow machines in the parks, as they are developed and notes there are currently no emission or sound standards for snowcoaches. He states that NPS will continue to use snowmobiles, and only when the NPS adopts coach only travel will it be fair to impose it on others.

Local Government Agencies

Comments were received from commissioners of: Park and Gallatin Counties, Montana; Park, Fremont and Teton Counties, Wyoming; and Teton and Fremont Counties, Idaho. A comment was also submitted by the Teton County (WY) Historic Preservation Board. Five counties were cooperating agencies in the effort.

The counties' general responses to the FEIS preferred alternative are:

- Park County Commissioners, Montana, express their total dissatisfaction with the FEIS. The timeline was unacceptable and the NPS has failed to comply with NEPA and its procedural requirements.
- Fremont County, Wyoming states that "the winter use plan you are planning to implement is unjust, and based on politics and emotions rather than science."
- Park County, Wyoming implores NPS to change its decision from the preferred alternative in the FEIS.
- Teton County Board of Commissioners, Wyoming, believes the selected preferred alternative did not receive adequate analysis and continues to be disappointed in how the NEPA process was used in the development of the winter use plans. Teton County initiated the "Clean Snowmobile Challenge", whose results indicate there are feasible ways to create a clean, quiet machine.
- Teton County Commissioners, Idaho, cannot support the preferred alternative G, stating the only alternative they can support is A, no action. They note agreement with Fremont County ID in declaring that the Reclamation Road is an RS2477 highway and is under local jurisdiction.

- Fremont County Board of Supervisors, Idaho, state: "Our greatest concerns come from the unknown outcomes as a result of the FEIS. Snowcoaches are the answer to all questions, according to alternative G, yet there is no plan for having clean and quiet, or adequate numbers, of said vehicles in place in the proposed 3 years."

- Gallatin County Commission, Montana, states: "Generally we do not find that the analysis and information that you use supports the preferred alternative. We base our concerns on inconsistencies between your statement of desired conditions, the data you provide, the criteria developed by the park service and a departure from the criteria developed at Idaho Falls in October 1998." Much of the letter quotes liberally from the Draft EIS to support their comments.

- Teton County Historic Preservation Board, Wyoming, indicates the board's consensus is supportive of preferred alternative G.

Common themes in all letters from the counties include the following:

- The preferred alternative has no basis in scientific fact. Instead of resolving issues that forced the development of the EIS, the NPS has opened the door to further litigation.
- Alternative G still provides for the administrative use of snowmobiles by employees living in the interior of Yellowstone. This is a glaring contradiction.
- The NPS made changes to the schedule without consultation or the consent of the cooperating agencies.
- The counties have repeatedly documented how delays in providing information and modeling data have precluded the counties from fulfilling their obligations.
- NPS reversed its decision to allow the cooperating agencies to participate on the FEIS planning team.
- The alternatives workshop in which the counties participated did not provide them with the opportunity to provide meaningful input.
- The FEIS ignores the utility of setting an overall carrying capacity for visitors.
- The FEIS ignores the utility of setting an overall carrying capacity for wildlife.
- The cooperating agencies do not support the incorporation of individual elements of the revised alternative E into the FEIS. The revised alternative E as submitted by the counties was not intended to be dissected and is only effective if incorporated as a whole.

- Leave the door open to all new technological advances for snowmobiles and allow them in the parks.

- The NPS has chosen to disregard and misconstrue the input the recommendations of the cooperating agencies.

- YNP was set aside as a preserve for recreational enjoyment and use, and should be continued to be managed with this intent.

- The economic impacts of eliminating snowmobiles will be devastating.

- Over regulation by the federal government has been the demise of many industries.

- NPS does not discuss or acknowledge the existence of current snowmobile technology that would help solve the problem.

- The counties strongly disagree with the characterization of how the alternatives were formulated; banning snowmobiles goes far beyond what was agreed to.

- Alternative G eliminates conflicts, but at the expense of an entire user group. It appears the resources could be protected and conflicts minimized while accommodating all user groups.

- There is much doubt about the feasibility of going to snowcoaches only, and how this affects other users and commercial operators. A feasibility analysis should have been done.

- The majority of winter visitors have told you that your preferred alternative is the one they prefer the least.

- We challenge NPS to demonstrate how they've been cooperative and how cooperation is consistent with the preferred alternative.

Environmental Groups

Comments were received from groups or from individuals identifying themselves as speaking in behalf of a group. Comments were received from the following groups.

- Jefferson County Environmental Network, Lakemills, Wisconsin
- Predator Conservation Alliance, Bozeman, Montana
- Blue Water Network, San Francisco, California
- American Lands Alliance, Washington D.C.
- Wildlands Center for Preventing Roads, Boulder, Colorado
- Aspen Wilderness Workshop, Aspen, Colorado
- Native Forest Network, Bozeman, Montana
- Wyoming Chapter of the Sierra Club, Jackson, Wyoming
- Greater Yellowstone Coalition, Bozeman, Montana
- Schubert and Associates, Glendale, Arizona

- The Ecology Center, Inc., Missoula, Montana

Comments from these groups fall into several categories. Some groups express support for Alternative G. Some groups give qualified support to the alternative. Others express support for eliminating snowmobiles, but also see the need to eliminate any groomed trails and motorized oversnow use in the parks.

Most groups that support Alternative G indicate that snowmobiles should be removed from the parks sooner than 3 years if at all possible. They state that there is broad public support for eliminating snowmobiles in parks, and are optimistic about elements in the business community that welcome snowcoach transport. Other related comments are:

- Snowmobilers have been given too much time to "develop their rights."
- There is no right to engage in a nonconforming use.
- NPS should better lay out its plan for transition to snowcoach only.
- Snowmobiles should be removed at the soonest time possible. Three year "phase-in" is unacceptable due to continuing impacts of noise, wildlife harassment, air pollution, and visitor disruption.
- Continued snowmobile use needs to be brought into compliance with laws.
- Snowmobile ban in the parks will not affect the snowmobile industry.
- Community business leaders recognize there could be benefits of a snowmobile ban.
- There are many places outside the parks that provide snowmobiling opportunities.
- There is broad public support for eliminating snowmobiles from parks.
- Sen. Thomas' solution of separating snowmobilers and skiers is inadequate because it doesn't address environmental impacts or noise.
- Snowmobilers disregard regulations, disrupting the integrity of wilderness and wildlife habitat.
- Changes will decrease noise, polluted air stresses to wildlife, and offer visitors a quality experience.
- Any trail grooming should still be done without conflicts with important wildlife habitat.
- The decision should also close YNP's east entrance and eliminate the use of military ordinance.
- Interpretation, information and education should be emphasized in winter management.
- NPS risks violation of statutes, regulations and executive orders. The ROD should express the role of monitoring and that violations would be cause to halt offending uses.

- Implementation of a snowcoach system represents benefits that far exceed those raised in the FEIS.

- NPS can be a catalyst for innovation in snowcoach technology.

- Snowcoach transport should be attractive for visitors and fit the unique winter setting of the parks. NPS should determine the best design for this purpose and include current manufacturers, purchasers and clientele served by existing snowcoaches.

- A transition task force should be convened—composed of NPS, affected businesses and concessioners, local officials and environmental groups.

- NPS should initiate education and outreach to assist in the marketing of new winter recreation opportunities, to the benefit of gateway economies.

- NPS should investigate programs and funding strategies to facilitate the creation of a snowcoach mass-transit system, and affected local businesses should be given initial preference in the new system.

Those who express qualified support state that the preferred alternative is an improvement over current management. They indicate:

- Pleased that the plan replaces snowmobile use with snowcoaches.
- Snowmobiles affect air, water, sound, visitor experience, wildlife, and bison movement.
- Snowcoach use would continue to facilitate bison leaving the park in the winter. Winter use should only be allowed to the extent that it doesn't have this impact.
- Would prefer alternative F in the DEIS, along with closure of YNP's east entrance.

Those who do not support the preferred alternative also generally express the idea that the "decision" is probably the only legal recourse for NPS because of its mandate. They note that, while the plans represent an improvement over current management, concerns remain. Replacing snowmobiles with snowcoaches also should not be permitted. They indicate:

- The parks wildlife and ecosystem will continue to suffer from groomed routes for snowcoaches.
- Continued snowmobile use has unacceptable impacts and they should be removed immediately.
- NPS has no legal mandate to provide motorized access.
- The Biological Assessment fails to consider the impacts of road grooming on federally listed species.
- The FEIS is deficient.
- A complete ban on groomed routes and termination of all oversnow motorized use should have been considered in the EIS (a "true no-action alternative).

- There are no regulations permitting road grooming or snowcoach operation.

- FEIS failed to properly analyze the adverse impact of road grooming on bison.

- NPS failed to properly consider and respond to several issues raised in comments on the DEIS.

- The FEIS range of alternatives is inadequate, based on the settlement agreement as mandated by the judge.

- Many of the analysis points raised in the FEIS actually affirm the contentions in the lawsuit.

- Reserves the right to participate in further litigation.

Business Community, Including Park Concessioners

Comments were received from groups or from individuals identifying themselves as speaking in behalf of a group. Comments were received from the following groups.

- Riverton Community Development Association, Riverton, Wyoming.
 - Pahaska Teepee Resort, Cody, Wyoming.
 - International Leisure Hosts, Ltd., dba Flagg Ranch Resort, Tempe, Arizona.
 - Cody Chamber of Commerce, Cody, Wyoming.
 - Jackson Hole Chamber of Commerce, Jackson, Wyoming.
 - West, South and East Gate Operators, YNP, West Yellowstone, Flagg Ranch, Pahaska Teepee.
 - Mattracks Inc., Karlstad, Minnesota.
 - Mr. David McCray, Two Top Snowmobile Rental, West Yellowstone, Montana.
 - Mr. F.W. Howell, Yellowstone Arctic Yamaha, West Yellowstone, Montana.
 - Mr. Pat Povah, Hamilton Stores, Yellowstone, Wyoming.
 - Mr. Randy Roberson, Yellowstone Vacations, West Yellowstone, Montana.
- Comments from most groups expressed firm opposition to alternative G. Some continue to express strong support for revised alternative E, and believe as stated in previous comments that E would meet the purpose and need for action. Statements from this body of comment include:*
- Closing YNP to public snowmobiling will shift use to other public lands, and result in impacts on them.
 - Alternative E is acceptable if the advisory groups are not packed with anti-multiple use advocates.
 - Actions of the federal government to eliminate access to most of the area in the county destroys our means of making a living.
 - Object to portions of the plan that limit or eliminate access or types of

access to the parks. This includes snowcoach only access, adaptive management, NPS managed snowcoaches, controlled stops in the parks, and limited to no access at the east entrance of YNP.

- Object to portions of the plan that have a negative economic impact on gateway communities—eliminating snowmobiles takes away the preferred mode of travel for 60% of YNPs historic visitors.

- Object to portions of the plan that allow administrative snowmobile use, that ignores safety concerns relative to snowcoaches, ignores inconvenience of snowcoaches, ignores other technical difficulties with implementing the alternative.

- “Snowcoaches only” is not financially feasible for a number of reasons.

- The FEIS fails to adequately analyze the effects of increased snow coach operations on air quality, wildlife, the NPS budget, visitor demographics and the economy.

- If numbers are a concern, we believe that all alternatives have a provision for establishing carrying capacities.

- Concerned that the interim use limits, if implemented this year, would prohibit fulfilling existing reservations.

- Because of the greater mileage most people would come to West Yellowstone, causing even greater congestion there.

- Snowcoach travel is too slow and too uncomfortable.

- Increasing snowcoaches will cause greater safety hazards. More people would be hurt in a single accident.

- Snowcoaches are too expensive, 20 snowcoaches would cost 1,400,000 a year and would sit idle for 9 months.

- Cleaner and quieter snowmobiles are available for purchase.

- The implementation of alternative G will result in devastating economic effects.

- From the east gate the only desirable destination would be Canyon

- Mechanical breakdowns (snowcoaches) would keep visitors waiting in the cold until help arrives.

- The increased speed and number of snowcoaches would increase safety hazards.

- The preferred alternative and the FEIS are biased against snowmobiles.

- In order to accommodate current use levels there would be lines of snowcoaches at the entrance gates.

- Snowcoaches have a 10% breakdown rate—who would retrieve them?

- The parking and storage requirements for the snowcoaches would be space and cost prohibitive.

- If snowmobiles must be banned, plow the road and use buses instead.

The “West, South and East Gate Operators”, YNP, West Yellowstone, Flagg Ranch, Pahaska Teepee corporately submitted a letter, stating that Alternative G will deny rather than provide access to the visiting public. The express the right of the public to enjoy the park is of paramount importance, second only to protecting the park for the future. Other statements include:

- Enjoyment of snowcoach travel vastly diminishes after 90 miles. The alternative eliminates enjoyment of travel to a number of popular places in the park.

- Flagg Ranch stipulates that the alternative would eliminate access from the south. If the road to Flagg Ranch is not plowed, the ranch will not open in the winter and it will not be a destination.

- From Pahaska, the only possible destination within the 90 mile enjoyment level would be the Grand Canyon of the Yellowstone. Also snowcoaches over Sylvan are not advisable due to safety concerns.

- Other objections to snowcoaches only are: Insufficient speed, safety, inadequate technology, capital investment necessary, mode of travel is not cheaper (than snowmobiles), the public prefers snowmobiles, and it would be devastating to the economy.

- The burden is on NPS to conduct a feasibility study of the alternative.

- Flagg Ranch cannot be a destination resort without a plowed road to it. The contract requires the plowed road. NPS assured Flagg Ranch that its contract would be honored.

- Interim snowmobile limits will limit the ranch’s ability to operate. This is also a breach of contract.

- Elimination of snowmobiles is a breach of the contract, which doesn’t expire until 2009.

- Not plowing the road from Colter Bay to Flagg Ranch would make all of Yellowstone inaccessible to those who have traditionally entered from the south entrance.

Matracks Inc., Karlstad, Minnesota, is the only respondent in this group to support the selection of alternative G as the preferred alternative and offers the following implementation suggestions:

- Suggests a passenger capacity of 6 to 15. A smaller vehicle does not achieve mass transit goals and larger vehicles may cause damage to resources.

- The NPS should implement EPA emission standards for snowcoaches.

- The NPS should require the use of rubber tracked vehicles instead of metal or cleated tracks to reduce the sound

levels of snowcoaches. These vehicles have a less aggressive track and may also run of pavement without causing damage.

- Snowcoaches should be of a single inclusive enclosure (no trailers with passengers).

Snowmobile or Snowcoach Industry, Advocates

Comments were received from:

- Birch, Horton, Bittner and Cherot and William P. Horn, Attorneys for the International Snowmobile Manufacturers Association.

- Mr. Virgil Koehler, American Council of Snowmobiles.

- Utah Snowmobile Association, Salt Lake City, Utah.

- Idaho State Snowmobile Association, Boise, Idaho.

- Ms. Adena Cook, Public Lands Director, Blue Ribbon Coalition, Idaho Falls, Idaho.

- Ms. Beth Walsh, Moran, Wyoming.

- Mr. Jim Gerber, St. Anthony, Idaho.

All comments in this group are opposed to the selection of alternative G. Some support the implementation of a revised alternative E but indicate that since this alternative was not included in the FEIS their support is given to alternative A, the no action alternative. Reasons for opposition to the implementation of alternative G in the parks for the following reasons:

- A 21 day review period is unacceptable for such a dramatic change in alternative preference.

- The expertise of a significant cross section of professionals (cooperating agencies) has been totally ignored.

- The snowmobile industry has made many improvements in technology since 1970.

- The benefit of snowcoach travel in the parks is pure conjecture.

- The misuse and abuse of the NEPA process in preparation of this FEIS is appalling.

- The FEIS was crafted to support a decision made in Washington D.C. requiring significant shifts from the DEIS alternatives.

- The FEIS fails to utilize constructive It would drastically reduce winter recreation use and enjoyment in derogation of the acts creating Yellowstone National Park and the national park system.

- Alternative G was concocted after the fact and the NPS has not allowed the public sufficient time to explore the plan and register informed comments.

- Alternative G would violate existing concessions contracts—(Flagg Ranch in particular).

- Alternative G would have devastating effects on the economies local communities.

- Snowmobiles produced after 1976 emit no more than 73 dB(A) at 15 MPH when tested using SAE J1161.
- Several studies are cited that indicate that deer are more likely to move away from ski trails than snowmobile trails and that they are unaffected by snowmobile traffic.
- A University of Wisconsin study found that snowmobile traffic has no effect on the grain yield of winter wheat.
- Six of the seven alternatives offered in the FEIS provide almost no range of proposals that could possibly be considered as conscientious multiple use management of public lands.
- The change in the preferred alternative from "B" to "G" without allowing the public to comment proves that land managers are only listening to the well-funded voices of the minority extreme advocacy groups.
- Comments submitted by ISSA, and the state of Wyoming.
- The FEIS exaggerates the environmental effects of snowmobiles.
- The economic analysis presented in the FEIS is superficial and inadequate.
- The FEIS fails to adequately define what would constitute acceptable impacts from snowmobiles.
- Revised alternative E was not seriously considered.
- The FEIS version of the "Existing Condition" and "Desired Condition" was significantly altered from the version in the DEIS.
- Alternative G is totally new and has not been validated by the public.
- The NPS has manipulated visitor use numbers to serve its own purposes.
- The FEIS describes natural soundscapes as a resource not a value.
- The Duffield study is pure conjecture, the FEIS should have incorporated the more factual State of Wyoming study.
- Additional information in the FEIS on social values, soundscapes and emissions need validation before any conclusions can be reached.
- The NPS was arbitrary and capricious in its decision to ban snowmobiles and require snowcoaches instead.
- The analysis of water quality for alternatives A through F states that there is no evidence of measurable changes in water quality from snowmobile emissions yet in alternative G the FEIS concludes that alternative G addresses the issue of water quality better than other alternatives.
- Snowcoaches will result in a loss of personal freedom and a poor experience in the parks.
- Snowcoaches will be cost prohibitive for many.
- Constructing new winter facilities at Colter Bay makes no sense because

the facilities at Flagg Ranch are currently under utilized.

- Construction new winter facilities at Colter Bay would negatively effect lynx habitat.
- If the park service does not plow the road from Colter to Flagg it will result in longer EMS response times.

[FR Doc. 00-30998 Filed 12-21-00; 8:45 am]

BILLING CODE 4310-01-P

DEPARTMENT OF THE INTERIOR

National Park Service

Notice of Inventory Completion for Native American Human Remains and Associated Funerary Objects from Connecticut in the Possession of the Peabody Museum of Natural History, Yale University, New Haven, CT

AGENCY: National Park Service

ACTION: Notice.

Notice is hereby given in accordance with provisions of the Native American Graves Protection and Repatriation Act (NAGPRA), 43 CFR 10.9, of the completion of an inventory of human remains and associated funerary objects in the possession of the Peabody Museum of Natural History, Yale University, New Haven, CT.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 43 CFR 10.2 (c). The determinations within this notice are the sole responsibility of the museum, institution, or Federal agency that has control of these Native American human remains and associated funerary objects. The National Park Service is not responsible for the determinations within this notice.

A detailed assessment of the human remains and associated funerary objects was made by Peabody Museum of Natural History professional staff in consultation with representatives of the Mashantucket Pequot Tribe.

In 1873, human remains representing one individual were donated to the Peabody Museum of Natural History by J. D. Fish. The remains were recovered near Mystic, CT. No known individual was identified. No associated funerary objects are present.

Based on the documentary evidence, examination of the human remains, and consultation with representatives of the Mashantucket Pequot Tribe, this individual is identified as Native American. The remains appear to be prehistoric or protohistoric in age. Cultural affiliation has been determined on the basis of geographic origin of the

remains, physical characteristics that identify them as Native American, published accounts of the traditional territory of the Mashantucket Pequot Tribe, and historical information provided by the Mashantucket Pequot Tribe. Historical documents indicate that the Mashantucket Pequot Tribe has occupied the area where the remains were recovered since the Late Woodland period, circa A.D. 1000.

In 1874, human remains representing three individuals were donated to the Peabody Museum of Natural History by Mrs. E. O. Dunning. The remains were recovered near Mystic, CT. No known individuals were identified. The one associated funerary object is a metal spoon.

Based on the documentary evidence, examination of the human remains, and consultation with representatives of the Mashantucket Pequot Tribe, these individuals are identified as Native American. The remains and the spoon probably date to the period of Euro-American contact. Cultural affiliation has been determined on the basis of geographic origin of the remains, physical characteristics that identify them as Native American, published accounts of the traditional territory of the Mashantucket Pequot Tribe, and historical information provided by the Mashantucket Pequot Tribe. Historical documents indicate that the Mashantucket Pequot Tribe has occupied the area where the remains were recovered since the Late Woodland period, circa A.D. 1000.

In 1948, human remains representing one individual was donated to the Peabody Museum of Natural History by Eva Butler. The remains were recovered near Groton, CT, on the property of the Spicer Ice and Coal Co. during excavation for a drain. No known individual was identified. No associated funerary objects are present.

Based on the documentary evidence, examination of the human remains, and consultation with representatives of the Mashantucket Pequot Tribe, this individual is identified as Native American. The remains appear to be prehistoric or protohistoric in age. Cultural affiliation has been determined on the basis of geographic origin of the remains, physical characteristics that identify them as Native American, published accounts of the traditional territory of the Mashantucket Pequot Tribe, and historical information provided by the Mashantucket Pequot Tribe. Historical documents indicate that the Mashantucket Pequot Tribe has occupied the area where the remains were recovered since the Late Woodland period, circa A.D. 1000.

Based on the above-mentioned information, officials of the Peabody Museum of Natural History have determined that, pursuant to 43 CFR 10.2 (d)(1), the human remains listed above represent the physical remains of five individuals of Native American ancestry. Officials of the Peabody Museum of Natural History also have determined that, pursuant to 43 CFR 10.2 (d)(2), the one object listed above is reasonably believed to have been placed with or near individual human remains at the time of death or later as a part of the death rite or ceremony. Lastly, officials of the Peabody Museum of Natural History have determined that, pursuant to 43 CFR 10.2 (e), there is a relationship of shared group identity that can be reasonably traced between these Native American human remains and the associated funerary object and the Mashantucket Pequot Tribe.

This notice has been sent to officials of the Mashantucket Pequot Tribe. Representatives of any other Indian tribe that believes itself to be culturally affiliated with these human remains and the associated funerary object should contact Dr. Richard Burger, Director, Peabody Museum of Natural History, Yale University, 170 Whitney Avenue, P.O. Box 208118, New Haven, CT 06520-8118, telephone (203) 432-3752, before January 22, 2001. Repatriation of the human remains and the associated funerary object to the Mashantucket Pequot Tribe may begin after that date if no additional claimants come forward.

Dated: December 14, 2000.

John Robbins,

Assistant Director, Cultural Resources Stewardship and Partnerships.

[FR Doc. 00-32659 Filed 12-21-00; 8:45 am]

BILLING CODE 4310-70-F

DEPARTMENT OF THE INTERIOR

National Park Service

Notice of Inventory Completion for Native American Human Remains and Associated Funerary Objects in the Possession of the Department of Anthropology, San Francisco State University, San Francisco, CA

AGENCY: National Park Service

ACTION: Notice.

Notice is hereby given in accordance with provisions of the Native American Graves Protection and Repatriation Act (NAGPRA), 43 CFR 10.9, of the completion of an inventory of human remains and associated funerary objects in the possession of the Department of

Anthropology, San Francisco State University, San Francisco, CA.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 43 CFR 10.2 (c). The determinations within this notice are the sole responsibility of the museum, institution, or Federal agency that has control of these Native American human remains and associated funerary objects. The National Park Service is not responsible for the determinations within this notice.

A detailed assessment of the human remains was made by the Department of Anthropology, San Francisco State University professional staff in consultation with representatives of the Tuolumne Band of Me-Wuk Indians of the Tuolumne Rancheria of California.

In 1970-71, human remains representing nine individuals were recovered from CA-TUO-279, a site located on a small peninsula that extended into the western side of the original Don Pedro Reservoir. During the construction of the new reservoir, an archeological data recovery project was undertaken by San Francisco State University. The site area is now inundated by the new Don Pedro Reservoir. No known individuals were identified. The four associated funerary objects are flaked stone fragments, modified bird bone, and an *olivella* bead.

In 1970-71, human remains representing 21 individuals were recovered from CA-TUO-300, a site located near LaGrange, CA, during archeological excavations conducted by San Francisco State University. The site area is now inundated by the new Don Pedro Reservoir. No known individuals were identified. The 49 associated funerary objects are flaked stone fragments.

In 1970-71, human remains representing nine individuals were recovered from CA-TUO-314, a site located on the southern bank of Moccasin Creek, near LaGrange, CA, during archeological excavations conducted by San Francisco State University. No known individuals were identified. The 52 associated funerary objects are flaked stone fragments; ground stone; and faunal materials including modified and unmodified animal bones and teeth, and modified bird bone.

The geographic location of the sites and archeological, historical, and oral history evidence indicate that these human remains and associated funerary objects are Native American. The objects are consistent with the material culture of the ancestral Sierra Miwok who

occupied this area during the Euro-American contact period, and all of the sites are located in an area that is documented as Central Sierra Miwok territory. Oral history evidence presented during consultation indicates that the area has been continuously occupied by the Miwok since the contact period and that there is cultural affiliation between the Tuolumne Band of Me-Wuk Indians of the Tuolumne Rancheria of California and the Sierra Miwok Indians.

Based on the above-mentioned information, officials of the Department of Anthropology, San Francisco State University have determined that, pursuant to 43 CFR 10.2 (d)(1), the human remains listed above represent the physical remains of 39 individuals of Native American ancestry. Officials of the Department of Anthropology, San Francisco State University also have determined that, pursuant to 43 CFR 10.2 (d)(2), the 105 objects listed above are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony. Lastly, officials of the Department of Anthropology, San Francisco State University have determined that, pursuant to 43 CFR 10.2 (e), there is a relationship of shared group identity that can be reasonably traced between these Native American human remains and associated funerary objects and the Tuolumne Band of Me-Wuk Indians of the Tuolumne Rancheria of California.

This notice has been sent to officials of the Tuolumne Band of Me-Wuk Indians of the Tuolumne Rancheria of California, and the Central Sierra Me-Wuk Cultural and Historic Preservation Committee. Representatives of any other Indian tribe that believes itself to be culturally affiliated with these human remains and associated funerary objects should contact Jeff Fentress, NAGPRA Coordinator, Department of Anthropology, San Francisco State University, 1600 Holloway Avenue, San Francisco, CA 94132, telephone (415) 338-2046, before January 22, 2001. Repatriation of the human remains and associated funerary objects to the Tuolumne Band of Me-Wuk Indians of the Tuolumne Rancheria of California, and the Central Sierra Me-Wuk Cultural and Historic Preservation Committee may begin after that date if no additional claimants come forward.

Dated: December 14, 2000.

John Robbins,

Assistant Director, Cultural Resources Stewardship and Partnerships.

[FR Doc. 00-32663 Filed 12-21-00; 8:45 am]

BILLING CODE 4310-70-F

DEPARTMENT OF THE INTERIOR**National Park Service****Notice of Inventory Completion for Native American Human Remains and Associated Funerary Objects in the Possession of the Department of Anthropology, San Francisco State University, San Francisco, CA****AGENCY:** National Park Service, Interior.**ACTION:** Notice.

Notice is hereby given in accordance with provisions of the Native American Graves Protection and Repatriation Act (NAGPRA), 43 CFR 10.9, of the completion of an inventory of human remains and associated funerary objects in the possession of the Department of Anthropology, San Francisco State University, San Francisco, CA.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 43 CFR 10.2 (c). The determinations within this notice are the sole responsibility of the museum, institution, or Federal agency that has control of these Native American human remains and associated funerary objects. The National Park Service is not responsible for the determinations within this notice.

A detailed assessment of the human remains was made by the Department of Anthropology, San Francisco State University professional staff in consultation with representatives of the United Auburn Indian Community, the Washoe Tribe of Nevada & California, and the Mooretown Rancheria of Maidu Indians of California.

In 1964, human remains representing five individuals were recovered from CA-PLA-17, a site near Ophir, CA, that was excavated by San Francisco State University as part of the Middle Fork American River project. No known individuals were identified. The seven associated funerary objects are flaked stone, ground stone, shell, and quartz crystals.

Archeological evidence, geographic location, historical documentation, and oral history records indicate that these human remains and associated funerary objects are Native American and are reasonably believed to be associated with the Maidu Indians. The typology of the basalt projectile points recovered from the site links them with the archeological Martis culture, a predecessor of the Maidu/Nisenan cultural group. Historical documents indicate that the Maidu people have occupied this area of California since the period of Euro-American contact,

and oral history records presented during consultation support this affiliation.

Based on the above-mentioned information, officials of the Department of Anthropology, San Francisco State University have determined that, pursuant to 43 CFR 10.2 (d)(1), the human remains listed above represent the physical remains of five individuals of Native American ancestry. Officials of the Department of Anthropology, San Francisco State University also have determined that, pursuant to 43 CFR 10.2 (d)(2), the seven objects listed above are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony. Lastly, officials of the Department of Anthropology, San Francisco State University have determined that, pursuant to 43 CFR 10.2 (e), there is a relationship of shared group identity that can be reasonably traced between these Native American human remains and associated funerary objects and the United Auburn Indian Community, the Washoe Tribe of Nevada & California, and the Mooretown Rancheria of Maidu Indians of California.

This notice has been sent to officials of the United Auburn Indian Community, the Washoe Tribe of Nevada & California, and the Mooretown Rancheria of Maidu Indians of California. Representatives of any other Indian tribe that believes itself to be culturally affiliated with these human remains and associated funerary objects should contact Jeff Fentress, NAGPRA Coordinator, Department of Anthropology, San Francisco State University, 1600 Holloway Avenue, San Francisco, CA 94132, telephone (415) 338-2046, before January 22, 2001. Repatriation of the human remains and associated funerary objects to the United Auburn Indian Community, the Washoe Tribe of Nevada & California, and the Mooretown Rancheria of Maidu Indians of California may begin after that date if no additional claimants come forward.

Dated: December 14, 2000.

John Robbins,*Assistant Director, Cultural Resources Stewardship and Partnerships.*

[FR Doc. 00-32660 Filed 12-21-00; 8:45 am]

BILLING CODE 4310-70-F**DEPARTMENT OF THE INTERIOR****National Park Service****Notice of Inventory Completion for Native American Human Remains and Associated Funerary Objects in the Possession of the Department of Anthropology, San Francisco State University, San Francisco, CA****AGENCY:** National Park Service, Interior.**ACTION:** Notice.

Notice is hereby given in accordance with provisions of the Native American Graves Protection and Repatriation Act (NAGPRA), 43 CFR 10.9, of the completion of an inventory of human remains and associated funerary objects in the possession of the Department of Anthropology, San Francisco State University, San Francisco, CA.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 43 CFR 10.2 (c). The determinations within this notice are the sole responsibility of the museum, institution, or Federal agency that has control of these Native American human remains and associated funerary objects. The National Park Service is not responsible for the determinations within this notice.

A detailed assessment of the human remains was made by the Department of Anthropology, San Francisco State University professional staff in consultation with representatives of the Round Valley Indian Tribes of the Round Valley Reservation, California.

In 1966, human remains representing one individual were recovered from CA-MEN-748, a site located in Williams Valley, CA, that was excavated by San Francisco State University during the Etsel-Franciscan Reservoir Project. No known individual was identified. The 11 associated funerary objects are *olivella* beads, trade beads, and chert flakes.

The geographic location of the site and archeological, historical, and oral history evidence indicate that these human remains and associated funerary objects are likely to be Native American and associated with the Yuki Indians. The area of Williams Valley is recognized as being in the historic territory of the Yuki at the time of Euro-American contact. The location of the site on a terrace above a valley is consistent with a contact-period pattern of settlement in which the Yuki relocated to secondary sites after being displaced from their traditional lands. Evidence presented during consultation indicates that the materials recovered

are consistent with Yuki material culture.

Based on the above-mentioned information, officials of the Department of Anthropology, San Francisco State University have determined that, pursuant to 43 CFR 10.2 (d)(1), the human remains listed above represent the physical remains of one individual of Native American ancestry. Officials of the Department of Anthropology, San Francisco State University also have determined that, pursuant to 43 CFR 10.2 (d)(2), the 11 objects listed above are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony. Lastly, officials of the Department of Anthropology, San Francisco State University have determined that, pursuant to 43 CFR 10.2 (e), there is a relationship of shared group identity that can be reasonably traced between these Native American human remains and associated funerary objects and the Round Valley Indian Tribes of the Round Valley Reservation, California.

This notice has been sent to officials of the Round Valley Indian Tribes of the Round Valley Reservation, California. Representatives of any other Indian tribe that believes itself to be culturally affiliated with these human remains and associated funerary objects should contact Jeff Fentress, NAGPRA Coordinator, Department of Anthropology, San Francisco State University, 1600 Holloway Avenue, San Francisco, CA 94132, telephone (415) 338-2046, before January 22, 2001. Repatriation of the human remains and associated funerary objects to the Round Valley Indian Tribes of the Round Valley Reservation, California may begin after that date if no additional claimants come forward.

Dated: December 14, 2000.

John Robbins,

Assistant Director, Cultural Resources Stewardship and Partnerships.

[FR Doc. 00-32661 Filed 12-21-00; 8:45 am]

BILLING CODE 4310-70-F

DEPARTMENT OF THE INTERIOR

National Park Service

Notice of Inventory Completion for Native American Human Remains and Associated Funerary Objects in the Possession of the Department of Anthropology, San Francisco State University, San Francisco, CA

AGENCY: National Park Service, Interior.

ACTION: Notice.

Graves Protection and Repatriation Act (NAGPRA), 43 CFR 10.9, of the completion of an inventory of human remains and associated funerary objects in the possession of the Department of Anthropology, San Francisco State University, San Francisco, CA.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 43 CFR 10.2 (c). The determinations within this notice are the sole responsibility of the museum, institution, or Federal agency that has control of these Native American human remains and associated funerary objects. The National Park Service is not responsible for the determinations within this notice.

A detailed assessment of the human remains was made by the Department of Anthropology, San Francisco State University professional staff in consultation with representatives of the Central Valley and Mountain Reinterment Association on behalf of Santa Rosa Indian Community of the Santa Rosa Rancheria, California.

In 1968, human remains representing a minimum of one individual were recovered from CA-MAD-UNK, a site located in Madera, CA. Collections documentation indicates that the human remains were recovered by Mr. Pat O'Rourke of the Madera Tribune newspaper and were sent by him to San Francisco State University for curation at an unknown date. No known individual was identified. No associated funerary objects are present.

This individual is identified as Native American based on geographic, historical, and oral history evidence. The site is located in the historic territory of the Northern Valley Yokuts Indians, occupied by them at the time of Euro-American contact. Oral history evidence presented during consultation indicates that there is an association between the Yokuts and the present-day Santa Rosa Indian Community of the Santa Rosa Rancheria, California.

In 1968, human remains representing six individuals were recovered from CA-MER-66, located in Dos Palos, CA. Collections documentation indicates that the remains were recovered during archeological excavations conducted by San Francisco State University. No known individuals were identified. The 124 associated funerary objects are charm stones, *haliotis* pendants, bird bone ornaments, bone tools, *olivella* beads, and *tivela* beads.

These individuals are identified as Native American based on geographic, archeological, and oral history evidence. The site is located in the historic territory of the Northern Valley Yokuts

Indians, occupied by them at the time of Euro-American contact. The artifact assemblage is consistent with the Yokuts culture. Oral history evidence presented during consultation indicates that there is an association between the Yokuts and the present-day Santa Rosa Indian Community of the Santa Rosa Rancheria, California.

Around 1962, human remains representing a minimum of two individuals were recovered from CA-STA-133, a site located near Patterson, CA. Collections documentation indicates that the site was recorded in 1962 by Leonard Foote and that the remains were recovered during archeological survey and excavations conducted by students at San Francisco State University. No known individuals were identified. No associated funerary objects are present.

These individuals are identified as Native American based on geographic and oral history evidence. The site is located in the historic territory of the Northern Valley Yokuts Indians, occupied by them at the time of Euro-American contact. Oral history evidence presented during consultation indicates that there is an association between the Yokuts and the present-day Santa Rosa Indian Community of the Santa Rosa Rancheria, California.

Based on the above-mentioned information, officials of the Department of Anthropology, San Francisco State University have determined that, pursuant to 43 CFR 10.2 (d)(1), the human remains listed above represent the physical remains of nine individuals of Native American ancestry. Officials of the Department of Anthropology, San Francisco State University also have determined that, pursuant to 43 CFR 10.2 (d)(2), the 124 objects listed above are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony. Lastly, officials of the Department of Anthropology, San Francisco State University have determined that, pursuant to 43 CFR 10.2 (e), there is a relationship of shared group identity that can be reasonably traced between these Native American human remains and associated funerary objects and the Santa Rosa Indian Community of the Santa Rosa Rancheria, California.

This notice has been sent to officials of the Central Valley and Mountain Reinterment Association and the Santa Rosa Indian Community of the Santa Rosa Rancheria, California. Representatives of any other Indian tribe that believes itself to be culturally affiliated with these human remains and associated funerary objects should

contact Jeff Fentress, NAGPRA Coordinator, Department of Anthropology, San Francisco State University, 1600 Holloway Avenue, San Francisco, CA 94132, telephone (415) 338-2046, before January 22, 2001. Repatriation of the human remains and associated funerary objects to the Central Valley and Mountain Reinterment Association on behalf of the Santa Rosa Indian Community of the Santa Rosa Rancheria, California may begin after that date if no additional claimants come forward.

Dated: December 14, 2000.

John Robbins,

Assistant Director, Cultural Resources Stewardship and Partnerships.

[FR Doc. 00-32662 Filed 12-21-00 ; 8:45 am]

BILLING CODE 4310-70-F

DEPARTMENT OF LABOR

Office of the Secretary

Labor Research Advisory Council; Renewal

In accordance with the provisions of the Federal Advisory Committee Act, and after consultation with General Services Administration (GSA), I have determined that renewal of the Labor Research Advisory Council is in the public interest in connection with the performance of duties imposed on the Department of Labor.

The Council will advise the Commissioner of Labor Statistics regarding the statistical and analytical work of the Bureau of Labor Statistics, providing perspectives on these programs in relation to the needs of the labor unions and their members.

Council membership and participation in the Council and its subcommittees are broadly representatives of union organizations of all sizes of membership, with national coverage that reflects the geographical, industrial, and occupational sectors of the economy.

The Council will function solely as an advisory body and in compliance with the provisions of the Federal Advisory Committee Act. The Charter is being filed simultaneously herewith with the Library of Congress and the appropriate congressional committees.

Interested persons are invited to submit comments regarding renewal of the Labor Research Advisory Council. Such comments should be addressed to: Deborah P. Klein, Associate Commissioner, Office of Publications and Special Studies, Bureau of Labor Statistics, Department of Labor, Postal

Square Building, 2 Massachusetts Avenue, NE., Washington, DC 20212, telephone: 202-691-5900.

Signed at Washington, DC, this 18th day of December 2000.

Alexis M. Herman,

Secretary of Labor.

[FR Doc. 00-32707 Filed 12-21-00; 8:45 am]

BILLING CODE 4510-24-M

DEPARTMENT OF LABOR

Employment and Training Administration

Proposed Collection: Comment Request

ACTION: Notice.

SUMMARY: The Department of Labor, as part of its continuing effort to reduce paperwork and respondent burden conducts a pre-clearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA95) [44 U.S.C. 3506(c)(2)(A)]. This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed. Currently, the National Office of Job Corps is soliciting comments concerning the proposed new collection of Job Corps' Graduate and Former Enrollee Placement Re-verification and Follow-up Surveys.

A copy of the proposed information collection request (ICR) can be obtained by contacting the office listed below in the addressee section of this notice.

DATES: Written comments must be submitted to the office listed in the addressee's section below on or before February 22, 2001.

ADDRESSES: Send comments to Edna Primrose-Coates, U.S. Department of Labor, Office of Job Corps, 200 Constitution Ave., NW., Room N4656, Washington, DC 20210, Tel. (202) 693-3135, Fax (202) 693-3113, or e-mail eprimrose-coates@doleta.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Job Corps is the nation's largest and most comprehensive residential education and job training program for at-risk youth, ages 16 and 24. Program participants are typically high school dropouts in need of further education

and vocational training. Authorized by the Workforce Investment Act (WIA) of 1998, Job Corps is operated by the Department of Labor through a nationwide network of 118 Job Corps centers. The program is primarily residential, operating 24 hours per day, 7 days per week, with non-resident students limited by legislation to 20 percent of national enrollment. These centers presently accommodate more than 42,000 students. While students may stay in Job Corps up to two years to complete their programs, the average length of stay is eight months. Thus, more than 68,000 young people receive training in Job Corps in a year.

When they separate from Job Corps, youth are prepared to pursue employment opportunities related to their Job Corps training, post-secondary educational and training experiences, or enter the Armed Forces. The purpose of this data collection effort is to provide the National Office of Job Corps with information on the status of Job Corps students after they separate from the program. Information will be collected on the status of placed graduates 13 weeks, 6 months, and 12 months after their initial placement in a job or school/training program. Similar information will also be collected on the status of former enrollees (non-graduates who stayed at least 60 days) 13 weeks after they separate from Job Corps, and on non-placed graduates 12 months after they complete the program. This data collection effort also includes re-verification of reported initial employment and/or school placements of graduates and former enrollees. These data will be used to:

- Provide information to Congress and the Secretary of Labor on the employment and education outcomes of Job Corps graduates and former enrollees per Workforce Investments act reporting requirements.
- Assess graduates' and former enrollees' satisfaction with their Job Corps experience in order to identify useful program aspects and those factors that contributed to decisions to withdraw from the program prior to graduation, where applicable.

Information to fulfill these objectives will be collected using telephone surveys. These telephone surveys will be conducted with graduates and former enrollees at the aforementioned times.

The Secretary of Labor will use the data collected to assess Job Corps' effectiveness in meeting its objectives according to the Workforce Investment Act. In addition, the Director of Job Corps will incorporate these data into its Outcome Measurement System to evaluate the short-term post-center

outcomes of graduates and former enrollees, as well as the long-term post-center outcomes of graduates. The Director will also use this information on student outcomes and customer feedback to develop and/or refine policies in order to improve its delivery of educational and job training services to at-risk youth.

II. Review Focus

The Department of Labor is particularly interested in comments which:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the agency's burden estimates for the proposed data collection, including the validity of the methodology and assumptions used;

- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses.

III. Current Actions

This submission requests approval of three surveys that will be used to collect follow-up data on individuals who are no longer actively participating in Job Corps. The surveys are comprised of modules that include questions designed to obtain the following information: re-verification of initial job and/or school placements; employment and educational experiences; job search

activities of those who are neither working nor in school; and information about former participants' satisfaction with the services provided by Job Corps.

Additionally, this submission requests approval of two brief surveys (one for employers and one of the schools or training institutions) that will be used to collect initial placement re-verification data for the subset of placed graduates and former enrollees that cannot be contacted directly.

Type of Review: New.

Agency: U.S. Department of Labor, National Office of Job Corps.

Title: Job Corps' Graduate and Former Enrollee Placement Re-Verification and Follow-up Surveys.

Agency Number: If applicable; otherwise omit this line entirely.

Affected Public: Individuals who separate from Job Corps; Business or other for-profit/Not-for-profit institutions.

Form	Total respondents	Frequency	Total responses	Average time per response (minutes)	Burden (hours)
Placed Former Enrollees at 13 Weeks	6,020	One time only	6,020	15	1,505
Placed Graduates at 13 Weeks	26,400	One time only	26,400	15	6,600
Non-Placed Former Enrollees at 13 Weeks	1,330	One time only	1,330	10	226
Non-Placed Graduates at 12 Months	1,365	One time only	1,365	10	228
Placed Graduates at 6 Months	24,640	One time only	24,640	12	4,928
Placed Graduates at 12 Months	23,000	One time only	23,000	10	3,833
Totals			82,745		17,320

Total Burden Cost (capital/startup): Job Corps will initiate its telephone data collection from former enrollees and graduates starting after January 2001. Computer Assisted Telephone Interviewing (CATI) centers are being established at two contractors' locations. The total cost is estimated at \$89,380, including \$43,380 for hardware, \$40,000 for software and \$6,000 for communications.

Total Burden Cost (operating/maintaining): The estimated annual cost of completing 82,755 interviews with Job Corps graduates and former enrollees is \$2,482,650. This includes \$220,500 for the former enrollee surveys—placed and non-placed; \$40,950 for the non-placed graduate survey at 12-months; \$792,000 for placed graduates at 13 weeks; and \$1,429,200 for placed graduate surveys and 6 and 12 months.

Comments submitted in response to this comment request will be summarized and/or included in the request for Office of Management and Budget approval of the information collection request; they will also become a matter of public record.

Dated: December 18, 2000.

Richard C. Trigg,

National Director of Job Corps.

[FR Doc. 00-32709 Filed 12-21-00; 8:45 am]

BILLING CODE 4510-30-M

DEPARTMENT OF LABOR

Employment and Training Administration

Notice Inviting Proposals for Selected Demonstration Projects for Youth Offenders; Correction

AGENCY: Employment and Training Administration, Department of Labor.

ACTION: Correction.

SUMMARY: In notice document 00-32018 beginning on page 79124 in the issue of Monday, December 18, 2000, make the following correction.

On page 79133, Appendix A—COVERSHEET, on the second line Application for funding under SGA/DFA-110 "Community Audits". This should be changed to Application for funding under SGA/DFA 01-101

"Youth Offender Demonstration Projects".

Signed at Washington, DC this date, December 19, 2000.

Laura A. Cesario,

Grant Officer, Division of Federal Assistance.

[FR Doc. 00-32708 Filed 12-21-00; 8:45 am]

BILLING CODE 4510-30-M

DEPARTMENT OF LABOR

Employment Standards Administration, Wage and Hour Division

Minimum Wages for Federal and Federally Assisted Construction; General Wage Determination Decisions

General wage determination decisions of the Secretary of Labor are issued in accordance with applicable law and are based on the information obtained by the Department of Labor from its study of local wage conditions and data made available from other sources. They specify the basic hourly wage rates and fringe benefits which are determined to be prevailing for the described classes of

laborers and mechanics employed on construction projects of a similar character and in the localities specified therein.

The determinations in these decisions of prevailing rates and fringe benefits have been made in accordance with 29 CFR Part 1, by authority of the Secretary of Labor pursuant to the provisions of the Davis-Bacon Act of March 3, 1931, as amended (46 Stat. 1494, as amended, 40 U.S.C. 276a) and of other Federal statutes referred to in 29 CFR Part 1, Appendix, as well as such additional statutes as may from time to time be enacted containing provisions for the payment of wages determined to be prevailing by the Secretary of Labor in accordance with the Davis-Bacon Act. The prevailing rates and fringe benefits determined in these decisions shall, in accordance with the provisions of the foregoing statutes, constitute the minimum wages payable on Federal and federally assisted construction projects to laborers and mechanics of the specified classes engaged on contract work of the character and in the localities described therein.

Good cause is hereby found for not utilizing notice and public comment procedure thereon prior to the issuance of these determinations as prescribed in 5 U.S.C. 553 and not providing for delay in the effective date as prescribed in that section, because the necessity to issue current construction industry wage determinations frequently and in large volume causes procedures to be impractical and contrary to the public interest.

General wage determination decisions, and modifications and supersedes decisions thereto, contain no expiration dates and are effective from their date of notice in the **Federal Register**, or on the date written notice is received by the agency, whichever is earlier. These decisions are to be used in accordance with the provisions of 29 CFR Parts 1 and 5. Accordingly, the applicable decision, together with any modifications issued, must be made a part of every contract for performance of the described work within the geographic area indicated as required by an applicable Federal prevailing wage law and 29 CFR Part 5. The wage rates and fringe benefits, notice of which is published herein, and which are contained in the Government Printing Office (GPO) document entitled "General Wage Determinations Issued Under The Davis-Bacon And Related Acts," shall be the minimum paid by contractors and subcontractors to laborers and mechanics.

Any person, organization, or governmental agency having an interest

in the rates determined as prevailing is encouraged to submit wage rate and fringe benefit information for consideration by the Department.

Further information and self-explanatory forms for the purpose of submitting this data may be obtained by writing to the U.S. Department of Labor, Employment Standards Administration, Wage and Hour Division, Division of Wage Determinations, 200 Constitution Avenue, N.W., Room S-3014, Washington, D.C. 20210.

Modifications to General Wage Determination Decisions

The number of decisions listed in the Government Printing Office document entitled "General Wage Determinations Issued Under the Davis-Bacon and related Acts" being modified are listed by Volume and State. Dates of publication in the **Federal Register** are in parentheses following the decisions being modified.

Volume I

Massachusetts

MA000001 (Feb. 11, 2000)
MA000002 (Feb. 11, 2000)
MA000003 (Feb. 11, 2000)
MA000006 (Feb. 11, 2000)
MA000007 (Feb. 11, 2000)
MA000008 (Feb. 11, 2000)
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MA000021 (Feb. 11, 2000)

New York

NY000001 (Feb. 11, 2000)
NY000002 (Feb. 11, 2000)
NY000003 (Feb. 11, 2000)
NY000004 (Feb. 11, 2000)
NY000006 (Feb. 11, 2000)
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NY000078 (Feb. 11, 2000)
NY000079 (Feb. 11, 2000)
RI000001 (Feb. 11, 2000)
RI000002 (Feb. 11, 2000)
RI000005 (Feb. 11, 2000)

Volume II

District of Columbia

DC000001 (Feb. 11, 2000)
DC000003 (Feb. 11, 2000)

Delaware

DE000002 (Feb. 11, 2000)
DE000005 (Feb. 11, 2000)
DE000008 (Feb. 11, 2000)

Maryland

MD000001 (Feb. 11, 2000)
MD000034 (Feb. 11, 2000)
MD000035 (Feb. 11, 2000)
MD000036 (Feb. 11, 2000)
MD000046 (Feb. 11, 2000)
MD000047 (Feb. 11, 2000)
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MD000056 (Feb. 11, 2000)
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Pennsylvania

PA000001 (Feb. 11, 2000)
PA000002 (Feb. 11, 2000)
PA000004 (Feb. 11, 2000)
PA000008 (Feb. 11, 2000)
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Virginia

VA000015 (Feb. 11, 2000)
VA000020 (Feb. 11, 2000)
VA000022 (Feb. 11, 2000)
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VA000076 (Feb. 11, 2000)
VA000078 (Feb. 11, 2000)
VA000079 (Feb. 11, 2000)
VA000092 (Feb. 11, 2000)
VA000099 (Feb. 11, 2000)

Volume III

Kentucky

KY000001 (Feb. 11, 2000)
KY000002 (Feb. 11, 2000)
KY000003 (Feb. 11, 2000)
KY000007 (Feb. 11, 2000)

KY000027 (Feb. 11, 2000)
 KY000029 (Feb. 11, 2000)
 KY000035 (Feb. 11, 2000)

Volume IV

Illinois

IL000008 (Feb. 11, 2000)
 IL000052 (Feb. 11, 2000)
 IL000065 (Feb. 11, 2000)

Indiana

IN000001 (Feb. 11, 2000)
 IN000002 (Feb. 11, 2000)
 IN000003 (Feb. 11, 2000)
 IN000004 (Feb. 11, 2000)
 IN000005 (Feb. 11, 2000)
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Michigan

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Ohio

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Volume V

Iowa

IA000001 (Feb. 11, 2000)

Louisiana

LA000005 (Feb. 11, 2000)
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 LA000012 (Feb. 11, 2000)
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LA000017 (Feb. 11, 2000)
 LA000018 (Feb. 11, 2000)
 LA000052 (Feb. 11, 2000)

Nebraska

NE000001 (Feb. 11, 2000)
 NE000009 (Feb. 11, 2000)
 NE000011 (Feb. 11, 2000)
 NE000019 (Feb. 11, 2000)
 NE000058 (Feb. 11, 2000)

Volume VI

Colorado

CO000003 (Feb. 11, 2000)
 CO000005 (Feb. 11, 2000)
 CO000010 (Feb. 11, 2000)

Montana

MT000001 (Feb. 11, 2000)
 MT000006 (Feb. 11, 2000)
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 MT000008 (Feb. 11, 2000)
 MT000034 (Feb. 11, 2000)
 MT000035 (Feb. 11, 2000)

North Dakota

ND000001 (Feb. 11, 2000)

South Dakota

SD000005 (Feb. 11, 2000)

Wyoming

WY000008 (Feb. 11, 2000)

Volume VII

Arizona

AZ000001 (Feb. 11, 2000)

California

CA000001 (Feb. 11, 2000)
 CA000002 (Feb. 11, 2000)
 CA000009 (Feb. 11, 2000)
 CA000027 (Feb. 11, 2000)
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General Wage Determination Publication

General wage determinations issued under the Davis-Bacon and related Acts, including those noted above, may be found in the Government Printing Office (GPO) document entitled "General Wage Determinations Issued Under The Davis-Bacon and Related Acts." This publication is available at each of the 50 Regional Government Depository Libraries and many of the 1,400 Government Depository Libraries across the country.

The general wage determinations issued under the Davis-Bacon and related Acts are available electronically by subscription to the FedWorld Bulletin Board System of the National Technical Information Service (NTIS) of the U.S. Department of Commerce at 1-800-363-2068.

Hard-copy subscriptions may be purchased from: Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402, (202) 512-1800.

When ordering hard-copy subscription(s), be sure to specify the State(s) of interest, since subscriptions may be ordered for any or all of the seven separate volumes, arranged by State. Subscriptions include an annual edition (issued in January or February) which includes all current general wage determinations for the States covered by each volume. Throughout the remainder of the year, regular weekly updates are distributed to subscribers.

Signed at Washington, D.C. this 14 day of December 2000.

Carl J. Poleskey,

Chief, Branch of Construction Wage Determinations.

[FR Doc. 00-32387 Filed 12-21-00; 8:45 am]

BILLING CODE 4510-27-M

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice 00-146]

NASA Advisory Council, Life and Microgravity Sciences and Applications Advisory Committee, Meeting

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, Public Law 92-463, as amended, the National Aeronautics and Space Administration announces a meeting of the NASA Advisory Council, Life and Microgravity Sciences and Applications Advisory Committee.

DATES: Thursday, February 15, 2001, 10:00 a.m. to 5:00 p.m.; and Friday, February 16, 2001, 8:00 a.m. to 12:00 Noon.

ADDRESSES: National Aeronautics and Space Administration Headquarters, 300 E Street, SW, MIC-7, Room 7H46, Washington, DC 20546.

FOR FURTHER INFORMATION CONTACT: Dr. Stephen C. Davison, Code UG, National Aeronautics and Space Administration, Washington, DC 20546, 202/358-0647.

SUPPLEMENTARY INFORMATION: The meeting will be open to the public up to the seating capacity of the room. The agenda for the meeting is as follows:

—Action Status
 —Office of Biological and Physical Research Strategic Plan and Advisory Committee Reorganization

—Education and Outreach Programs
 —Biomedical Research and Crew Health
 —Interagency Activities
 —Radiation Health and Safety
 —Commercial Space Center Activities
 —ISS Non-Governmental Organization Status
 —Code U ISS Research Plans
 —Subcommittee Reports
 —Discussion of Committee Findings and Recommendations

It is imperative that the meeting be held on this date to accommodate the scheduling priorities of the key participants. Visitors will be requested to sign a visitor's register.

Dated: December 19, 2000.

Beth M. McCormick,

*Advisory Committee Management Officer,
 National Aeronautics and Space Administration.*

[FR Doc. 00-32719 Filed 12-21-00; 8:45 am]

BILLING CODE 7510-01-P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice 00-145]

U.S. Centennial of Flight Commission

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of Meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, Public Law 92-463, as amended, the National Aeronautics and Space Administration announces a meeting of the U.S. Centennial of Flight Commission.

DATES: Wednesday, January 17, 2001, 9:00 a.m. to 11:00 a.m.

ADDRESSES: Smithsonian National Air and Space Museum, 7th and Independence Avenue, SW, Director's Conference Room, 3rd Floor, Washington, DC 20560. Attendees must check in at the Information Desk to be cleared to the 3rd floor.

FOR FURTHER INFORMATION CONTACT: Ms. Beverly Farmarco, Code ZC, National Aeronautics and Space Administration, Washington, DC 20546, 202/358-1903.

SUPPLEMENTARY INFORMATION: The meeting will be open to the public up to the seating capacity of the room. The agenda for the meeting is as follows:

—Administrative/Follow Up Actions
 —Aviation World's Fair 2003 w/Mr. Tom Kallman
 —Criteria for U.S. Centennial of Flight Commission Endorsement
 —Role of the First Flight Centennial Federal Advisory Board
 —Communications Plan
 —New Business Opportunities

—Discussion/Adjournment

It is imperative that the meeting be held on this date to accommodate the scheduling priorities of the key participants.

Visitors will be requested to sign a visitor's register.

Dated: December 19, 2000.

Beth M. McCormick,

*Advisory Committee Management Officer,
 National Aeronautics and Space Administration.*

[FR Doc. 00-32718 Filed 12-21-00; 8:45 am]

BILLING CODE 7510-01-P

OVERSEAS PRIVATE INVESTMENT CORPORATION

Sub-Saharan African Infrastructure Fund

AGENCY: Overseas Private Investment Corporation.

ACTION: Call for proposals.

SUMMARY: This Call for Proposals invites qualified prospective fund managers to submit proposals for consideration by the Overseas Private Investment Corporation ("OPIC") for management of a sub-Saharan African infrastructure fund (the "Fund"). The Fund will be a private equity fund with aggregate capital of up to \$350 million that will invest in privately sponsored infrastructure projects in the countries of sub-Saharan Africa. A portion of the Fund's total capital must be unguaranteed private equity, and the remainder will be senior secured indebtedness guaranteed by OPIC. The primary purpose of any such fund will be to achieve long-term capital appreciation through investments in infrastructure projects in sub-Saharan Africa. This fund will succeed a previously approved fund of the same size with the same primary purpose. Prospective managers may obtain an OPIC Investment Funds Program Description and an evaluation Questionnaire from OPIC's web site (<http://www.opic.gov>) or by contacting OPIC. OPIC may periodically post additional information on its web site in the form of Supplements to the Call for Proposals. The identity of all persons submitting proposals will be posted on OPIC's web site.

DATES: Submit proposals to OPIC no later than 5 p.m. Eastern Standard Time on December 29, 2000.

ADDRESSES: Proposals must be received at OPIC's offices at 1100 New York Avenue, N.W., Washington, D.C. 20527.

FOR FURTHER INFORMATION CONTACT: Jeffrey T. Griffin, Vice-President,

Investment Funds Department, OPIC, by telephone at (202) 336-8620.

SUPPLEMENTARY INFORMATION: The Overseas Private Investment Corporation ("OPIC") is a self-sustaining U.S. government agency that assists U.S. private investment in over 140 emerging market economies and developing countries through four principal activities: project finance, political risk insurance, private equity investment funds and outreach activities. OPIC assisted projects are required to uphold important American values relating to human rights, workers' rights, the environment, and the impact on the U.S. economy as well as other matters.

OPIC is announcing that it is inviting proposals with respect to a private equity fund with aggregate capital of up to \$350 million that will invest in privately sponsored infrastructure projects in the countries of sub-Saharan Africa. A portion of the fund's total capital must be unguaranteed private equity, and the remainder will be senior secured indebtedness guaranteed by OPIC. The primary purpose of any such fund will be to achieve long-term capital appreciation through investments in infrastructure projects in sub-Saharan Africa. Such investments will provide capital for project development, business expansion, restructurings and privatizations.

This fund will succeed a previously approved fund of the same size with the same primary purpose.

OPIC would expect "infrastructure" to include, among other things:

- Environmental services such as urban and rural water supply and distribution, sanitation, solid waste disposal and waste treatment projects;
- Bulk water supply such as water reservoirs and transfer schemes utilizing methods such as dams and pipelines;
- Transportation systems such as toll roads, harbors, light and heavy rail systems and equipment, and airports and related services including airlines;
- Energy related projects such as power generation at independent power plants, transmission and distribution, and oil and gas processing and transportation; and
- Telecommunications such as international cable links, satellite communications, wireless communications, fixed line expansions and other related supplier and operator activities.

The fund will also seek to provide support to woman entrepreneurs and to innovative investments that expand opportunities for women and maximize employment opportunities for poor individuals.

The fund will be privately owned and privately managed. OPIC is seeking proposals from qualified prospective fund managers. The proposed fund manager must demonstrate experience and success on at least the following four criteria: Capital raising capability; private equity management; a broad infrastructure investment record; and sub-Saharan Africa experience.

Proposals should identify the sources of capital that the proposer would expect to approach on behalf of the fund (either directly or through an independent securities placement agent). OPIC's preference is for a majority of the fund's equity to be provided by U.S. investors.

Proposals should describe the legal, financial and management structure that the proposed fund manager recommends for the fund. This should include the level of economic return and the other benefits that the various investors would look for, as well as the proposed compensation for the fund's management. The fund should be structured to ensure that it fully covers the cost of the program, including the OPIC-guaranteed debt, as well as projected fees and profit participations.

OPIC's evaluation of proposals will be based primarily on the following criteria:

- The ability of the fund sponsors to raise the required private capital in a reasonable period of time.
- The credibility and thoughtfulness of the fund's strategic concept and business plan.
- The experience and depth of the proposed management, both in the U.S. and in the countries where investments are to be made. OPIC seeks fund managers with a track record in direct equity investments and relevant regional experience. OPIC will weigh heavily the team's experience in infrastructure investment and project finance. The fund manager is expected to add value to the portfolio investments by providing management expertise and enhancing the business of portfolio investments, and to have a strategy for the eventual liquidation of investments.
- The amount and terms of the OPIC-guaranteed debt required by the fund.
- The responsiveness of the fund to current foreign policy objectives of the United States.

An OPIC Investment Funds Program Description, and a Questionnaire, may be obtained on OPIC's web site (<http://www.opic.gov>). The Questionnaire is designed to identify information that will be helpful to OPIC in evaluating proposals.

OPIC may periodically post additional information on its internet web site in

the form of Supplements to the Call for Proposals. Any information so designated on OPIC's web site may supplement or modify, and will be considered a part of, the information set forth in this Call for Proposals. The identity of all persons submitting proposals will be promptly posted on OPIC's web site, so that they are known to each other.

Proposals must be submitted both in writing and on diskette. Five copies of each proposal, together with a copy on diskette in Microsoft Word or Excel 97 format, as appropriate, must be received by OPIC by 5:00 p.m., Eastern Standard Time, on Friday, December 29, 2000. Proposals submitted after this time will not be accepted. OPIC may make a determination based solely on the written proposals. OPIC will begin review of proposals as they are received. Proposals submitted may be supplemented at any time up to the deadline for submission of proposals. Information contained in proposals or questions from submitters will not be given proprietary treatment. OPIC may suggest its own formulation from among the proposals it receives or based on its own analysis, which formulation may include a suggestion that certain proposals be combined. Such a suggestion from OPIC would not reinitiate this Call for Proposals process. OPIC also reserves the right not to select any of the proposals or alternatives and to re-initiate this Call for Proposals. The issuance of this Call for Proposals does not obligate OPIC to provide support to any proposal nor any fund.

Jeffrey T. Griffin,

Vice President/Investment Funds, Overseas Private Investment Corporation.

[FR Doc. 00-32729 Filed 12-21-00; 8:45 am]

BILLING CODE 3210-01-U

POSTAL SERVICE BOARD OF GOVERNORS

Sunshine Act Meeting

Time and Dates: 1 p.m., Monday, January 8, 2001; 8:30 a.m., Tuesday, January 9, 2001.

Place: Washington, DC, at U.S. Postal Service Headquarters, 475 L'Enfant Plaza, SW., in the Benjamin Franklin Room.

Status: January 8 (Closed); January 9 (Open).

Matters to be Considered:

Monday, January 8—1:00 p.m. (Closed)

1. Business Initiative.
2. Financial Performance.
3. Strategic Planning.

4. Compensation Issues.

5. Personnel Matters.

Tuesday, January 9—8:30 a.m. (Open)

1. Minutes of the Previous Meetings, December 1, and December 4-5, 2000.
2. Remarks of the Postmaster General/Chief Executive Officer.
3. Consideration of Board Resolution on Capital Funding.
4. Annual Report on Government in the Sunshine Act Compliance.
5. Consideration of Fiscal Year 2000 Annual Report.
6. Quarterly Report on Financial Results.
7. Capital Investments.
 - a. Integrated Data System Upgrade.
 - b. Time and Attendance Collection System.
 - c. Standard Accounting for Retail Annual Report.
 - d. Postal Field Computing Infrastructure.
8. Election of Chairman and Vice Chairman of the Board of Governors.
9. Tentative Agenda for the February 5-6, 2001, meeting in San Antonio, Texas.

Contact Person for More Information: David G. Hunter, Secretary of the Board, U.S. Postal Service, 475 L'Enfant Plaza, SW., Washington, DC 20260-1000. Telephone (202) 268-4800.

David G. Hunter,

Secretary.

[FR Doc. 00-32839 Filed 12-20-00; 2:50 pm]

BILLING CODE 7710-12-M

RAILROAD RETIREMENT BOARD

Proposed Collection; Comment Request

SUMMARY: In Accordance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 which provides opportunity for public comment on new or revised data collections, the Railroad Retirement Board (RRB) will publish periodic summaries of proposed data collections.

Comments are invited on: (a) Whether the proposed information collection is necessary for the proper performance of the functions of the agency, including whether the information has practical utility; (b) the accuracy of the RRB's estimate of the burden of the collection of the information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden related to the collection of information on respondents, including the use of

automated collection techniques or other forms of information technology.

Title and purpose of information collection; Application for Employee Annuity Under the Railroad Retirement Act; OMB 3220-0002.

Section 2 of the Railroad Retirement Act (RRA), provides for payment of age and service, disability and supplemental annuities to qualified employees. The basic requirements for a regular employee annuity retirement annuity under the RRA is 120 months (10 years) of creditable railroad service. Benefits then become payable after the employee meets certain other requirements, which depend, in turn, on the type of annuity payable. The requirements relating to the annuities are prescribed in 20 CFR 216, and 220.

The forms used by the RRB to collect information needed for determining entitlement and the amount of, an employee retirement annuity follow: Form AA-1, Application for Employee Annuity Under the Railroad Retirement Act, is completed by an applicant for either an age and service or disability annuity. It obtains information about the

applicants marital history, work history, military service, benefits from other governmental agencies and railroad pensions. Form AA-1d, Application for Determination of Employee Disability, is completed by an employee who is filing for a disability annuity under the RRA, or a disability freeze under the Social Security Act for early Medicare based on a disability. Form G-204, Verification of Workers Compensation/ Public Disability Benefit Information, is used to obtain and verify information concerning worker's compensation or public disability benefits that are or will be paid by a public agency to a disabled railroad employee. Completion of the forms is required to obtain a benefit. One response is requested of each respondent.

The RRB proposes minor non-burden impacting editorial and formatting changes to Forms AA-1, AA-1d and G-204. The RRB estimates that 13,4000 Form AA-1's, 5,650 AA-1d's and 50 G-204's are completed annually. The estimated completion time for Form AA-1 is 37 to 62 minutes per response.

The estimated completion time for Form AA-1d is 35 to 60 minutes per response. The estimated completion time for Form G-204 is 15 minutes per response.

The renewal of this information collection will continue the RRB's initiative to consolidate information collections by major functional areas. The purpose of the initiative is to bring related collection instruments together in one collection, better manage the instruments, and prepare for the electronic collection of this information. (A collection instrument can be an individual form, electronic collection, interview, or any other method that collects specific information from the public.)

As part of the OMB renewal process, the RRB proposes that this collection (OMB 3220-0002). Application for Employee Annuity under the Railroad Retirement Act, be renamed RRA Benefit Applications. Upon approval by OMB, the RRB intends to merge the following OMB approved collections into this collection by the expected expiration date(s).

OMB collection No.	Title	RRB forms	Expected expiration date
3220-0016	Certification of Relinquishment of Rights	G-88	5/31/2002
3220-0021	Evidence of Marital Relationship; Living with Requirements.	G-124, G-124a, G-237, G-238, G-238a	1/31/2003
3220-0030	Application for Survivor Insurance Annuities	AA-17, AA-17 CERT, AA-17b, AA-18, AA-19, AA-20.	2/28/2004
3220-0031	Application for Survivor Death Benefits	AA-21, G-273a, AA-11a, G-131, AA-21 CERT ...	1/31/2003
3220-0032	Survivor Questionnaire	RL-94-F	6/30/2003
3220-0042	Application for Spouse Annuity Under the Railroad Retirement Act.	AA-3	6/30/2003
3220-0083	Evidence for Application of Overall Minimum	G-319, G-320	11/30/2003
3220-0099	Statement Regarding Contributions and Support ...	G-134	6/30/2002
3220-0106	Application for Search of Census Records	G-256	7/31/2001
3220-0123	Student Beneficiary Monitoring	G-315, G-315a, G-315a.1	11/30/2003
3220-0136	Public Service Pension Questionnaire	G-208, G-212	3/31/2004
3220-0138	Self-Employment Questionnaire	AA-4	3/31/2004
3220-0140	Employee's Certification	G-346	1/31/2003
3220-0154	Employee Noncovered Service Pension Questionnaire.	G-209	7/31/2002
3220-0155	Supplement to Claim of Person Outside the United States.	G-45	6/30/2001
3220-0195	Statement Regarding Contributions and Support of Children.	G-139	2/28/2002

Revisions to existing collection instruments and, occasionally, a new instrument related to this program function may be required during the three-year cycle of this information collection. The RRB currently estimates the completion time for Form G-88, Certification of Termination of Service and Relinquishment of Rights at 6 minutes, Form G-124, Statement of Marital Relationship at 15 to 20 minutes, Form G-124a, Statement Regarding Marriage at 10 minutes, Form G-237, Statement Regarding Marital

Status at 15 to 20 minutes, Form G-238, Statement of Residence at 3 to 5 minutes, Form G-238a, Statement Regarding Divorce or Annulment at 10 minutes, Form AA-17, Application for Widow(ers) Annuity at 47 minutes, Form AA-17cert, Application Summary and Certification at 20 minutes, Form AA-17b, Application for Determination of Widow(ers) Disability at 40 to 50 minutes, Form AA-18, Application for Mother's/Father's and Child's Annuity at 47 minutes, Form AA-19, Application for Child's Annuity at 47 minutes, Form

AA-20, Application for Parent's Annuity at 47 minutes, Form AA-21, Application for Lump-Sum Death Payments and Annuities Unpaid at Death at 40 minutes, Form G-273a, Funeral Director's Statement of Burial Charges at 10 minutes, Form AA-11a, Designation or Change of Beneficiary for Residual Lump Sum at 10 minutes, Form G-131, Authorization of Payment and Release of All Claims to a Death Benefit or Accrued Annuity Payment at 5 minutes, Form AA-21CERT, Application Summary and Certification,

at 20 minutes, Form RL-94-F. Survivor Questionnaire, at 5 to 11 minutes, Form AA-3, Application for Spouse/Divorce Spouse Annuity, at 14 to 30 minutes, Form G-319, Employee Annuitant's Statement Regarding Family and Earnings, at 25 to 60 minutes, Form G-320, Statement by Employee Annuitant Regarding Student Age 18-19, at 14-30 minutes, Form G-134, Statement Regarding Contributions and Support, at 75 to 85 minutes, Form G-256, Application for Search of Census Records, at 10 minutes, Form G-315, Student Questionnaire, at 7 minutes, Form G-315a, Statement by School Official of Student's Full-Time Attendance, at 2 minutes, Form G-315a.1, Notice of Cessation of Full-Time Attendance, at 2 minutes, Form G-208, Public Service Pension Questionnaire, at 15 minutes, Form G-212, Public Service Pension Monitoring Questionnaire, at 3 minutes, Form AA-4, Self-Employment and Substantial Service Questionnaire, at 40 to 70 minutes, Form G-346, Employee's Certification, at 5 minutes, G-209, Employee Noncovered Service Pension Questionnaire at 1 to 8 minutes, G-45, Supplement to Claim of Person Outside the United States, at 10 minutes, G-139, Statement Regarding Contributions and Support of Children, at 15 minutes.

After the last information collection is merged and other necessary adjustments are made, the resultant information collection is expected to total approximately 17,904 annual burden hours. A justification for each action described above (merge collection, revised collection instrument, new collection instrument) will be provided to OMB with a Correction Change Worksheet (OMB Form 83-C) at the time the action occurs. With the next renewal of this collection, the RRB will update the information collection package to account for the consolidation and other interim adjustments.

ADDITIONAL INFORMATION OR COMMENTS:

To request more information or to obtain a copy of the information collection justification, forms, and/or supporting material, please call the RRB Clearance Officer at (312)751-3363. Comments regarding the information collection should be addressed to Ronald J. Hodapp, Railroad Retirement Board, 844 North Rush Street, Chicago, Illinois 60611-2092. Written comments should be received within 60 days of this notice.

Chuck Mierzwa,
Clearance Officer.

[FR Doc. 00-32739 Filed 12-21-00; 8:45 am]

BILLING CODE 7905-01-M

SECURITIES AND EXCHANGE COMMISSION

Submission for OMB Review; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of Filings and Information Services, Washington, D.C. 20549.

Extension: Rule 154; SEC File No. 270-438; OMB Control No. 3235-0495.

Notice is hereby given that, under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520), the Securities and Exchange Commission (the "Commission") has submitted to the Office of Management and Budget a request for extension of the previously approved collection of information discussed below.

The federal securities laws generally prohibit an issuer, underwriter, or dealer from delivering a security for sale unless a prospectus meeting certain requirements accompanies or precedes the security for sale unless a prospectus meeting certain requirements accompanies or precedes the security. Rule 154 [17 CFR 230.154] under the Securities Act of 1933 [15 U.S.C. 77a] (the "Securities Act") permits, under certain circumstances, delivery of a single prospectus to investors who purchase securities from the same issuer and share the same address ("householding") to satisfy the applicable prospectus delivery requirements.¹ The purpose of rule 154 is to reduce the amount of duplicative prospectuses delivered to investors sharing the same address.

Under rule 154, a prospectus is considered delivered to all investors at a shared address, for purposes of the federal securities laws, if the person relying on the rule delivers the prospectus to the shared address and the investors consent to the delivery of a single prospectus. The rule applies to prospectuses and prospectus supplements. Currently, the rule permits householding of all prospectuses except those required to be delivered for business combinations, exchange offers, or reclassifications of

securities.² Rule 154 permits householding of prospectuses by an issuer, underwriter, or dealer relying on the rule if, in addition to the other conditions set forth in the rule, the issuer, underwriter, or dealer has obtained from each investor written or implied consent to householding.³ The rule requires issuers, underwriters, or dealers that wish to household prospectuses with implied consent to send a notice to each investor stating that the investors in the household will receive one prospectus in the future unless the investors provide contrary instructions. In addition, at least once year, issuers, underwriters, or dealers, relying on rule 154 for the householding of prospectuses, must explain to investors who have provided written or implied consent how they can revoke their consent. Preparing and sending the initial notice and the annual explanation of the right to revoke are collections of information.

The rule allows issuers, underwriters, or dealers to household prospectuses and prospectus supplement if certain conditions are met. Among the conditions with which a person relying on the rule must comply are providing notice to each investor that only one prospectus will be sent to the household and providing to each investor who consents to householding an annual explanation of the right to revoke consent to the delivery of a single prospectus to multiple investors sharing an address. The purpose of the notice and annual explanation requirements of the rule is to ensure that investors who wish to receive individual copies of shareholder reports are able to do so.

Although rule 154 is not limited to investment companies, the Commission believes that it is used mainly by mutual funds and by broker-dealers that deliver mutual fund prospectuses. The Commission is unable to estimate the number of issuers other than mutual funds that rely on the rule.

The Commission estimates that there are approximately 3000 mutual funds, approximately 545 of which engage in

² The Commission has proposed an amendment to rule 154 that would permit the householding of prospectuses required to be delivered for business combinations, exchange offers, or reclassifications of securities. See Delivery of Proxy and Information Statement to Households, Securities Act Rel. No. 7767; Securities Exchange Act Rel. No. 42102; Investment Company Act Rel. No. 24124 (Nov. 4, 1999) [64 FR 62548 (Nov. 16, 1999)]. The proposed amendment has not been adopted as of the date of this notice.

³ Rule 154 permits the householding of prospectuses that are delivered electronically to investors only if delivery is made to a shared electronic address and the investors give written consent to householding. Implied consent is not permitted in such a situation. See rule 154(b)(4).

¹ The Securities Act requires the delivery of prospectuses to investors who buy securities from an issuer or from underwriters or dealers who participate in a registered distribution of securities. See Securities Act sections 2(a)(10), 4(1), 4(3), 5(b) [15 U.S.C. 77b(a)(10), 77d(1), 77d(3), 77e(b)]; see also rule 174 under the Securities Act [17 CFR 230.174] (regarding the prospectus delivery obligation of dealers); rule 15c2-8 under the Securities and Exchange Act of 1934 [17 CFR 240.15c2-8] (prospectus delivery obligations of brokers and dealers).

direct marketing and therefore deliver their own prospectuses. The Commission estimates that each direct-marketed mutual fund will spend an average of 20 hours per year complying with the notice requirement of the rule, for a total of 10,900 hours. The Commission estimates that each direct-marketed fund will also spend 1 hour complying with the explanation of the right to revoke requirement of the rule, for a total of 545 hours. The Commission estimates that as of year-end 1998, there were approximately 300 broker-dealers that carry customer accounts and, therefore, may be required to deliver mutual fund prospectuses. The Commission estimates that each affected broker-dealer will spend, on average, approximately 20 hours complying with the notice requirement of the rule, for a total of 6,000 hours. Each broker-dealer will also spend 1 hour complying with the annual explanation of the right to revoke requirement, for a total of 300 hours. Therefore, the total number of respondents for rule 154 is 845 (545 mutual funds plus 300 broker-dealers), and the estimated total hour burden is 17,745 hours (11,445 hours for mutual funds plus 6,300 hours for broker-dealers).

The estimate of average burden hours is made solely for the purposes of the Paperwork Reduction Act, and is not derived from a comprehensive or even a representative survey or study of the costs of Commission rules and forms.

Compliance with the collection of information requirements of the rule is necessary to obtain the benefit of relying on the rule. Responses to the collections of information will not be kept confidential. The rule does not require these records be retained for any specific period of time. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid control number.

Please direct general comments regarding the above information to the following persons: (i) Desk Officer for the Securities and Exchange Commission, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Washington, D.C. 20503; and (ii) Michael E. Bartell, Associate Executive Director, Office of Information Technology, Securities and Exchange Commission, 450 Fifth Street, N.W., Washington, D.C. 20549. Comments must be submitted to OMB within 30 days after this notice.

Dated: December 12, 2000.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 00-32648 Filed 12-21-00; 8:45 am]

BILLING CODE 8010-01-M

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-43727; File No-CBOE-00-65]

Self-Regulatory Organizations; Notice of Filing and Immediate Effectiveness of Proposed Rule Change by Chicago Board Options Exchange, Inc. to Extend the Pilot Period Relating to the Processing of Live Ammo Orders Until January 31, 2001

December 14, 2000.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),¹ and Rule 19b-4 thereunder,² notice is hereby given that on December 7, 2000, the Chicago Board Options Exchange, Inc. ("CBOE" or "Exchange") filed with the Securities and Exchange Commission ("SEC" or "Commission") the proposed rule changes as described in Items I, II, and III below, which Items have been prepared by the CBOE. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to extend, until January 31, 2001, the pilot program that allows an Order Book Official ("OBO") or a Designated Primary Market-Maker ("DPM") to designate certain booked orders to be electronically executed. The text of the proposed rule change is available at the Office of the Secretary, CBOE and at the Commission.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, CBOE included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of the statements may be examined at the places specified in Item IV below. The CBOE prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

On February 2, 2000, the Commission approved, on a pilot basis, a system change that allows an OBO or a DMP to reroute orders on the electronic book screen that displays market orders and limit orders that improve the market ("Live Ammo") to the Retail Automatic Executive System ("RAES"), if the orders are RAES-eligible.³ The pilot, which was originally scheduled to expire on October 31, 2000, was extended to expire on December 15, 2000.⁴

The Exchange now proposes to extend the pilot until January 31, 2001. An extension of the pilot will permit consideration of the Exchange's proposal to adopt the Live Ammo to RAES processing system on a permanent basis.⁵ The Exchange believes that the proposed extension of the pilot until January 31, 2001 will permit the benefits of Live Ammo to RAES system to remain in place while the Commission considers the Exchange's proposal to permanently adopt the system.

2. Basis

The Exchange believes that because the Live Ammo to RAES processing system has provided for the more timely execution of marketable orders, the proposed rule change is consistent with Section 6(b) of the Act,⁶ in general, and furthers the objectives of Section 6(b)(5),⁷ in particular, because it would foster cooperation and coordination with persons engaged in regulating, clearing, settling, and processing information with respect to, and facilitating transactions in securities, and would remove impediments to and perfect the mechanism of a free and open market in manner consistent with the protection of investors and the public interest.

B. Self-Regulatory Organization's Statement on Burden on Competition

CBOE does not believe that the proposed rule change will impose any burden on competition not necessary or

³ Securities Exchange Act Release No. 42379, 65 FR 6665 (February 10, 2000). The Exchange rule pertaining to the processing of Live Ammo orders is CBOE Rule 7.4(g).

⁴ Securities Exchange Act Release No. 43499 (October 31, 2000) 65 FR 67023 (November 8, 2000).

⁵ See Securities Exchange Act Release No. 43646 (November 30, 2000), 65 FR 77403 (December 11, 2000).

⁶ 15 U.S.C. 78f(b).

⁷ 15 U.S.C. 78f(b)(5).

appropriate in furtherance of purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the proposed rule change: (1) Does not significantly affect the protection of investors or the public interest; (2) does not impose any significant burden on competition; and (3) does not become operative for 30 days from the date of filing, or such shorter time as the Commission may designate if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to section 19(b)(3)(a) of the Act⁸ and Rule 19b-4(f)(6)⁹ thereunder.¹⁰

A proposed rule change filed under Rule 19b-4(f)(6)¹¹ normally does not become operative prior to 30 days after the date of filing. However, Rule 19b-4(f)(6)(ii)¹² permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange seeks to have the proposed rule change become operative immediately in order to allow the pilot to continue in effect on an uninterrupted basis.

The Commission, consistent with the protection of investors and the public interest, has determined to make the proposed rule change operative immediately through January 31, 2001. The extension of the pilot will provide the Commission with the time necessary to review and evaluate the Exchange's proposal to permanently adopt the Live Ammo to RAES system. The Commission notes that unless the pilot is extended, the Pilot will expire on December 15, 2000, which the Commission believes could result in confusion regarding how orders on the Live Ammo screen should be handled. Therefore, the Commission believes that it is in the public interest to extend the pilot.

Based on these reasons, the Commission believes that it is consistent with the protection of investors and the public interest that the proposed rule change become operative immediately through January 31, 2001.¹³ At any time within 60 days of the filing of the proposed rule change, the Commission may summarily abrogate such rule change if it appears that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549-0609. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room. Copies of such filing will also be available for inspection and copying at the principal office of CBOE. All submissions should refer to File No. SR-CBOE-00-65 and should be submitted by January 12, 2001.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.¹⁴

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 00-32654 Filed 12-21-00; 8:45 am]

BILLING CODE 8010-01-M

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-43718; File No. SR-NASD-00-36]

Self-Regulatory Organizations; The National Association of Securities Dealers, Inc.; Order Approving Proposed Rule Change Relating to Options Position Reporting Requirements and Application of Options Position and Exercise Limits to Trades With Non-member Brokers and Dealers

December 13, 2000.

I. Introduction

On June 14, 2000, the National Association of Securities Dealers, Inc. ("NASD" or "Association"), through it wholly owned subsidiary, NASD Regulation, Inc. ("NASD Regulation"), submitted to the Securities and Exchange Commission ("SEC" or "Commission"), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")¹ and Rule 19b-4 thereunder,² a proposed rule change to apply options position reporting requirements and options position and exercise limits to trades with non-member brokers and dealers.

The proposed rule change was published for comment in the **Federal Register** on September 7, 2000.³ No comments were received. This order approves the proposal.

II. Description of the Proposal

Presently, the NASD's options position limits, exercise limits, and reporting requirements, Rules 2860(b)(3), 2860(b)(4) and 2860(b)(5), respectively, apply to: (1) Account in which a member has an interest; (2) an account in which a member's partner, officer, director or employee has an interest, or (3) a customer account.

However, the NASD's definition of "customer" excludes a broker or dealer; therefore, non-member brokers and dealers are currently outside the scope of these rules. To bring non-member brokers and dealers within the purview of NASD Rule 2860, the NASD proposed to amend the rule to: (1) Require members to report the options positions that they effect for non-member brokers and non-member dealers where such positions meet the reporting thresholds under NASD rules; (2) apply the NASD's options position and exercise limits to members that effect trades for

⁸ 15 U.S.C. 78s(b)(3)(A).

⁹ 17 CFR 240.19b-4(f)(6).

¹⁰ As required under rule 19b-4(f)(6)(iii), the Exchange provided the Commission with written notice of its intent to file the proposed rule change at least five business days prior to the filing date.

¹¹ 17 CFR 240.19b-4(f)(6).

¹² 17 CFR 240.19b(f)(6)(iii).

¹³ For purposes only of accelerating the operative date of this proposal, the Commission has considered the rule's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

¹⁴ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ Securities Exchange Act Release No. 43220 (August 29, 2000), 65 FR 54334.

non-member brokers and non-member dealers; (3) codify an interpretive position with respect to which firms are required to report standardized options positions under the NASD's options position reporting requirements; and (4) clarify that a member may have its clearing firm report options positions to the NASD.

In addition, the NASD proposed several technical amendments to the options position reporting requirements to take into account staff interpretive positions with respect to reporting standardized and conventional options. Specifically, the amendments codify options position reporting requirements set forth in Notice to Members 94-46, which states that the reporting requirements are "applicable to all standardized options positions established by members of their customers." Access firms are defined in the requirements as NASD members that conduct a business in exchange-traded options but are not themselves members of the options exchange upon which such options are listed and traded. Limiting reporting of standardized options positions under NASD rules to access firms only avoids imposing duplicative reporting requirements on NASD members who are also members of an options exchange, inasmuch as members of an options exchange (*i.e.*, dual members) are required to report positions on standardized options pursuant to the rules of the options exchange(s) of which they are a member.

Finally, the rule proposal clarifies that, consistent with current practice, a member may report positions directly to the Association or have such positions reported to the Association by another firm. According to the Association, this amendment would not eliminate the member's ultimate responsibility to ensure that the firm reporting the positions on the member's behalf makes the necessary filings with the NASD.

III. Discussion

The Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to national securities association. Specifically, the Commission finds that the proposal to amend NASD Rule 2860 is consistent with section 15A(b)(6) of the Act.⁴

Section 15A(b)(6)⁵ requires that the rules of the registered national securities association be designed to prevent fraudulent and manipulative acts and

practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest.⁶

The Commission believes that the proposed rule change will protect individual investors and the public by enabling the NASD to better monitor the financial exposure of its member firms. The Commission also believes that the proposed rule change will result in consistent application of position and exercise limits by ensuring that trades effected by NASD members on behalf of non-member brokers and non-member dealers are also subject to those limits. Finally, the Commission believes that the proposed provisions clarifying options reporting procedures, and other technical amendments, are also consistent with the overall objective of the rule proposal.

It Is Therefore Ordered, pursuant to section 19(b)(2) of the Act,⁷ that the proposed rule change (SR-NASD-00-36) be, and hereby is, approved.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.⁸

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 00-32649 Filed 12-21-00; 8:45 am]

BILLING CODE 8010-01-M

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-43714; File No. SR-PCX-00-21]

Self-Regulatory Organizations; Notice of Filing of Proposed Rule Change by the Pacific Exchange, Inc. Relating to Financial Arrangements of Options Floor Members

December 12, 2000.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")¹ and Rule 19b-4 thereunder,² notice is hereby given that on July 7, 2000, the Pacific Exchange, Inc. ("PCX" or "Exchange") filed with the Securities

and Exchange Commission ("SEC" or "Commission") the proposed rule change as described in Items I, II and III below, which Items have been prepared by the PCX.³ On November 30, 2000, the Exchange submitted Amendment No. 1 to the proposed rule change.⁴ The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The PCX is proposing to eliminate its current PCX Rule 6.40 on financial arrangements of options floor members and is also proposing to adopt supplemental rules on options floor members who are trading for the same joint account. The text of the proposed rule change follows. Additions are in *italics*; deletions are in [brackets].

¶ 3809 Disclosure of Financial Arrangements of Members

Rule 4.18(a)-(b)—No change.

[(c) The Exchange may restrict the trading activity of Members with financial arrangements pursuant to Rule 6.40. Such restrictions are subject to appeal, pursuant to Rule 11.7.]

¶ 4953 Financial Arrangements of Options Floor Members

Rule 6.40(a)—*Reserved* [Financial Arrangements Defined. Two Members have a "financial arrangement" with each other for purposes of this Rule if:]

[(1) One Member directly finances the other Member's dealings upon the Exchange, the amount financed is \$5,000 or more, and the Member providing the financing is entitled to a share of the other Member's trading profits; or

(2) Both Members are registered with the Exchange as nominees of the same Member Organization; or

(3) Both Members are registered with the Exchange to trade on behalf of the same joint account; or

(4) Both Members' dealings upon the Exchange are financed by the same source, the amount financed is \$5,000 or more, and the Member providing the financing is entitled to a share of each of the other Members' trading profits.]

[For purposes of this Rule, the term "Member" shall include both Members and Member Organizations.]

[(b) Options Floor Trading Restrictions.]

³ The PCX subsequently submitted the text of the proposed rule change language properly formatted for publication in the **Federal Register**. The reformatted version did not contain any substantive changes to the proposed rule change language. See letter dated November 1, 2000, from Michael D. Pierson, PCX, to Kelly Riley, Division of Market Regulation, SEC.

⁴ The PCX amended the original filing by way of letter amendment. See letter dated November 29, 2000, from Michael D. Pierson, PCX, to Nancy J. Sanow, Assistant Director, Division of Market Regulation, SEC.

⁴ 15 U.S.C. 78o-3(b)(6).

⁵ *Id.*

⁶ In approving this rule change, the Commission notes that it has considered the proposal's impact on efficiency, competition, and capital formation, consistent with Section 3 of the Act. 15 U.S.C. 78c(f).

⁷ 15 U.S.C. 78s(b)(2).

⁸ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

[(1) A Market Maker who has a "financial arrangement" with another Member of Member Organization (as specified herein) and the Member or Member Organization having a "financial arrangement" with that Market Maker, may not bid, offer and/or trade in the same trading crowd at the same time in the absence of an exemption from the Options Floor Trading Committee, as provided in subsection (b)(4), below.

(2) Any order of a Market Maker with an existing financial arrangement, that is represented or executed by a Floor Broker, shall be so represented or executed in accordance with the procedures set forth in Rule 6.85. Additionally, a Market Maker may not bid, offer and/or trade in a trading crowd in which a Floor Broker holds an order on behalf of a Market Maker with whom he has an existing financial arrangement may not be concurrently represented, by one or more Floor Brokers, in a particular trading crowd.

(3) Two or more Lead Market makers (LMMs) who are trading on behalf of the same Member organization may not bid, offer and/or trade in the same option series at the same time. However, two or more LMMs who do not have financial arrangements with each other, as defined in subsection (a) of this Rule, or who have been granted an exemption pursuant to subsection (b)(4), below, may bid, offer and/or trade in the same option series at the same time.

(4) Exemptions. Members with financial arrangements may be exempted from the trading restrictions set forth in this subsection, as follows:]

[(A) Long-Term Exemptions. The Options Floor Trading Committee may grant long-term exemptions to Members on a case-by-case basis if it determines that a fair and orderly market would not be impaired by allowing such Members with financial arrangements to trade in the same trading crowd at the same time. In making such determinations, the Committee shall consider the following factors: (1) The nature of the financial arrangement; (2) the degree of independence to be maintained by the applicants in making trading decisions; (3) the impact on competition in the trading crowd if an exemption were granted; (4) the applicants' prior patterns of trading if they have previously traded in the same trading crowd at the same time; (5) and any other information relevant to whether the applicants would tend collectively to dominate the market in a particular trading crowd or a particular option series. The Committee may revoke any long-term exemption granted pursuant to this subsection if it determines that a fair and orderly market would otherwise be impaired by a continuation of the exemption. The Committee will review, on at least an annual basis, all long-term exemptions that are in effect at the time.]

[(B) Short-term Exemptions. Two Floor Officials may grant short-term exemptions to Members on a case-by-case basis if such Floor Officials determine that a fair and orderly market would not be impaired and that the need for liquidity in the trading crowd warrants such action. Unless otherwise specified, any exemption granted pursuant to this Rule shall extend for no

longer than the trading day on which it is provided. The Committee shall review, on a regular basis, each exemption granted pursuant to this subsection (b).]

[(c) Reporting to the Exchange. Market Makers, Floor Brokers and Member Organizations are required to report the terms of their financial arrangements to the Exchange pursuant to Rule 4.18 ("Disclosure of Financial Arrangements of Members").]

[Commentary

.01 The purpose of Rule 6.40 is to prevent Market Makers who have financial arrangements with each other from unfairly dominating the market in any option issues or series, as prohibited by Rule 6.37(c)(2). The Options Floor Trading Committee has determined that any Market Makers who are not technically covered by the terms of Rule 6.40, but who unfairly dominate the market in any option issue or series, shall be considered to be in violation of their obligation to contribute to the maintenance of fair and orderly markets and to act in accordance with use and equitable principles of trade.]

* * * * *

¶ 5193 Joint Accounts

Rule 6.84(a)–(e)—No change.

[(f) Participants in a joint account must comply with the trading restrictions provided in Rule 6.40]

[(g)–(h)]—(f)–(g)—No change.

(h) *The following trading restrictions apply to Members who are registered with the Exchange to trade on behalf of the same joint account:*

(1) *A joint account may be simultaneously represented in a trading crowd only by participants who are trading in-person. Orders for a joint account may not be entered in a trading crowd in which a participant of the joint account is trading in-person for the joint account. If no participant is trading in-person in the trading crowd for the joint account, then a Floor Broker may represent orders in the trading crowd on behalf of the joint account as long as the same option series is not concurrently represented for the same joint account by more than one Floor Broker.*

(2) *Market Makers may alternate trading in-person between their individual and joint accounts while in the trading crowd. Market Makers who alternate trading between accounts must ensure that while trading the joint account another participant does not enter orders through a Floor Broker for the joint account in the same trading crowd.*

(3) *Before beginning trading on behalf of a joint account, participants in the joint account are responsible for determining whether any Floor Brokers are representing orders in the same trading crowd on behalf of the same joint account.*

(4) *Floor Brokers may not represent a joint account of which they are a participant.*

(5) *Market Makers who are trading in person in a trading crowd may not enter orders with a Floor Broker either for joint accounts in which they are participants or for their individual accounts.*

(6) *The following trades are prohibited:*

(A) *Trades between a joint account participant's individual account and a joint account in which that person is a participant.*

(B) *Trades between two joint accounts having common participants.*

(C) *Trades in which the buyer and seller are representing the same joint account and are on opposite sides of the transaction.*

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the PCX included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The PCX has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange is proposing to eliminate PCX Rule 6.40 (Financial Arrangements of Options Floor Members), which currently prohibits options floor members with financial arrangements from trading in the same trading crowd without receiving either a short-term or long-term exemption from the Options Floor Trading Committee ("OFTC"). The Commission approved the most recent version of PCX Rule 6.40 in 1996.⁵ Based on its experience with the rule since that time, the PCX now believes that many of its current provisions do not prevent the activities that the rule was designed to deter. Therefore, after careful consideration, the Exchange is now proposing to replace PCX Rule 6.40 with new PCX Rule 6.84(h).

a. *Definition of Financial Arrangement.* PCX Rule 6.40(a) currently defines the term "financial arrangement" very broadly, so that it covers both members who are trading for the same firm as well as members who are backed by the same source (even though they may be trading for different firms).⁶

⁵ See Exchange Act Release No. 37543 (August 8, 1996), 61 FR 42458 (August 15, 1996). See also Exchange Act Release No. 35277 (January 25, 1995), 60 FR 6330 (February 1, 1995); Exchange Act Release No. 32775 (August 20, 1993), 58 FR 45368 (August 27, 1993).

⁶ PCX Rule 6.40(a) provides:

Two Members have a 'financial arrangement' with each other for purposes of this Rule if: (1) One Member directly finances the other Member's

b. *Trading Prohibitions.* PCX Rule 6.40(b)(1) currently prohibits market makers with common financial arrangements from trading in the same trading crowd at the same time, unless they have an exemption from the OFTC.⁷ PCX Rule 6.40(b)(2) prohibits market makers from trading in a crowd where an order is being represented by a floor broker on behalf of another market maker who is affiliated with the original market maker.⁸ In addition, PCX Rule 6.40(b)(3) restricts multiple lead market maker ("LMM") representatives from trading simultaneously in the same option series.⁹ As discussed below, the PCX is proposing to eliminate these restrictions except for those relating to multiple representation of market maker accounts through the use of floor brokers.

c. *Exemptions to Current Rule.* PCX Rule 6.40(b)(4)(A) permits the OFTC to grant long-term exemptions to the trading restrictions in PCX Rule 6.40.¹⁰

dealings upon the Exchange, the amount financed is \$5,000 or more, and the Member providing the financing is entitled to a share of the other Member's trading profits; or (2) Both Members are registered with the Exchange as nominees of the same Member Organization; or (3) Both Members are registered with the Exchange to trade on behalf of the same joint account; or (4) Both Members' dealings upon the Exchange are financed by the same source, the amount financed is \$5,000 or more, and the Member providing the financing is entitled to a share of each of the other Members' trading profits. For purposes of this Rule, the term 'Member' shall include both Members and Member Organizations.

⁷ PCX Rule 6.40(b)(1) provides:

A Market Maker who has a 'financial arrangement' with another Member or Member Organization (as specified herein) and the Member or Member Organization having a 'financial arrangement' with that Market Maker, may not bid, offer and/or trade in the same trading crowd at the same time in the absence of an exemption from the Options Floor Trading Committee, as provided in subsection (b)(4), below.

⁸ PCX Rule 6.40(b)(2) provides:

Any order of a Market Maker with an existing financial arrangement, that is represented or executed by a Floor Broker, shall be so represented or executed in accordance with the procedures set forth in Rule 6.85. Additionally, a Market Maker may not bid, offer and/or trade in a trading crowd in which a Floor Broker holds an order on behalf of a Market Maker with whom he has an existing financial arrangement. Orders of a Market Maker having an existing financial arrangement may not be concurrently represented, by one or more Floor Brokers, in a particular trading crowd.

⁹ PCX Rule 6.40(b)(3) provides:

Two or more Lead Market Makers (LMMs) who are trading on behalf of the same Member Organization may not bid, offer and/or trade in the same option series at the same time. However, two or more LMMs who do not have financial arrangements with each other, as defined in subsection (a) of this Rule, or who have been granted an exemption pursuant to subsection (b)(4), below, may bid, offer and/or trade in the same option series at the same time.

¹⁰ PCX Rule 6.40(b)(4)(A) provides:

Long-Term Exemptions. The Options Floor Trading Committee may grant long-term

PCX Rule 6.40(b)(4)(B) permits two floor officials to grant short-term exemptions.¹¹ To obtain a long-term exemption, members are currently required to submit an application to the OFTC and to provide information relevant to the factors set forth in PCX Rule 6.40(b)(4)(A). In assessing an application, the OFTC considers the stated purpose of PCX Rule 6.40, which is "to prevent Market Makers who have financial arrangements with each other from unfairly dominating the market in any option issues or series, as prohibited by [PCX] Rule 6.37(c)(2)."¹²

d. *Elimination of PCX Rule 6.40.* The Exchange is now proposing to eliminate PCX Rule 6.40. The current rule informs the OFTC (i.e., floor officials) of common financial arrangements among other floor members. As noted above, the purpose of PCX Rule 6.40 is to prevent market makers who have financial arrangements with each other from unfairly dominating the market in any option issue or series, as prohibited by PCX Rule 6.37(c)(2). Unfair domination of the market, however, is prohibited by PCX Rule 6.37(c)(2) regardless of whether the parties involved have a "financial arrangement" with each other. The Exchange believes that the value of the current administrative process relating to exemptions is minimal with regard to assuring compliance with applicable

exemptions to Members on a case-by-case basis if it determines that a fair and orderly market would not be impaired by allowing such Members with financial arrangements to trade in the same trading crowd at the same time. In making such determinations, the Committee shall consider the following factors: (1) The nature of the financial arrangement; (2) the degree of independence to be maintained by the applicants in making trading decisions; (3) the impact on competition in the trading crowd if an exemption were granted; (4) the applicants' prior patterns of trading if they have previously traded in the same trading crowd at the same time; (5) and any other information relevant to whether the applicants would tend collectively to dominate the market in a particular trading crowd or a particular option series. The committee may revoke any long-term exemption granted pursuant to this subsection if it determines that a fair and orderly market would otherwise be impaired by a continuation of the exemption. The Committee will review, on at least an annual basis, all long-term exemptions that are in effect at the time.

¹¹ PCX Rule 6.40(b)(4)(B) provides:

Short-term Exemptions. Two Floor Officials may grant short-term exemptions to Members on a case-by-case basis if such Floor Officials determine that a fair and orderly market would not be impaired and that the need for liquidity in the trading crowd warrants such action. Unless otherwise specified, any exemption granted pursuant to this Rule shall extend for no longer than the trading day on which it is provided. The Committee shall review, on a regular basis, each exemption granted pursuant to this subsection (b).

¹² See PCX Rule 6.40, Commentary .01.

rules.¹³ The Exchange notes that it will continue to require members to submit detailed information on their financial arrangements to Exchange staff, as currently required.¹⁴ This will allow the Exchange to continue to conduct its surveillance and enforcement efforts relating to any fraudulent, manipulative, or other illegal trading practices by members with financial affiliations that may occur.

The Exchange believes that eliminating PCX Rule 6.40 is consistent with the important objective of allowing market makers and other PCX members to participate freely in trading crowds to provide maximum market depth and liquidity.¹⁵ The Exchange does not believe that floor officials' knowledge, based on the exemption process, of other members' financial arrangements helps to deter illicit trading practices.

The Exchange also believes that the restriction on LMMs in PCX Rule 6.40(b)(3)—i.e., the prohibition against more than one LMM representative simultaneously bidding, offering, or trading in the same option series without an exemption from floor officials—is unwarranted. If there is a large influx of orders in a particular option series, an LMM may reasonably need to have more than one of its traders in the same trading crowd simultaneously trading that series.¹⁶ The Exchange does not believe that

¹³ In that regard, the Exchange notes that it has not identified domination of the market in violation of PCX Rule 6.37(c)(2), wash sale trade violations, or any other violations as a result of the application of PCX Rule 6.40.

¹⁴ See PCX Rule 4.18(a), which provides in part:

(a) A Market Maker, Floor Broker, Specialist or Member Organization who enters into a financial arrangement with any other person or entity shall disclose to the Exchange the identity of such person or entity and the terms of the arrangement. For the purposes of this rule, a financial arrangement is defined as:

- (1) The direct financing of a Member's dealings upon the Exchange; or
- (2) Any direct equity investment or profit sharing arrangement; or
- (3) Any consideration over the amount of \$5,000.00, including, but not limited to, gifts, loans, annual salaries or bonuses.

(b) Exchange Members with financial arrangements must submit to the Exchange notification of the initiation, modification or termination of such financial arrangements in a form, time and manner approved by the Exchange within ten business days of the effective date of such arrangements or within such shorter period of time as the Exchange may require. Failure to disclose the terms of such financial arrangements to the Exchange may result in disciplinary action.

¹⁵ The Exchange believes that no other options exchange has a rule that prohibits affiliated members from trading in the same crowd without an exemption.

¹⁶ The Exchange that notes the current restriction on trading in the same series previously applied to all market makers with common financial arrangements. See Exchange Act Release No. 32775 (August 20, 1993), 58 FR 45368 (August 27, 1993).

there is a compelling reason to require the LMM to obtain an exemption from floor officials under these circumstances.

e. *New Provisions on Joint Accounts.* PCX Rule 6.85 currently provides that a market maker and any orders represented by a floor broker on behalf of the market maker may not be concurrently represented at a trading post. This principle against dual representation of a market maker account has been extended to cover joint accounts, as currently provided in PCX Rule 6.84, Commentary .04.¹⁷ The Exchange is now proposing to adopt supplemental procedures that apply to situations where a joint account is being concurrently represented by more than one market maker representative, and to situations where a joint account is being represented by a floor broker.¹⁸

Specifically, the Exchange is proposing to add new subsection (h) to PCX Rule 6.84, its current rule on joint accounts. Subsection (h)(1) of the proposed PCX Rule 6.84 states that a joint account may be simultaneously represented in a trading crowd only by participants who are trading in-person. It further provides that orders for a joint account may not be entered in a trading crowd in which a participant of the joint account is trading in-person for the joint account. If no participant is trading in-person in the trading crowd for the joint account, then a floor broker may represent orders in the trading crowd on behalf of the joint account as long as the same option series is not concurrently represented by more than one floor broker.

Subsection (h)(2) of proposed PCX Rule 6.84 provides that market makers may alternate trading in-person between their individual and joint accounts while in the trading crowd. It further provides that market makers who alternate trading between accounts must ensure that while trading the joint account another participant does not

enter orders through a floor broker for the joint account in the same trading crowd.

Subsection (h)(3) of proposed PCX Rule 6.84 provides that before beginning trading on behalf of a joint account, participants in the joint account are responsible for determining whether any floor brokers are representing orders in the same trading crowd on behalf of the same joint account.¹⁹

Subsection (h)(4) of proposed PCX Rule 6.84 provides that floor brokers may not represent a joint account of which they are a participant.

Subsection (h)(5) of proposed PCX Rule 6.84 provides that market makers who are trading in-person in a trading crowd may not enter orders with a floor broker either for joint accounts in which they are participants or for their individual accounts.

Subsection (h)(6) of proposed PCX Rule 6.84 provides that the following trades are prohibited: (a) Trades between a joint account participant's individual account and a joint account in which that person is a participant; (b) trades between two joint accounts having common participants; (c) trades in which the buyer and seller are representing the same joint account and are on opposite sides of the transaction.

Finally, the Exchange is proposing to make technical changes to PCX Rule 4.18 and PCX Rule 6.84 by removing cross-reference to PCX Rule 6.40.

The Exchange believes that the provisions of proposed PCX Rule 6.84 are reasonably designed to assure appropriate representation of joint accounts in the trading crowds, consistent with the PCX's current rules. In particular, the Exchange believes that proposed subsections (1) and (5) of PCX Rule 6.84 are consistent with the second and third sentences of current PCX Rule 6.84, Commentary .04, and with PCX Rule 6.85. Finally, the Exchange believes that the elimination of PCX Rule 6.40, in conjunction with the codification of new PCX Rule 6.84(h), will help to assure an appropriate balance between reasonable trading restrictions by joint account participants and the need to allow PCX members to participate freely in trading crowds to provide maximum depth and liquidity.

2. Basis

The Exchange believes that the proposal is consistent with Section 6(b) of the Act²⁰ in general and Section 6(b)(5)²¹ in particular because it is

designed to promote just and equitable principles of trade, to facilitate transactions in securities, to remove impediments to and perfect the mechanism of a free and open market, and to protect investors and the public interest.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The PCX neither solicited nor received written comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 35 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

A. by order approve such proposed rule change, or

B. institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed is consistent with the Act. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549-0609. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room. Copies of such filing will also be available for inspection and copying at the principal office of the PCX. All

¹⁷ This Commentary provides:

Any order of a joint account participant, which is executed by a Floor Broker, shall be in accordance with procedures set forth in Rule 6.85, except that the joint account trading number with its alpha identification should appear in the 'executing firm' area. Additionally, a joint account participant may not bid, offer, purchase, sell, or enter orders in an option series in which a Floor Broker holds an order on behalf of the joint account or for the proprietary account of another participant in the joint account. Orders of joint account participants in a particular option series may not be concurrently represented by one or more Floor Brokers.

¹⁸ The Exchange believes that these procedures are substantially the same as those set forth in Regulatory Circular RG-98-94 of the Chicago Board Options Exchange (Joint Account Participant Trading in Equity Options) (September 9, 1998), CCH ¶ 5291.

¹⁹ Cf. PCX Rule 6.85, Commentary .01 (similar requirement applicable to market makers).

²⁰ 15 U.S.C. 78f(b).

²¹ 15 U.S.C. 78f(b)(5).

submissions should refer to File No. SR-PCX-00-21 and should be submitted by January 12, 2001.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.²²

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 00-32652 Filed 12-21-00; 8:45 am]

BILLING CODE 8010-01-M

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-43721; File No. SR-Phlx-00-32]

Self-Regulatory Organizations; Order Approving a Proposed Rule Change by the Philadelphia Stock Exchange, Inc. Relating to Rule 748, Supervision

December 13, 2000.

On July 31, 2000, the Philadelphia Stock Exchange, Inc. ("Phlx" or "Exchange") filed with the Securities and Exchange Commission ("SEC" or "Commission") pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")¹ and Rule 19b-4 thereunder,² a proposed rule change to amend Rule 748, Supervision.³ On October 11, 2000, the Exchange submitted Amendment No. 1 to the proposed rule change.⁴ Notice of the proposed rule change, as amended, was published for comment in the **Federal Register**.⁵ No comments were submitted on the proposed rule change. This order approves the proposed rule change, as amended.

I. Description of the Proposal

The Exchange proposes to amend Rule 748, Supervision, in several respects. First, the proposed amendment to Rule 748 would expand the definition of who must be supervised to include employees and associated persons of members, member organizations, participants, or participant organizations. The proposed

amendment to Rule 748 would also require that all offices, locations, departments, and business activities of members, member organizations, participants, and participant organizations ("members and related organizations") be supervised.

Second, the proposed amendment to Rule 748 would add a requirement for periodic compliance reviews and office inspections. Members and related organizations for which the Exchange is the Designated Examining Authority ("DEA") would have to conduct compliance meetings with their personnel at least on an annual basis. In addition, members and related organizations for which the Exchange is the DEA would have to conduct office inspections according to an inspection cycle established in their written supervisory procedures.

Third, the proposed amendment to Rule 748 would require that members and related organizations have written supervisory procedures that set forth the specific supervisory system and other essential information regarding supervisory personnel.

Fourth, the proposed amendment to Rule 748 would contain standards for supervision and for written supervisory procedures. Written supervisory procedures and the system for applying such procedures would have to be reasonably designed to prevent and detect, insofar as practicable, violations of the applicable securities laws and regulations, including the by-laws and rules of Exchange. A similar standard for supervision would be applicable to those entrusted with the duty to supervise others.⁶

II. Discussion

The Commission finds that the proposed rule change is consistent with the provisions of Section 6(b)(5) of the Act,⁷ which require, among other things, that the rules of the exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with respect to facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in

general, to protect investors and the public interest.⁸

The Commission believes that the Exchange's proposal to expand the definition of who must be supervised is reasonable and will help to enhance the ability of the members and related organizations to adequately monitor and enforce supervision within their organizations.

The Commission also believes that the Exchange's proposal to add requirements for periodic compliance reviews and office inspections will strengthen the ability of the members and related organizations to carry out their compliance and surveillance functions.

Lastly, the Commission believes that the Exchange's proposal to require that members and related organizations have written supervisory procedures, setting forth the specific supervisory system and other pertinent information, as well as requiring that standards are implemented for supervision and written supervisory procedures, will help to ensure that members and related organizations carry out their supervisory responsibilities efficiently, particularly over branch offices of member firms conducting business away from the floor of the Exchange.

III. Conclusion

It Is Therefore Ordered, pursuant to Section 19(b)(2) of the Act,⁹ that the proposed rule change (SR-Phlx-00-32), as amended, be and hereby is approved.

For the Commission by the Division of Market Regulation, pursuant to delegated authority.¹⁰

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 00-32650 Filed 12-21-00; 8:45 am]

BILLING CODE 8010-01-M

²² 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ Exchange Rule 748, which is generally based on NYSE Rule 342, was originally filed in 1993 and amended once in 1994. See Securities Exchange Act Release Nos. 33303 (Dec. 8, 1993), 58 FR 65609 (Dec. 15, 1993) and 34842 (Oct. 14, 1994), 59 FR 53002 (Oct. 20, 1994).

⁴ See Letter from Jurij Trypupenko, Director of Litigation and Operations, Phlx, to Nancy Sanow, Assistant Director, Division of Market Regulation, Commission (October 11, 2000). Amendment No. 1 corrected structural errors that appeared in the proposed rule language.

⁵ Securities Exchange Act Release No. 43407 (Oct. 20, 2000), 65 FR 64469 (Oct. 27, 2000) (SR-Phlx-00-32).

⁶ The standard for supervision and standard for written supervisory procedures found in the proposed rule change are based generally on Section 15(b)(4)(E)(i) of the Act. 15 U.S.C. 78o(b)(4)(E)(i).

⁷ 15 U.S.C. 78f(b)(5).

⁸ In approving the proposal, the Commission has considered the rule's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

⁹ 15 U.S.C. 78s(b)(2).

¹⁰ 17 CFR 200.30-3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-43719; File No. SR-PHLX-00-97]

Self-Regulatory Organizations; Notice of Filing and Immediate Effectiveness of Proposed Rule Change by the Philadelphia Stock Exchange, Inc. Relating to the Establishment of a Systems Change and a Fee to Members and Member Organizations for Receiving On-line Options Information

December 13, 2000.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),¹ and Rule 19b-4 thereunder,² notice is hereby given that on November 14, 2000, the Philadelphia Stock Exchange, Inc. ("Phlx" or "Exchange") filed with the Securities and Exchange Commission ("Commission" or "SEC") the proposed rule change as described in Items I, II and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Phlx proposes to effect a systems change and adopt a real-time, trade information fee of \$.0025 per contract for members or member organizations receiving option trade information on-line (i.e., electronically) from the Exchange.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Phlx included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Phlx has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of this proposed rule change is to effect an information-

related enhancement to the AUTOM System³ and to amend the Phlx's fee schedule to impose a \$.0025 per contract fee to members and member organizations who choose to use this enhancement.

Recently, the Exchange made available a back-office enhancement to the AUTOM System on the options floor that provides option trade information on-line (meaning electronically) on a real-time basis. Members and member organizations can now choose to connect and log on to an interface with the AUTOM System to receive options (equity and index options) transaction information real-time. Specifically, once transaction information is in the AUTOM System, it becomes available to member organizations, who may connect to the feature; member organizations may determine to offer such information to their floor traders electronically.⁴ The transaction information covered by this feature includes the type of information generally captured in Exchange systems as a trade.⁵

Currently, such information is available in hard copy (paper ticket) form, which can be confirmed against floor trader positions. The Exchange has created this electronic link in order to facilitate electronic position monitoring for options. The feature is voluntary and does not replace the current hard-copy printing of transaction information. Member organizations choosing to log on to the feature will be charged \$.0025 per contract. The Exchange chooses to charge a per contract fee rather than a flat fee for the service to encourage more firms, including small firms, to use this important risk management tool.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with Section 6(b)(4) and (b)(5) of the Act⁶ in that it provides for the equitable allocation of reasonable dues, fees and other charges among its members and other persons using its facilities and promotes just and equitable principles of trade.

³ AUTOM is the Phlx's Automated Options Market System. See Phlx Rule 1080.

⁴ According to the Exchange, members and member organizations that are logged on to the AUTOM System and choose to receive the options transaction information real-time may determine how to distribute the information to their floor traders, including using hand-held devices. As per telephone conversation between John Dayton, Assistant Secretary and Counsel, Phlx, and Heather Traeger, Attorney, SEC, Division of Market Regulation, on December 13, 2000.

⁵ This information includes the symbol, volume, price, time and clearing information of the traded security.

⁶ 15 U.S.C. 78f(b)(4) and (b)(5).

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange has neither solicited nor received written comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change, which (1) establishes or changes a due, fee, or other charge imposed by the Exchange and (2) effects a change in an existing order-entry or trading system of the Exchange that (i) does not significantly affect the protection of investors or the public interest; (ii) does not impose any significant burden on competition; and (iii) does not have the effect of limiting the access to or availability of the system, has become effective pursuant to Section 19(b)(3)(A) of the Act⁷ and subparagraph (f)(2) and (f)(5) of Rule 19b-4 thereunder.⁸ At any time within 60 days of the filing of the proposed rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interest persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549-0609. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying at the Commission's Public Reference Room. Copies of such filing also will be available for inspection and copying at

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

⁷ 15 U.S.C. 78s(b)(3)(A).

⁸ 17 CFR 240.19b-4(f)(2) and (f)(5).

the principal office of the Phlx. All submissions should refer to File No. SR-PHLX-00-97 and should be submitted by January 12, 2001.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.⁹

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 00-32651 Filed 12-21-00; 8:45 am]

BILLING CODE 8010-01-M

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-43717; File No. SR-Phlx-00-54]

Self-Regulatory Organizations; Notice of Filing and Order Granting Accelerated Approval of a Proposed Rule Change and Amendment Nos. 1 and 2 Thereto by the Philadelphia Stock Exchange, Inc. Relating to the Listing and Trading of Trust Shares

December 13, 2000.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),¹ and Rule 19b-4 thereunder,² notice is hereby given that on June 19, 2000, the Philadelphia Stock Exchange, Inc. ("Phlx" or "Exchange") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Phlx. On August 30, 2000, the Exchange submitted Amendment No. 1 to the proposed rule change.³ On December 12, 2000, the Exchange submitted Amendment No. 2 to the proposed rule change.⁴ The Commission is publishing

this notice to solicit comments on the proposed rule change from interested persons and to grant accelerated approval of the proposed rule change, as amended.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Phlx proposes to amend its rules to permit the listing and trading, or the trading pursuant to unlisted trading privileges ("UTP"), of Trust Shares. New Section (i) of Phlx Rule 803 provides listing standards for Trust Shares, which represent interests in a unit investment trust operating on an open-end basis and holding a portfolio of securities. In conjunction with Rule 803(i), the Exchange is also: amending its "Hours of Business" Rule (Rule 101) to address Trust Shares; making conforming changes to its PACE Rule (Rule 229) regarding automatic price improvement; and adopting new Rule 136 regarding trading halts in Trust Shares. The Exchange is also proposing to trade shares of the Nasdaq-100 Trust ("Nasdaq-100 Index Tracking Stock") on a UTP basis. The text of the proposed rule change is set forth below. Proposed new language is in italics; proposed deletions are in brackets.

* * * * *

Rule 101 Dealings Upon the Exchange Hours of Business

* * * * *

Supplementary Material

* * * * *

.02 [Post-Primary Session] *Equity Trading Hours.* Trading in any equity security on the Exchange's equity trading floor shall commence at 9:30 a.m. and end at 4 p.m. each business day, unless otherwise announced by the Exchange, except that:

(i) the Post-Primary Session ("PPS") will operate from 4 to 4:15 p.m. for PPS-designated orders pursuant to Rule 232(b)[, and]

(ii) the after hours trading facility for GTX orders will operate pursuant to Rule 232(c), and

(iii) *Transactions in Nasdaq-100 Index Tracking Stock may be effected on the Exchange until 4:15 p.m. each business day as well as pursuant to Rule 232(c).*

Rule 229. Philadelphia Stock exchange Automated Communication and Execution System (PACE)

* * * * *

Supplementary Material

* * * * *

.07

(c) Price Improvement for PACE Orders

(i) Automatic Price Improvement—Where the specialist voluntarily agrees to provide

automatic price improvement to all customers and all eligible market orders in a security, automatically executable market and marketable limit orders in New York Stock Exchange and American Stock Exchange listed securities received through PACE for 599 shares or less shall be provided with automatic price improvement of $\frac{1}{8}$ (or $\frac{1}{64}$ in the case of Nasdaq-100 Index Tracking Stock) for equities trading in fractions, or .01 for equities trading in decimals from the PACE Quote where received beginning at 9:30 a.m., except where:

(A) a buy order would be improved to a price less than the last sale or a sell order would be improved to a price higher than the last sale (except as provided in (E) below);

or

(B) a buy order would be improved to the last sale which is a downtick or a sell order would be improved to the last sale price which is an uptick (except as provided in (E) below). The PACE System will determine whether the last sale price is a downtick or an uptick. The PACE System does not recognize changes from the previous day's close.

In these situations, the order is not eligible for automatic price improvement, and is, instead, automatically executed at the PACE Quote. A specialist may voluntarily agree to provide automatic price improvement to larger orders in a particular security to all customers under this provision. A specialist may choose to provide automatic price improvement for equities trading in fractions where the PACE Quote is (I) $\frac{3}{16}$ or greater, [or] (II) $\frac{1}{8}$ or greater, or (III) solely with respect to Nasdaq-100 Index Tracking Stock, $\frac{1}{16}$ or greater. [for equities trading in fractions, or] A specialist may choose to provide automatic price improvement where the PACE Quote is .03 or greater or .05 or greater for equities trading in decimals.

* * * * *

.17 *Except for transactions in Nasdaq-100 Index Tracking Stock: (a) Orders received by 4:00 p.m. Eastern Time as determined electronically by the PACE system are eligible for execution[.] (b) Orders received after such time will be rejected and returned to order entry firm[.], and (c) From 4 to 4:15 p.m., Eastern Standard Time, PACE may be used as a routing system for PPS eligible orders. Orders in Nasdaq-100 Index Tracking Stock received by 4:15 p.m. Eastern Time as determined electronically by the PACE system are eligible for execution.*

Rule 136. Trading Halts in Certain Exchange Traded Funds

Rule 1047A(c) shall apply to the trading of Trust shares listed pursuant to the terms of Rule 803(i). The term "option" as used therein shall be deemed for the purposes of this rule only to include a Trust Share.

Rule 803. Criteria for Listing—Tier I

* * * * *

(i) Trust Shares

(1) Definitions.

(i) Trust Shares. The term "Trust Share" means a security (a) that is based on a unit investment trust ("Trust") which holds the securities which comprise an index or portfolio underlying a series of Trust Shares;

⁹ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ In Amendment No. 1, the Phlx clarified references to Trust Shares series in the text of the Exchange's proposed rule. See Letter to Nancy Sanow, Assistant Director, Division of Market Regulation, Commission, from Nandita Yagnik, Attorney, Phlx (August 29, 2000).

⁴ In Amendment No. 2, the Phlx proposed: trading Nasdaq-100 Index Tracking Stock until 4:15 p.m.; establishing conditions for a specialist to provide automatic price improvement in Nasdaq-100 Index Tracking Stock on the Philadelphia Stock Exchange Automated Communication and Execution ("PACE") System; renumbering and retitling a new rule governing trading halts; and clarifying that transactions in Nasdaq-100 Index Tracking Stock would be reported to the Exchange's consolidated tape. Amendment No. 2 also indicated that securities now known as "Nasdaq-100 Index Tracking Stock" were formerly called "Nasdaq-100 Shares;" substituted "Nasdaq Investment Product Services, Inc." for "Nasdaq-Amex Investment Product Services, Inc." as sponsor; and made a technical change to the text of the proposed rule change. See Letter to Nancy Sanow, Assistant Director, Division of Market Regulation,

Commission, from Carla Behnfeldt, Counsel, Phlx (December 12, 2000).

(b) that is issued by the Trust in a specified aggregate minimum number in return for a "Portfolio Deposit" consisting of specified numbers of shares of stock plus a cash amount; (c) that, when aggregated in the same specified minimum number, may be redeemed from the Trust which will pay to the redeeming holder the stock and cash then comprising the "Portfolio Deposit"; and (d) that pays holders a periodic cash payment corresponding to the regular cash dividends or distributions declared with respect to the component securities of the stock index or portfolio of securities underlying the Trust Shares, less certain expenses and other charges as set forth in the Trust prospectus.

(ii) *Reporting Authority.* The term "Reporting Authority" in respect of a particular series of Trust Shares means the Exchange, a wholly-owned subsidiary of the Exchange, an institution (including the Trustee for Trust Shares), or a reporting service designated by the Exchange or its subsidiary or by the exchange that lists a particular series of Trust Shares (if the Exchange is trading such series pursuant to unlisted trading privileges) as the official source for calculating and reporting information relating to such series, including, but not limited to, any current index or portfolio value; the current value of the portfolio of securities required to be deposited to the Trust in connection with issuance of Trust Shares; the amount of any dividend equivalent payment or cash distribution to holders of Trust Shares, net asset value, or other information relating to the creation, redemption or trading of Trust Shares.

(2) *Applicability.* This Rule is applicable only to Trust Shares. Except to the extent inconsistent with this Rule, or unless the context otherwise requires, the provisions of the By-Laws and all other rules and policies of the Board of Governors shall be applicable to the trading on the Exchange of such securities. Trust Shares are included within the definition of "security" or "securities" as such terms are used in the By-Laws and Rules of the Exchange.

(3) *Disclosure Requirements.* Members and member organizations shall provide to all purchasers of a series of Trust Shares a written description of the terms and characteristics of such securities, in a form approved by the Exchange, not later than the time a confirmation of the first transaction in such series is delivered to such purchaser. In addition, members and member organizations shall include such a written description with any sales material relating to a series of Trust Shares that is provided to customers or the public. Any other written materials provided by a member or member organization to customers or the public making specific reference to a series of Trust Shares as an investment vehicle must include a statement in substantially the following form: "A circular describing the terms and characteristics of (the series of Trust Shares) is available from your broker. It is recommended that you obtain and review such circular before purchasing (the series of Trust Shares). In addition, upon request you may obtain from your broker a prospectus for (the series of Trust Shares)."

A member or member organization carrying an omnibus account for a non-member broker-dealer is required to inform such non-member that execution of an order to purchase a series of Trust Shares for such omnibus account will be deemed to constitute agreement by the non-member to make such written description available to its customers on the same terms as are directly applicable to members and member organizations under this rule.

Upon request of a customer, a member or member organization shall also provide a prospectus for the particular series of Trust Shares.

(4) *Designation of an Index or Portfolio.* The trading of Trust Shares based on one or more stock indexes or securities portfolios, whether by listing or pursuant to unlisted trading privileges, shall be considered on a case by case basis. The Trust Shares based on each particular stock index or portfolio shall be identified as a separate series and shall be identified by unique symbol. The stocks that are included in an index or portfolio on which Trust Shares are based shall be selected by the Exchange or its agent, a wholly-owned subsidiary of the Exchange, or by such other person as shall have a proprietary interest in and authorized use of such index or portfolio, and may be revised from time to time as may be deemed necessary or appropriate to maintain the quality and character of the index or portfolio.

(5) *Initial and Continued Listing and/or Trading.* A Trust upon which a series of Trust Shares are based will be traded on the Exchange, whether by listing or pursuant to unlisted trading privileges, subject to application of the criteria:

(A) *Commencement of Trading*—For each Trust, the Exchange will establish a minimum number of Trust Shares required to be outstanding at time of commencement of trading on the Exchange.

(B) *Continued Trading*—Following the initial twelve month period following formation of trust and commencement of trading on the Exchange, the Exchange will consider the suspension of trading in or removal from listing of or termination of unlisted trading privileges for a Trust upon which a series of Trust Shares are based under any of the following circumstances:

(i) if the Trust has more than 60 days remaining until termination and there are fewer than 50 record and/or beneficial holders of Trust Shares for 30 or more consecutive trading days; or

(ii) if the value of the index or portfolio of securities on which the Trust is based is no longer calculated or available; or

(iii) if such other event shall occur or condition exists which in the opinion of the Exchange, makes further dealings on the Exchange inadvisable.

(C) *Termination of Trust*—Upon termination of a Trust, the Exchange requires that Trust Shares issued in connection with such Trust be removed from Exchange listing or have their unlisted trading privileges terminated. A Trust may terminate in accordance with the provisions of the Trust prospectus, which may provide for termination if the value of securities in the Trust falls below a specified amount.

(6) *Term.* The stated term of the Trust shall be as stated in the Trust prospectus.

However, a Trust may be terminated under such earlier circumstances as may be specified in the Trust prospectus.

(7) *Trustee.* The trustee must be a trust company or banking institution having substantial capital and surplus and the experience and facilities for handling corporate trust business. In cases where, for any reason, an individual has been appointed as trustee, a qualified trust company or banking institution must be appointed co-trustee.

(8) *Voting.* Voting rights shall be as set forth in the Trust prospectus. The Trustee of a Trust may have the right to vote all of the voting securities of such Trust.

(9) *Limitation of Exchange Liability.* Neither the Exchange, the Reporting Authority nor any agent of the Exchange shall have any liability for damages, claims, losses or expenses caused by any errors, omissions, or delays in calculating or disseminating any current index or portfolio value; the current value of the portfolio of securities required to be deposited to the Trust; the amount of any dividend equivalent payment or cash distribution to holders of Trust Shares; net asset value; or other information relating to the creation, redemption or trading of Trust Shares, resulting from any negligent act or omission by the Exchange, or the Reporting Authority, or any agent of the Exchange, or any act, condition or cause beyond the reasonable control of the Exchange or its agent, or the Reporting Authority, including, but not limited to, an act of God; fire; flood; extraordinary weather conditions; war; insurrection; riot; strike; accident; action of government; communications or power failure; equipment or software malfunction; or any error, omission or delay in the reports of transactions in one or more underlying securities. The Exchange makes no warranty, express or implied, as to results to be obtained by any person or entity from the use of Trust Shares or any underlying index or data included therein and the Exchange makes no express or implied warranties, and disclaims all warranties of merchantability or fitness for a particular purpose with respect to Trust Shares or any underlying index or data included therein. This limitation of liability shall be in addition to any other limitation contained in the Exchange's Articles of Incorporation or By-Laws or elsewhere in the Rules.

(10) *Listing Fees and Other Rules.* The Exchange may, in its discretion, waive listing fees for any issuer of any particular series of Trust Shares listed on the Exchange pursuant to Rule 803(i). The provisions of Rules 847, 849, 850 and 851 do not apply to unit investment trusts issuing Trust Shares listed on the Exchange pursuant to Rule 803(i), or to the trustees or the sponsors thereof. In addition, consideration of the suspension of trading in or removal from listing of any Trust Shares pursuant to Rule 810 will be made pursuant to the criteria set forth in section 5(B) of this Rule 803(i) rather than the specific criteria set forth in subsections (1) through (5) of Rule 810(a).

Commentary

01 The Nasdaq Stock Market, Inc. ("Nasdaq") has licensed the use of the Nasdaq-100 Index for certain purposes in connection with trading in a particular series of Trust Shares on the Exchange. Nasdaq and its affiliates do not guarantee the accuracy and/or completeness of the Nasdaq-100 Index or any data included therein. Nasdaq, the Exchange and their affiliates make no warranty, express or implied, as to results to be obtained by any person or entity from the use of the Nasdaq-100 Index or any data included therein in connection with the rights licensed or for any other use. Nasdaq, the Exchange and their affiliates make no express or implied warranties, and disclaim all warranties of merchantability or fitness for a particular purpose with respect to the Nasdaq-100 Index or any data included therein. Without limiting any of the foregoing, in no event shall Nasdaq, the Exchange and their affiliates have any liability for any lost profits or special, punitive, incidental, indirect, or consequential damages, even if notified of the possibility of such damages. In addition, Nasdaq, the Exchange and their affiliates shall have no liability for any damages, claims, losses or expenses caused by any errors or delays in calculating or disseminating the Nasdaq-100 Index.

* * * * *

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Phlx included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item V below. The Exchange has prepared summaries, set forth in Sections A, B and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Trust Shares Listing Standards. The Exchange proposes to adopt new rules and rule amendments to accommodate the trading of Trust Shares, *i.e.*, securities that are interests in a unit investment trust ("Trust") holding a portfolio of securities linked to an index. Each Trust would provide investors with an instrument that: (1) Closely tracks the underlying portfolio of securities; (2) trades like a share of common stock; and (3) pays holders of the instrument periodic dividends proportionate to those paid with respect to the underlying portfolio of securities,

less certain expenses (as described in the Trust prospectus).⁵

Listing standards for Trust Shares are established in Rule 803(i) ("Rule"). Under the Rule, the Exchange may list and trade, or trade pursuant to UTP, Trust Shares based on one or more stock indexes or securities portfolios.⁶ Trust Shares based on each particular stock index or portfolio will be designated as a separate series and identified by a unique symbol. The stocks that are included in an index or portfolio on which Trust Shares are based will be selected by the Exchange or its agent, a wholly-owned subsidiary of the Exchange, or by another person having a proprietary interest in and authorized use of such index or portfolio, and may be revised as may be deemed necessary or appropriate to maintain the quality and character of the index or portfolio.⁷

In connection with an initial listing, the Exchange proposes that, for each listing of Trust Shares, the Exchange will establish a minimum number of Trust Shares required to be outstanding at the time of commencement of Exchange trading. If the Exchange trades a particular Trust Share pursuant to UTP, the Exchange will follow the listing exchange's determination of the appropriate minimum number of securities included in the Trust.

Because the Trust operates on an open-end type basis, and because the number of Trust Share holders is subject to substantial fluctuations depending on market conditions, the Exchange

⁵ The listing standards for Trust Shares set forth in proposed new Section (i) of Rule 803 are substantially similar to existing rules of the American Stock Exchange ("Amex") applicable to Portfolio Depository Receipts ("PDRs") and of the Chicago Board Options Exchange ("CBOE") applicable to Index Portfolio Receipts ("IPRs"). See Amex Rules 1000-1003; *see also* CBOE Rule 1.1, Interpretations and Policies Section .02, and Rules 30.54, 31.5.L and 31.94.F.

⁶ As explained more fully below, Phlx intends to trade Trust Shares on the Nasdaq-100 Index pursuant to UTP under the listing standards approved herein. If Phlx intends to trade, pursuant to UTP, Trust Shares listed on another exchange by using listing standards that are different from current Phlx listing standards or the listing standards set forth in its proposed rule change, the Phlx represents that it will file a rule change proposal pursuant to Section 19(b)(1) of the Act and Rule 19b-4 thereunder to adopt the different listing standards before the Phlx trades those Trust Shares.

⁷ The Exchange represents that its proposal would result in Trust Shares being listed as Tier I securities and therefore "covered securities" for purposes of Section 18 of the Securities Act of 1933. 15 U.S.C. 77r. (The Exchange has established Tier I listing criteria and Tier II listing criteria for companies listing on the Phlx. Tier I listing requires a company to meet certain higher numerical listing criteria than are required for Tier II listing. Tier II listing standards are intended to accommodate smaller companies.) The Exchange believes that, as "covered securities," Trust Shares would be exempt from state securities registration requirements.

believes that it would be inappropriate and burdensome on Trust Share holders to consider suspending trading in or delisting a series of Trust Shares, with the consequent termination of the Trust, unless the number of holders remains severely depressed during an extended time period. Therefore, following twelve months after the formation of a Trust and commencement of Exchange trading, the Exchange will consider suspension of trading in, or removal from listing of, a Trust when, in the Exchange's determination, further dealing in such securities appears unwarranted under the following circumstances:

(a) If the Trust on which the Trust Shares are based has more than 60 days remaining until termination and there have been fewer than 50 record and/or beneficial holders of the Trust Shares for 30 or more consecutive trading days;

(b) if the index on which the Trust is based is no longer calculated; or

(c) if such other event occurs or condition exists, which, in the opinion of the Exchange, makes further dealings in such securities on the Exchange inadvisable.⁸

The stated term of the Trust will be set forth in the Trust prospectus. A Trust may also terminate under such conditions as may be set forth in the Trust prospectus. For example, the sponsor of the Trust, following notice to Trust Share holders, will have discretion to direct that the Trust be terminated if the value of securities in such Trust falls below a specified amount.

Rule 803(i)(3) requires that members and member organizations provide to all purchasers of each series of Trust Shares a written description of the terms and characteristics of such securities, in a form approved by the Exchange, not later than the time a confirmation of the first transaction in such series of Trust Shares is delivered to such purchaser. In this regard, a member or member organization carrying an omnibus account for a non-member broker-dealer

⁸ Proposed Phlx Rule 803(i)(10) would provide that a determination to delist or suspend Trust Shares shall be based upon the criteria set forth in proposed Rule 803(i)(5)(B), applicable specifically to Trust Shares. Therefore, those criteria would apply rather than the criteria set forth in subsections (1) through (5) of Rule 810(a), which are applicable generally to securities other than Trust Shares. However, Exchange Rule 810(c), which provides that the Exchange may at any time suspend dealings in any security from listed or unlisted trading privileges, would continue to apply. Telephone conversations between Carla Behnfeldt, Counsel, Phlx and Gordon Fuller, Special Counsel, Division of Market Regulation ("Division"), Commission, and Steven Johnston, Special Counsel, Division, Commission (October 11, 2000).

will be required to inform such non-member that execution of an order to purchase Trust Shares for such omnibus account will be deemed to constitute an agreement by the non-member to make such written description available to its customers on the same terms as are directly applicable to member or member organizations. The written description must be included with any sales material on that series of Trust Shares that a member provides to the public. Moreover, other written materials provided by a member or member organization to the public making specific reference to a series of Trust Shares as an investment vehicle must include a statement in substantially the following form: "A circular describing the terms and characteristics of [the Trust Shares] is available from your broker. It is recommended that you obtain and review such circular before purchasing [the Trust Shares]. In addition, upon request you may obtain from your broker a prospectus for [the Trust Shares]." Additionally, the Exchange would require that members and member organizations provide customers with a copy of the prospectus for a series of Trust Shares upon request.

Finally, Rule 803(i)(10) provides the Exchange with the discretion, in its business judgment, not to charge a listing fee for a particular series of Trust Shares. It also clarifies that certain of the listing rules designed for application to other kinds of securities will not apply to Trust Shares.⁹

Trading of Trust Shares. Dealings in Trust Shares on the Exchange would be conducted pursuant to the Exchange's general agency-auction trading rules. The general dealing and settlement rules of the Phlx would apply, including its rules on clearance and settlement of securities transactions and its equity margin rules. Transactions on the Exchange in Nasdaq-100 Index Tracking Stock will be reported to the consolidated tape.¹⁰ Other generally applicable Exchange equity rules and procedures would also apply, including, among others, rules governing the priority, parity and precedence of orders and the responsibilities of specialists.¹¹

⁹ Rules 847 (Annual Meetings), 849 (Audit Committee/Conflict of Interest), 850 (Shareholder Approval Policy) and 851 (Independent Directors) all contemplate a corporate governance structure that has no meaning in the context of Trust Shares.

¹⁰ See Amendment No. 2.

¹¹ In SR-Phlx-99-41, which is pending before the Commission, the Phlx proposed new rules and rule amendments to accommodate the listing and trading of certain Trust Shares. As noted before, the Phlx intends to trade Trust Shares on the Nasdaq-

The Exchange is proposing procedures to govern the application of trading halts in Trust Shares. Phlx Rule 1047A currently governs trading rotations, halts and suspensions with respect to index option contracts. New Rule 136 provides that trading in Trust Shares will be halted on the same basis as trading in index options, as provided in Rule 1047A(c). Specifically, Rule 136 provides that trading on the Exchange in Trust Shares *may* be halted with the approval of two Floor Officials, with the concurrence of a Phlx Market Regulation officer, whenever trading on the primary market in underlying securities representing more than 10 percent of the current index value is halted or suspended. Trading would be *required* to be halted whenever two Floor Officials, with the concurrence of a Phlx Market Regulation officer, deem such action appropriate in the interests of a fair and orderly market and to protect investors. Among the factors that could be considered are: (1) Whether trading has been halted or suspended in the market that is the primary market for a plurality of underlying stocks; (2) whether the current calculation of the index derived from the current market prices of the stocks is not available; or (3) other unusual conditions or circumstances detrimental to the maintenance of a fair and orderly market are present. Additionally, the trading of Trust Shares would be halted, along with the trading of all other listed or traded stocks, if "circuit breaker" thresholds are reached.¹² The Exchange would issue a circular to its members and member organizations informing them of Exchange policies regarding trading halts in such securities.

UTP Trading of Nasdaq-100 Index Tracking Stock. As noted above, pursuant to Rule 12f-5 under the Act,¹³ the Exchange proposes to trade Nasdaq-100 Index Tracking Stock on a UTP basis under the proposed Trust Share rules discussed above. The Nasdaq-100 Trust is a unit investment trust sponsored by Nasdaq Investment Product Service, Inc. with a portfolio based on the component stocks of the Nasdaq-100 Index. The Exchange proposes to permit dealings in Nasdaq-

100 Index pursuant to UTP under the listing standards approved in this Order.

¹² See Phlx Rule 133 ("Trading Halts Due to Extraordinary Market Volatility") and Securities and Exchange Act Release No. 39846 (April 9, 1998), 63 FR 18477 (April 15, 1998) (establishing uniform market-wide "circuit breaker" thresholds among all domestic securities exchanges, and approving SR-Phlx-98-15).

¹³ 17 CFR 240.12f-5.

100 Tracking Stock in increments of $\frac{1}{64}$ of \$1.00.

These shares are currently traded on the American Stock Exchange ("Amex") in increments of $\frac{1}{64}$ of \$1.00 and, thus, the Exchange believes it is appropriate to trade these securities on the Exchange with the same minimum increment.¹⁴

Additionally, in connection with the Exchange's license agreement with the Nasdaq Stock Market ("Nasdaq") relating to, among other things, the use of the name "Nasdaq-100 Index Tracking Stock," and the disclaimers of liability relating to the Nasdaq-100 Index, the Exchange is proposing to adopt Commentary .01 to proposed Rule 803(i) to codify a rule governing disclaimers of liability relating to the Nasdaq-100 Index.¹⁵

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act¹⁶ in general and furthers the objectives of Section 6(b)(5)¹⁷ in particular in that it is designed to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest, and is not designed to permit unfair discrimination between customers, issuers, brokers or dealers. Specifically, the proposed rule change would increase competition in unit investment trust share markets by permitting Exchange members to compete for unit investment trust share order flow. The Exchange represents that the adoption of the proposed rule change would

¹⁴ See Securities Exchange Act Release No. 41119 (February 26, 1999), 64 FR 11510 (March 9, 1999), Nasdaq-100 Index Tracking Stock are also traded on a UTP basis by the Chicago Stock Exchange ("CHX"), the Boston Stock Exchange ("BSE") and the Pacific Exchange ("PCX") in increments of $\frac{1}{64}$ of \$1.00. See Securities Exchange Act Release No. 41605 (July 7, 1999), 64 FR 38060 (July 14, 1999); Securities Exchange Act Release No. 41664 (July 27, 1999), 64 FR 42424 (August 4, 1999); and Securities Exchange Act Release No. 41712 (August 5, 1999), 64 FR 44072.

¹⁵ The Phlx represents that the language of the disclaimer rule is substantially similar to BSE Chapter XXIV, Section 7, CHX Article XXVIII, Rule 25 and PCX Rule 8.300(g). The Phlx also represents that the language of the disclaimer rule is nearly identical to that adopted by Amex and approved in Securities Exchange Act Release No. 41119 (February 26, 1999), 64 FR 11510; and Securities Exchange Act Release No. 41562 (June 25, 1999), 64 FR 36057 (July 2, 1999).

¹⁶ 15 U.S.C. 78f(b).

¹⁷ 15 U.S.C. 78f(b)(5).

result in increased efficiency and price competition in those markets.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Phlx does not believe that the proposed rule change would impose any inappropriate burden on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Phlx has requested that the proposed rule change, as amended, be given accelerated effectiveness pursuant to Section 19(b)(2) of the Act.

IV. Commission's Findings and Order Granting Accelerated Approval of Proposed Rule Change

After careful consideration, the Commission finds that the proposed rule change, as amended, is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange, and, in particular, with the requirements of Section 6(b)(5).¹⁸

A Trust Share is an interest in a Trust holding a portfolio of securities linked to an index. Each Trust is intended to provide investors with an instrument that closely tracks the underlying securities index or portfolio, trades like a share of common stock, and pays holders a periodic cash payment proportionate to the dividends paid on the underlying portfolio of securities.¹⁹ The definition of Trust Share is therefore substantively identical to the definition of PDRs or IPRs as those definitions appear in the previously approved rules of the Amex and CBOE, respectively.²⁰ The Phlx rule change proposal itself is also substantively identical to proposals filed by CBOE, BSE, CHX, and PCX, and approved by the Commission.²¹ Therefore, this

proposal raises no new regulatory issues.

Moreover, the Commission believes that Amendment Nos. 1 and 2 are reasonable. Specifically, the new rule language regarding hours of trading, and the undertaking by Phlx to report transactions in Trust Shares to the Phlx consolidated tape, brings the proposal into conformity with the Amex's listing standards for PDRs, which the Commission previously approved.²² In addition, the Commission believes that it is reasonable for the Phlx to amend its PACE rule to provide automatic price improvement for trades in Nasdaq-100 Index Tracking Stock in increments of $\frac{1}{64}$ (instead of $\frac{1}{16}$) where the Pace Quote²³ is $\frac{1}{16}$ (instead of $\frac{3}{16}$ to $\frac{1}{8}$) or greater. These changes are appropriate because Nasdaq-100 Index Tracking Stock currently trades in increments of $\frac{1}{64}$ instead of $\frac{1}{16}$.

The Commission emphasizes that this Order only approves the trading of Nasdaq-100 Index Tracking Stock under the listing standards approved herein. If the Phlx wishes to list and trade additional series of Trust Shares, it may be required to file a proposed rule change with the Commission under Section 19(b)(1) of the Act.²⁴

The Commission finds good cause for approving the proposed rule change, as amended, prior to the thirtieth day after the date of publication of notice thereof in the **Federal Register** pursuant to Section 19(b)(2) of the Act²⁵ in order to expand investor choice and encourage competition among exchanges for order flow related to essential identical securities products.

V. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change, as amended, is consistent with the Act. Persons making written submissions should file six copies thereof with the Secretary, Securities

and Exchange Commission, 450 Fifth Street, NW, Washington, DC 20549-0609. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room. Copies of such filing will also be available for inspection and copying at the principal office of the Phlx. All submissions should refer to File No. SR-Phlx-00-54 and should be submitted by January 12, 2001.

VI. Conclusion

It Is Therefore Ordered, pursuant to Section 19(b)(2) of the Act²⁶ that SR-Phlx-00-54 is hereby approved on an accelerated basis.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.²⁷

Margaret H. McFarland,
Deputy Secretary.

[FR Doc. 00-32653 Filed 12-21-00; 8:45 am]

BILLING CODE 8010-010-M

SMALL BUSINESS ADMINISTRATION

Global Environment Strategic Technology Partners, L.P. (Applicant No. 99000410); Notice Seeking Exemption Under Section 312 of the Small Business Investment Act, Conflicts of Interest

Notice is hereby given that Global Environment Strategic Technology Partners, L.P., 1225 Eye Street, NW., Suite 900 Washington DC 20005, an applicant for a Federal License under the Small Business Investment Act of 1958, as amended ("the Act"), in connection with the financing of a small concern, has sought an exemption under section 312 of the Act and section 107.730, *Financings which Constitute Conflicts of Interest of the Small Business Administration* ("SBA") rules and regulations (13 CFR 107.730 (2000)). Global Environment Strategic Technology Partners, L.P., proposes to provide equity financing to Athena Technologies, Inc., 9950 Wakeman Drive Manassas Virginia 20110. The financing is contemplated for research and development.

²⁵ *Id.*

²⁷ 17 CFR 200.30-3(a)(12).

¹⁸ 15 U.S.C. 78f(b)(5).

¹⁹ In approving this rule, the Commission has considered the proposed rule change's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

²⁰ See Securities Exchange Act Release No. 31591 (December 11, 1992), 57 FR 60253 (December 18, 1992) (approving Amex Rules 1000 *et seq.* regarding listing standards for PDRs); Securities Exchange Act Release No. 39581 (January 26, 1998), 63 FR 5579 (February 3, 1998) (approving CBOE rules regarding listing standards for IPRs).

²¹ See Securities Exchange Act Release No. 39581 (January 26, 1998), 63 FR 5579 (February 3, 1998) (approving CBOE rules regarding listing and trading standards for IPRs); Securities Exchange Act

Release No. 39660 (February 12, 1998), 63 FR 9026 (February 23, 1998) (approving BSE rules regarding listing and trading standards for PDRs); Securities Exchange Act Release No. 39076 (September 15, 1997), 62 FR 49270 (September 19, 1997) (approving CSE rules regarding listing and trading standards for PDRs); and Securities Exchange Act Release No. 39461 (December 17, 1997), 62 FR 67674 (December 29, 1997) (approving PCX rules relating to listing and trading standards for PDRs).

²² See *supra* note 20.

²³ Phlx Rule 229 defines the PACE Quote as the best bid/ask quote among the American, Boston, Cincinnati, Chicago, New York, Pacific or Philadelphia Stock Exchanges, or the Intermarket Trading System/Computer Assisted Execution System ("ITS/CAES") quote, as appropriate.

²⁴ 15 U.S.C. 78s(b)(2).

²⁵ *Id.*

The financing is brought within the purview of Sec. 107.730(a)(1) of the Regulations because Global Environment Capital Co., LLC, an Associate of Global Environment Strategic Technology Partners, L.P., currently owns greater than 10 percent of Athena Technologies, Inc. and therefore Athena Technologies, Inc. is considered an Associate of Global Environment Strategic Technology Partners, L.P., as defined in § 107.50 of the regulations.

Notice is hereby given that any interested person may submit written comments on the transaction to the Associate Administrator for Investment, U.S. Small Business Administration, 409 Third Street, SW., Washington, DC 20416.

Dated: December 12, 2000.

Don A. Christensen,

Associate Administrator for Investment.

[FR Doc. 00-32626 Filed 12-21-00; 8:45 am]

BILLING CODE 8025-01-P

SMALL BUSINESS ADMINISTRATION

(Declaration of Disaster #3309) State of Oklahoma; (Amendment #2)

In accordance with information received from the Federal Emergency Management Agency dated December 8, 2000, the above-mentioned Declaration is hereby amended to include Oklahoma County in the State of Oklahoma as a disaster area due to damages caused by severe storms and flooding beginning on October 21, 2000 and continuing through October 29, 2000.

In addition, applications for economic injury loans from small businesses located in the following contiguous counties may be filed until the specified date at the previously designated location: Kingfisher, Lincoln, Logan, and Pottawatomie Counties in Oklahoma.

Any counties contiguous to the above-named primary counties and not listed herein have been previously declared.

All other information remains the same, *i.e.*, the deadline for filing applications for physical damage is January 26, 2001, and for economic injury the termination date is August 27, 2001.

(Catalog of Federal Domestic Assistance Program Nos. 59002 and 59008)

Dated: December 14, 2000.

Herbert L. Mitchell,

Acting Associate Administrator for Disaster Assistance.

[FR Doc. 00-32625 Filed 12-21-00; 8:45 am]

BILLING CODE 8025-01-U

DEPARTMENT OF STATE

[Public Notice 3517]

Office of Visa Services; Sixty-Day Notice of Proposed Information Collection (OMB 1405-0096); Nonimmigrant Fiance(e) Visa Application, DS-2052 (formerly OF-156K)

AGENCY: Department of State.

ACTION: Notice.

SUMMARY: The Department of State is seeking Office of Management and Budget (OMB) approval for the information collection described below. The purpose of this notice is to allow 60 days for public comment in the **Federal Register** preceding submission to OMB. This process is conducted in accordance with the Paperwork Reduction Act of 1995.

The following summarizes the information collection proposal submitted to OMB:

Type of Request: Extension of currently approved collection.

Originating Office: Bureau of Consular Affairs, Office of Visa Services (CA/VO).

Title of Information Collection: Nonimmigrant Fiance(e) Visa Application.

Frequency: Once.

Form Number: DS-2052 (formerly OF-156K).

Respondents: All nonimmigrant fiance(e) visa applicants.

Estimated Number of Respondents: 18,500.

Average Hours Per Response: 2 hours.

Total Estimated Burden: 37,000 hours.

Public comments are being solicited to permit the agency to:

- Evaluate whether the proposed information collection is necessary for the proper performance of the functions of the agency.

- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection, including the validity of the methodology and assumptions used.

- Enhance the quality, utility, and clarity of the information to be collected.

- Minimize the reporting burden on those who are to respond, including through the use of automated collection techniques or other forms of technology.

FOR ADDITIONAL INFORMATION: Public comments, or requests for additional information, regarding the collection listed in this notice should be directed to Eric Cohan, 2401 E ST NW, RM L-703, Tel: 202-663-1164, U.S. Department of State, Washington, DC 20520.

Dated: December 8, 2000.

George Lannon,

Deputy Assistant Secretary of State for Visa Services, Bureau of Consular Affairs, Department of State.

[FR Doc. 00-32744 Filed 12-21-00; 8:45 am]

BILLING CODE 4710-06-U

DEPARTMENT OF STATE

[Public Notice 3518]

Office of Visa Services; Sixty-Day Notice of Proposed Information Collection (OMB 1405-0101); Nonimmigrant Treaty Trader/Investor Application, DS-2051 (formerly OF-156E)

AGENCY: Department of State.

ACTION: Notice.

SUMMARY: The Department of State is seeking Office of Management and Budget (OMB) approval for the information collection described below. The purpose of this notice is to allow 60 days for public comment in the **Federal Register** preceding submission to OMB. This process is conducted in accordance with the Paperwork Reduction Act of 1995.

The following summarizes the information collection proposal submitted to OMB:

Type of Request: Extension of currently approved collection.

Originating Office: Bureau of Consular Affairs, Office of Visa Services (CA/VO).

Title of Information Collection: Nonimmigrant Treaty Trader/Investor Application.

Frequency: Once.

Form Number: DS-2051 (formerly OF-156E).

Respondents: All nonimmigrant treaty trader/investor visa applicants.

Estimated Number of Respondents: 17,000.

Average Hours Per Response: 2 hours.

Total Estimated Burden: 34,000 hours.

Public comments are being solicited to permit the agency to:

- Evaluate whether the proposed information collection is necessary for the proper performance of the functions of the agency.

- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection, including the validity of the methodology and assumptions used.

- Enhance the quality, utility, and clarity of the information to be collected.

- Minimize the reporting burden on those who are to respond, including

through the use of automated collection techniques or other forms of technology.

FOR ADDITIONAL INFORMATION: Public comments, or requests for additional information, regarding the collection listed in this notice should be directed to Eric Cohan, 2401 E ST, NW, RM L-703, Tel: 202-663-1164, U.S. Department of State, Washington, DC 20520.

Dated: December 8, 2000.

George Lannon,

Deputy Assistant Secretary of State for Visa Services, Bureau of Consular Affairs, Department of State.

[FR Doc. 00-32745 Filed 12-21-00; 8:45 am]

BILLING CODE 4710-06-U

DEPARTMENT OF STATE

[Public Notice 3519]

Office of Visa Services; Sixty-Day Notice of Proposed Information Collection (OMB 1405-0091); Application To Determine Returning Resident Status, DSP-117

AGENCY: Department of State.

ACTION: Notice.

SUMMARY: The Department of State is seeking Office of Management and Budget (OMB) approval for the information collection described below. The purpose of this notice is to allow 60 days for public comment in the **Federal Register** preceding submission to OMB. This process is conducted in accordance with the Paperwork Reduction Act of 1995.

The following summarizes the information collection proposal submitted to OMB:

Type of Request: Extension of currently approved collection.

Originating Office: Bureau of Consular Affairs, Office of Visa Services (CA/VO).

Title of Information Collection: Application to Determine Returning Resident Status.

Frequency: Once.

Form Number: DSP-117.

Respondents: All applicants for returning resident status.

Estimated Number of Respondents: 1,000.

Average Hours Per Response: 0.5 hours.

Total Estimated Burden: 500 hours.

Public comments are being solicited to permit the agency to:

- Evaluate whether the proposed information collection is necessary for the proper performance of the functions of the agency.
- Evaluate the accuracy of the agency's estimate of the burden of the

proposed collection, including the validity of the methodology and assumptions used.

- Enhance the quality, utility, and clarity of the information to be collected.
- Minimize the reporting burden on those who are to respond, including through the use of automated collection techniques or other forms of technology.

FOR ADDITIONAL INFORMATION: Public comments, or requests for additional information, regarding the collection listed in this notice should be directed to Eric Cohan, 2401 E ST NW, RM L-703, Tel: 202-663-1164, U.S. Department of State, Washington, DC 20520.

Dated: December 8, 2000.

George Lannon,

Deputy Assistant Secretary of State for Visa Services, Bureau of Consular Affairs, Department of State.

[FR Doc. 00-32746 Filed 12-21-00; 8:45 am]

BILLING CODE 4710-06-U

DEPARTMENT OF STATE

Office of Visa Services

[Public Notice 3516]

60-Day Notice of Proposed Information Collection (OMB 1405-0015); Application for Immigrant Visa and Alien Registration, DS-2083 (Formerly OF-230)

AGENCY: Department of State.

ACTION: Notice.

SUMMARY: The Department of State is seeking Office of Management and Budget (OMB) approval for the information collection described below. The purpose of this notice is to allow 60 days for public comment in the **Federal Register** preceding submission to OMB. This process is conducted in accordance with the Paperwork Reduction Act of 1995.

The following summarizes the information collection proposal submitted to OMB:

Type of Request: Extension of Currently Approved Collection.

Originating Office: Bureau of Consular Affairs, Office of Visa Services (CA/VO).

Title of Information Collection: Application for Immigrant Visa and Alien Registration.

Frequency: Once.

Form Number: DS-2083 (formerly OF-230).

Respondents: All immigrant visa applicants.

Estimated Number of Respondents: 750,000.

Average Hours Per Response: 2 hours.
Total Estimated Burden: 1,500,000 hours.

Public comments are being solicited to permit the agency to:

- Evaluate whether the proposed information collection is necessary for the proper performance of the functions of the agency.
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection, including the validity of the methodology and assumptions used.
- Enhance the quality, utility, and clarity of the information to be collected.
- Minimize the reporting burden on those who are to respond, including through the use of automated collection techniques or other forms of technology.

FOR ADDITIONAL INFORMATION: Public comments, or requests for additional information, regarding the collection listed in this notice should be directed to Eric Cohan, 2401 E St., NW, RM L-703, Tel: 202-663-1164, U.S. Department of State, Washington, DC 20520.

Dated: December 8, 2000.

George Lannon,

Deputy Assistant Secretary of State for Visa Services, Bureau of Consular Affairs, U.S. Department of State.

[FR Doc. 00-32743 Filed 12-21-00; 8:45 am]

BILLING CODE 4710-06-P

OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

Trade Policy Staff Committee; Public Comments on Proposed United States-Singapore Free Trade Agreement

AGENCY: Office of the United States Trade Representative.

ACTION: Notice of extension of time to provide comments.

SUMMARY: This publication gives notice that the Trade Policy Staff Committee (TPSC) is extending the deadline for the public to provide written comments to assist the United States Trade Representative (USTR) in formulating objectives for the negotiations with the Republic of Singapore to conclude a free trade agreement and to provide advice on how specific goods and services and other matters should be treated under the agreement.

DATES: Public comments should be received by noon, January 5, 2001.

FOR FURTHER INFORMATION CONTACT: For procedural questions concerning public comments, contact Gloria Blue, Executive Secretary, TPSC, Office of the

USTR, 600 17th Street, NW., Washington, DC 20508 (202) 395-3475. All other questions regarding the negotiations should be addressed to Barbara Weisel, Deputy Assistant US Trade Representative for Bilateral Asian Affairs, Office of the USTR (202) 395-6813.

SUPPLEMENTARY INFORMATION: On November 16, 2000, President Clinton agreed with Singapore's Prime Minister Goh Chok Tong to negotiate a bilateral free trade agreement. In the negotiations, the United States and Singapore will seek to eliminate duties and commercial barriers to bilateral trade in U.S.-and Singaporean-origin goods and also expect to address trade in services, investment, trade-related aspects of intellectual property rights, trade-related environmental and labor matters, and other issues. Two-way trade between the United States and Singapore totaled \$34.4 billion in 1999. The free trade agreement will be modeled upon the recently signed free trade agreement between Jordan and the United States, but will recognize the substantial volume of trade between Singapore and the United States.

In a notice published in the **Federal Register** on November 29, 2000, USTR requested written comments from the public to assist USTR in formulating negotiating objectives for the agreement and to provide advice on how specific goods and services and other matters should be treated under the agreement, to be submitted no later than December 19, 2000. USTR has decided to extend the deadline for submission of comments to January 5, 2001. 65 FR 71197.

Written Comments

Written comments should conform to the instructions indicated in the notice published on November 29, 2000.

Carmen Suro-Bredie,

Chair, Trade Policy Staff Committee, Office of the U.S. Trade Representatives.

[FR Doc. 00-32646 Filed 12-21-00; 8:45 am]

BILLING CODE 3190-01-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Agency Information Collection Activity Under OMB Review

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), this notice

announces that the Information Collection Request (ICR) abstracted below has been forwarded to the Office of Management and Budget (OMB) for extension of currently approved collection. The ICR describes the nature of the information collection and the expected burden. The **Federal Register** Notice with a 60-day comment period soliciting comments on the following collections of information was published on October 2, 2000, [FR 65, page 58838].

DATES: Comments must be submitted on or before January 22, 2001. A comment to OMB is most effective if OMB receives it within 30 days of publication.

FOR FURTHER INFORMATION CONTACT: Judy Street on (202) 267-9895.

SUPPLEMENTARY INFORMATION:

Federal Aviation Administration (FAA)

Title: Notice of Landing Area Proposal.

Type of Request: Extension of a currently approved collection.

OMB Control Number: 2120-0036.

Form(s): FAA Form 7480-1.

Affected Public: Anyone who intends to construct, activate, deactivate, or change the status of an airport, runway or taxiway. An average of 3,868 respondents.

Abstract: 14 CFR part 157 requires that each person who intends to construct, activate, deactivate, or change the status of an airport, runway or taxiway shall notify the FAA.

Estimated Annual Burden Hours: 2,901.

ADDRESSES: Send comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725-17th Street, NW, Washington, DC 20503, Attention FAA Desk Officer.

Comments are Invited on: Whether the proposed Collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; the accuracy of the Department's estimate of the burden of the proposed information collection; ways to enhance the quality, utility and clarity of the information to be collected; and ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques or other forms of information technology.

Issued in Washington, DC, on December 19, 2000.

Steve Hopkins,

Manager, Standards and Information Division, APF-100.

[FR Doc. 00-32734 Filed 12-21-00; 8:45 am]

BILLING CODE 4910-13-M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Agency Information Collection Activity Under OMB Review

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), this notice announces that the Information Collection Request (ICR) abstracted below has been forwarded to the Office of Management and Budget (OMB) for an extension of the currently approved collection. The ICR describes the nature of the information collection and the expected burden. The **Federal Register** Notice with a 60-day comment period soliciting comments on the following collections of information was published on June 30, 2000 (FR 65, page 40716).

DATES: Comments must be submitted on or before January 22, 2001. A comment to OMB is most effective if OMB receives it within 30 days of publication.

FOR FURTHER INFORMATION CONTACT: Judy Street on (202) 267-9895.

SUPPLEMENTARY INFORMATION:

Federal Aviation Administration (FAA)

Title: Pilot Records Improvement Act of 1996.

Type of Request: Extension of a currently approved collection.

OMB Control Number: 2120-0607.

Form(s): FAA Forms 8060-10 and 8060-11.

Affected Public: Air Carriers.

Abstract: 49 U.S.C. 44936(f)(1), mandates that all air carriers request and receive FAA records, air carrier and other records, and National Driver Register records before allow an individual to begin service as a pilot. An air carrier may use the forms to request the records of all applicants for the position of pilot. The information collected on the form will be used to facilitate search and retrieval of the requested records.

Estimated Annual Burden Hours: 101,708 burden hours annually.

ADDRESSES: Send comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725—17th Street, NW., Washington, DC 20503, Attention FAA Desk Officer.

Comments are invited on: Whether the proposed collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; the accuracy of the Department's estimate of the burden of the proposed information collection; ways to enhance the quality, utility and clarity of the information to be collected; and ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques or other forms of information technology.

Issued in Washington, DC, on December 18, 2000.

Steve Hopkins,

Manager, Standards and Information Division.

[FR Doc. 00-32735 Filed 12-21-00; 8:45 am]

BILLING CODE 4910-13-M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Agency Information Collection Activity Under OMB Review

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), this notice announces that the Information Collection Request (ICR) abstracted below has been forwarded to the Office of Management and Budget (OMB) for extension of the currently approved collection. The ICR describes the nature of the information collection and the expected burden. The Federal Register Notice with a 60-day comment period soliciting comments on the following collections of information was published on October 2, 2000 (FR 65, page 58838).

DATES: Comments must be submitted on or before January 22, 2001. A comment to OMB is most effective if OMB receives it within 30 days of publication.

FOR FURTHER INFORMATION CONTACT: Judy Street on (202) 267-9895.

SUPPLEMENTARY INFORMATION:

Federal Aviation Administration (FAA)

Title: Special Federal Aviation Regulation No. 71.

Type of Request: Extension of a currently approved collection.

OMB Control Number: 2120-0620.

Form(s): N/A.

Affected Public: Air tour operators in Hawaii.

Abstract: Special Federal Aviation Regulation (SFAR) No. 71 applies to air tour operators in Hawaii. The SFAR requires Part 121 and 135 air tour operators to verbally brief the passengers on safety, particularly related to overwater operations before each air tour flight.

Estimated Annual Burden Hours: 6,667 burden hours annually.

ADDRESSES: Send comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725—17th Street, NW, Washington, DC 20503, Attention FAA Desk Officer.

Comments are invited on: Whether the proposed Collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; the accuracy of the Department's estimate of the burden of the proposed information collection; ways to enhance the quality, utility and clarity of the information to be collected; and ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques or other forms of information technology.

Issued in Washington, DC, on December 15, 2000.

Steve Hopkins,

Manager, Standards and Information Division.

[FR Doc. 00-32736 Filed 12-21-00; 8:45am]

BILLING CODE 4910-13-M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Definition of Terms Applicable to In-Flight Icing Events

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of intent.

SUMMARY: This document contains proposed definitions of inflight icing terminology to be used by the FAA and other aviation related entities. Some commonly used terms have been changed for clarification. One term was eliminated from official usage while others have been introduced for the first time in order to meet the requirements of a changing technological environment. The FAA solicits public comment on these proposed definitions.

DATES: Send your comments on or before January 22, 2000.

ADDRESSES: Address your comments to the Docket Management System, U.S. Department of Transportation, Room PL401, 400 Seventh Street, SW., Washington, DC. You must identify Docket Number FAA-2000-8560 at the beginning of your comments.

You may also submit comments through the Internet to <http://dms.dot.gov>. You may also review the entire public docket for this notice at that same site. You may also review the public docket in person in the Docket Office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Docket Office is on the plaza level of the Department of Transportation.

FOR FURTHER INFORMATION CONTACT: Daniel Meier, Flight Standards Service, Federal Aviation Administration, 800 Independence Avenue, SW, Washington, DC 20591; Telephone: (202) 267-3749.

SUPPLEMENTARY INFORMATION:

Comments Invited

Anyone may participate in this proposal by providing such written data, views, or arguments. Identify the regulatory docket and submit your comments to the DOT Rules Docket address specified above.

The FAA will file all comments received, as well as a report summarizing each substantive public contact with FAA personnel on this rulemaking. The docket is available for public inspection before and after the comment closing date.

The FAA will consider all comments received on or before the closing date before we take action on this proposal. We will consider comments received late as far as possible without incurring expense or delay.

If you want the FAA to acknowledge receipt of your comments, include a pre-addressed, stamped postcard with those comments. On the card write "Comments to Docket No. FAA-2000-8560." We will date stamp the card and mail it back to you.

Availability of This Notice

You can get an electronic copy of this notice from the docket with the following steps:

- (1) Go to the search function of the Department of Transportation's electronic Docket Management system (DMS) web page (<http://dms.dot.gov/search>).
- (2) On the search page, type in the last four digits of the Docket number shown at the beginning of this document. Click on "search".

(3) On the next page, which contains the Docket summary information for the Docket you selected, click on the notice.

You can also get an electronic copy using the Internet through the Federal Register's web page at http://www.access.gpo.gov/su_docs/aces/acrs140.htm.

You can also get a copy of this notice by mail by submitting a request to the Federal Aviation Administration, at the address given under for **FOR FURTHER INFORMATION CONTACT**.

Background

Following the icing conference of 1996 the FAA devised a plan to accomplish the recommendations and concerns which arose from that conference. To satisfy one of its responsibilities under the in-flight Icing Plan, the FAA undertook the task of clarifying and redefining icing terminology applied to in-flight operations. The FAA was to: First, ensure that this icing terminology (*e.g.*, known, forecast, observed, trace, light, moderate, severe, and "Appendix C" icing) is used consistently and clearly by the Flight Standards Service, pilots, dispatchers, the National Weather Service (NWS), Aviation Weather Center, the Aircraft Certification Service, and Air Traffic; and second, to update guidance related to icing reporting and pilot, Air Traffic Control, and dispatcher actions.

To accomplish these objectives the FAA established the Task 1B working group (WG) which comprised representatives from FAA, National Oceanic and Atmospheric Administration (NOAA), and the University Corporation for Atmospheric Research (UCAR). The goal of the WG was to review the definitions of all icing-related terms that appear in government aviation regulations, weather-related handbooks, aircraft flight manuals, etc. Based on its findings, the WG was to make recommended changes to the definitions where they needed to be updated or improved. These recommendations would endeavor to eliminate misunderstanding in their use among and between the previously mentioned sources.

This work was accomplished through a series of meetings by the WG, and the result was a set of proposed definitions for in-flight icing terminology. The WG did not consider or propose any changes to the aviation regulations or icing forecasting procedures, although it became clear to the WG that existing regulatory wording and existing policy within the U.S. National Weather Service (NWS) and the International

Civil Aviation Organization (ICAO) limited the freedom of the WG to change the icing-related terms in use.

Discussion

The following is a list of terms recommended by the Task 1b terminology sub-committee as an updated replacement for current terminology used in reference to in-flight icing of aircraft. The FAA intends to update the current terminology with the following proposed terms that the FAA is presenting, in this publication, for public comment. The term "trace ice" has been eliminated from the in-flight icing vocabulary. The definition of trace ice implied that it was not hazardous to flight, however, experience and research have shown that trace ice can be hazardous in certain conditions. It follows therefore that if trace ice can be hazardous, then light and moderate icing intensity can also be hazardous. Additionally, eliminating the term "trace ice" complies with NTSB recommendations A-98-88 which states: "Amend the definition of trace ice contained in Federal Aviation Administration (FAA) Order 7110.10L, "Flight Services" (and in other FAA documents as applicable) so that it does not indicate that trace icing is not hazardous."

Proposed Definitions

Light ¹

The rate of ice accumulation may require occasional use of ice protection systems to remove/prevent accumulation.

Moderate ²

The rate of ice accumulation is such that frequent use of ice protection systems is necessary.

Severe ³

The rate of ice accumulation is such that ice protection systems fail to remove the accumulation of ice.

Note: Ice types are not used in forecasting or pilot reports and have no relevance as to effects on an airplane in flight. They will be removed from the AIM, but for other purposes the following definitions are proposed for inclusion in the AIM.)

¹ A representative accretion rate for forecasting or reference purposes is 1/4 inch in 15 minutes to an hour on outer wing or tailplane (prior to activation of any ice protection equipment).

² A representative accretion rate for forecasting or reference purposes is 1/4 inch in 5 to 15 minutes to an hour on outer wing or tailplane (prior to activation of any ice protection equipment).

³ A representative accretion rate for forecasting or reference purposes is 1/4 inch in 15 minutes to an hour on outer wing or tailplane (prior to activation of any ice protection equipment).

Rime Ice

A rough, milky, opaque ice formed by the instantaneous freezing of supercooled water drops as they strike the aircraft. The fact that the droplets maintain their nearly spherical shape upon freezing and thus trap air between them gives the ice its opaque appearance and makes it porous and brittle.

Glaze Ice

A coating of ice, sometimes clear and smooth, but usually containing some air pockets which result in a lumpy translucent appearance. Glaze ice results from supercooled liquid water striking a surface but not freezing instantaneously on contact. Glaze ice is denser, harder and sometimes more transparent than rime ice. Factors, which favor glaze formation, are those that favor slow dissipation of the heat of fusion (*i.e.* slight supercooling and rapid accretion).

Clear Ice

A glossy, transparent ice formed by the relatively slow freezing of supercooled water droplets.

Mixed Ice

Simultaneous appearance or a combination of rime and clear ice.

Known or Observed/Detected Icing

Actual ice observed visually on the aircraft by the flight crew, or identified by on-board sensors.

Forecast Icing Conditions

Environmental conditions expected by the approved weather service to be conducive to the formation of in-flight icing on aircraft.

Potential Icing Conditions

Atmospheric conditions conducive to ice accretion on aircraft components. Visible moisture and temperatures colder than a specific temperature typically define these conditions. The aircraft manufacturer normally defines these conditions.

Known Icing Conditions

Atmospheric conditions in which the formation of ice is observed or detected in flight. (Note: Because of the variability in space and time of atmospheric conditions, the existence of a report of known icing does not assure the presence or intensity of icing conditions at a later time, nor can a report of no icing assure the absence of icing conditions at a later time.)

Freezing Rain (FZRA)

Rain is precipitation on the ground or aloft in the form of liquid water drops which have diameters greater than 0.5mm. Freezing rain is rain that exists at air temperatures less than 0 degrees C, remains in liquid form, and freezes upon contact with objects on the surface or airborne. While the temperature of the ground and glazed objects initially must be near or below freezing, it is necessary that the water drops be supercooled before striking. When encountered by an aircraft in flight, freezing rain can cause a dangerous accretion of icing.

Freezing Precipitation

Freezing precipitation is freezing rain or freezing drizzle.

Freezing Drizzle (FZDZ)

Drizzle is precipitation on the ground or aloft in the form of liquid water drops which have diameters less than 0.5mm and greater than 0.05mm. Freezing drizzle is drizzle that exists at air temperatures less than 0 degrees C, remains in liquid form, and freezes upon contact with objects on the ground or airborne. While the temperature of the ground surface and glazed objects initially must be near or below freezing, it is necessary that the water drops be supercooled before striking. When encountered by an aircraft in flight, freezing drizzle can cause a dangerous accretion of icing.

Icing in Precipitation

Icing resulting from an encounter with freezing precipitation, that is, supercooled drops with diameters exceeding 50 microns (defined as SLD, which includes both freezing drizzle and freezing rain). The Precipitation may be either within or outside of (usually below) the visible cloud.

Icing in Cloud

Icing occurring within cloud (visible moisture) and temperature below freezing, but without precipitation visible. Cloud droplets (diameters <50 microns) will be present. SLD may or may not be present.

Supercooled Large Drops (SLD)

SLD includes freezing rain or freezing drizzle.

Supercooled Drizzle Drops (SCDD)

Are synonymous with freezing drizzle aloft.

Appendix C Icing Conditions

Conditions for ice protection certification found in Appendix C of CFR 14 part 25.

L. Nicholas Lacey,

Director of Flight Standards.

[FR Doc. 00-32526 Filed 12-21-00; 8:45 am]

BILLING CODE 4910-13-M

DEPARTMENT OF TRANSPORTATION**Federal Aviation Administration**

**RTCA Special Committee 188;
Minimum Aviation System
Performance Standards For High
Frequency Data Link**

Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463, 5 U.S.C., Appendix 2), notice is hereby given for Special Committee 188 meeting to be held January 18, 2001, starting at 1 p.m. The meeting will be held at RTCA, Inc., 1140 Connecticut Avenue, NW., Suite 1020, Washington, DC 20036.

The agenda will include: (1) Welcome and Introduction of the New Chairman, SC-188; (2) Opening comments; (3) WG-1, High Frequency Data Link Minimum Operational Performance (MOPS), Status Report and Future Plans; (4) WG-2, High Frequency Data Link Minimum Aviation System Performance Standards (MASPS), (5) Review Action Items; (6) Date and Location of Next Meeting; (7) Other Business; (8) Closing.

Attendance is open to the interested public but limited to space availability. With the approval of the chairman, members of the public may present oral statements at the meeting. Persons wishing to present statements or obtain information should contact the RTCA Secretariat, 1140 Connecticut Avenue, NW., Suite 1020, Washington, DC 20036; (202) 833-9339 (phone); (202) 833-9434 (fax); or <http://www.rtca.org> (web site). Members of the public may present a written statement to the committee at any time.

Issued in Washington, DC, on December 18, 2000.

Janice L. Peters,

Designated Official.

[FR Doc. 00-32732 Filed 12-21-00; 8:45 am]

BILLING CODE 4910-13-M

DEPARTMENT OF TRANSPORTATION**Federal Aviation Administration**

**RTCA Special Committee 196; Night
Vision Goggle (NVG) Appliances &
Equipment**

Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (P.L. 92-463, 5 U.S.C., Appendix 2), notice is hereby given for Special Committee (SC)-196 meeting to be held January 8-10, starting at 8:00 a.m. each day. The meeting will be held at RTCA, Inc., 1140 Connecticut Avenue, N.W., Suite 1020, Washington, DC 20036.

The agenda will include: (1) Welcome and Introductory Remarks; (2) Agenda Overview; (3) Review/Approval of Previous Meeting Minutes; (4) Action Item Status Review; (5) Overview of SC-196 Working Group (WG) Activities: (a) WG-1, Operational Concept/Requirements; (b) WG-2, Night Vision Goggles Minimum Operational Performance Standards; (c) WG-3, Night Vision Imaging System Lighting; (d) WG-4, Maintenance/Serviceability; (e) WG-5, Training Guidelines/Considerations; (6) WG-1 Comments Review; (7) Operational Concept/Requirements PMC Comment Process; (8) Open Issue List Review; (9) Other Business; (10) Establish Agenda for Next Meeting; (11) Date and Location of Next Meeting; (12) Working Group Chairperson meeting; (13) Closing.

Attendance is open to the interested public but limited to space availability. With the approval of the chairman, members of the public may present oral statements at the meeting. Persons wishing to present statements or obtain information should contact the RTCA Secretariat, 1140 Connecticut Avenue, NW., Suite 1020, Washington, DC, 20036; (202) 833-9339 (phone); (202) 833-9434 (fax); or <http://www.rtca.org> (web site). Members of the public may present a written statement to the committee at any time.

Issued in Washington, DC, on December 18, 2000.

Janice L. Peters,

Designated Official.

[FR Doc. 00-32733 Filed 12-21-00; 8:45 am]

BILLING CODE 4910-13-M

DEPARTMENT OF TRANSPORTATION**Surface Transportation Board****[STB Finance Docket No. 33407]****Dakota, Minnesota & Eastern Railroad Corporation Construction Into the Powder River Basin**

AGENCY: Lead: Surface Transportation Board. Cooperating: U.S.D.A Forest Service; U.S.D.I. Bureau of Land Management; U.S. Army Corps of Engineers; U.S.D.I. Bureau of Reclamation; U.S. Coast Guard.

ACTION: Extension of public comment period on Draft Environmental Impact Statement.

On September 27, 2000, the Draft Environmental Impact Statement (EIS) was issued in this proceeding. The Draft EIS provided a 90-day period (to and including January 5, 2001) for interested parties to submit comments.

The Board's Section of Environmental Analysis (SEA) and the cooperating agencies¹ have received requests from a wide variety of groups and individuals, including several public officials and the U.S. Environmental Protection Agency, to extend the January 5, 2001 comment due date. The majority of the requests ask for a 90-day extension, generally citing the length of the Draft EIS and the scope and complexity of the proposal. While a few commenters argue that no extension is necessary, others have asked for as much as a 6-month or 1-year extension of time.

Discussion and Conclusions

In establishing a 90-day comment period—which is twice as long as the minimum set forth in the Council on Environmental Quality's Guidelines (40 CFR 1506.10)—SEA believed that all interested parties would have sufficient time to review and comment on the Draft EIS. However, during the same time the public is reviewing and preparing comments on the Draft EIS, SEA and the cooperating agencies are also seeking public comment on the other documents contained in it (U.S. Forest Service Forest Plan Amendments, the Programmatic Agreement and Identification Plan, the Memorandum of Agreement, and the Biological Assessment). In addition, the comment period is running on Dakota, Minnesota & Eastern Railroad's (DM&E's) two permit applications to the U.S. Army Corps of Engineers under Section 404 of

the Clean Water Act and Section 10 of the Rivers and Harbors Act (Section 404 permit applications). Many of the requests for additional time stated that it has been difficult to review simultaneously all of these documents. Moreover, at the recent public meetings on the Draft EIS, including the Native American Tribal meeting on the Rosebud Sioux Reservation, a number of participants argued that environmental justice communities could participate more effectively with more time to file comments.

It is important to move the environmental review process in this and every case forward without undue delay. But those requesting an extension here have made a strong case that more time is needed to provide an adequate opportunity for meaningful review and comment by the public, including environmental justice communities, on the Draft EIS and the other related documents in this particularly complex case. In these circumstances, the comment period will be extended for an additional 60 days, or until March 6, 2001. The extension will apply to the Draft EIS itself, the documents appended to it (the Forest Plan Amendments, the Programmatic Agreement and Identification Plan, the Memorandum of Agreement, and the Biological Assessment), and the Section 404 permit applications.² Comments on all of these documents must be postmarked by March 6, 2001. In order to issue the Final EIS in a timely manner, no further extensions will be granted absent compelling, unforeseen circumstances.

We note that, at the recent public meetings conducted to hear comments on the Draft EIS, a number of participants contended that additional mitigation measures are needed to adequately protect residents of the communities potentially impacted by DM&E's proposal. The extended comment period will provide an opportunity for DM&E and the affected communities to explore mutually acceptable ways to reduce potential impacts on communities, and to submit any agreements that are reached to the Board. The Board encourages railroads and communities to negotiate private solutions addressing specific local environmental concerns because these agreements are generally more effective, and in some cases, more far-reaching

than environmental mitigation options we could impose unilaterally. In the absence of negotiated agreements submitted to the Board,³ SEA, in preparing the Final EIS, will give careful consideration to what measures it should recommend for mitigating adverse impacts to community residents if, following the completion of environmental review, we give final approval to this project.

How to Submit Comments

Comments on the Draft EIS must be postmarked by March 6, 2001, and mailed to the address below. For comment letters over 5 pages, please mail a signed original plus 10 copies. For comment letters 5 pages or less, a signed original is sufficient. Comments must be mailed to: Office of the Secretary, Case Control Unit, STB Finance Docket No. 33407, Surface Transportation Board 1925 K Street, NW, Washington, DC 20423-0001. Please write the following in the lower left hand corner of the envelope: Attention: Victoria Rutson, Environmental Project Director, Environmental Filing.

Comments on the Forest Plan Amendments should be filed directly with the U.S. Forest Service. Please send written comments on the Forest Plan Amendments to Wendy Schmitzer, USFS Project Coordinator, Douglas Ranger District, 2250 East Richards Street, Douglas, WY 82633, or call (307) 358-1634. You may email comments on the Forest Plan Amendments to: wschmitzer@fs.fed.us.

Comments on the U.S. Army Corps of Engineers permitting requirements, specifically on DM&E's Section 404 permit applications, should be filed directly with the appropriate Corps of Engineers district office. Please send comments on the Section 404 permit application relating to Minnesota to Mr. Timothy Fell, U.S. Army Corps of Engineers, St. Paul District, 190 5th Street East, St. Paul, MN 55101-1638. Please send comments on the Section 404 permit application relating to South Dakota and Wyoming to Mr. Jerry Folkers, U.S. Army Corps of Engineers, Omaha District, 215 North 17th Street, Omaha, NE 68102-4978.

When submitting comments, please be as specific as possible and

¹ U.S. Department of Agriculture, Forest Service; the U.S. Department of the Interior, Bureau of Land Management; the U.S. Army Corps of Engineers; the U.S. Department of the Interior, Bureau of Reclamation; and the U.S. Coast Guard.

² The U.S. Army Corps of Engineers has notified SEA that it will issue a decision extending the comment period on DM&E's Section 404 permit applications to the U.S. Army Corps of Engineers to March 6, 2001, to coincide with the due date for comments on the Draft EIS and associated documents.

³ Our practice is to impose as a condition to our decisions approving railroad transactions a requirement that the railroad comply with the terms of all negotiated agreements developed with states, local communities, and other entities regarding environmental issues. These agreements substitute for specific local mitigation for a community that otherwise would be imposed. However, we cannot impose conditions based on negotiated agreements without knowing the terms of those agreements.

substantiate your concerns and recommendations.

By the Board, Chairman Morgan, Vice Chairman Burkes, and Commissioner Clyburn.

Vernon A. Williams,
Secretary.

[FR Doc. 00-32716 Filed 12-21-00; 8:45 am]

BILLING CODE 4915-00-P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[STB Finance Docket No. 33967]

Safe Handling Rail, Inc.—Modified Rail Certificate

On December 1, 2000, Safe Handling Rail, Inc. (SHR), a noncarrier, filed a notice for a modified certificate of public convenience and necessity under 49 CFR 1150, Subpart C, *Modified Certificate of Public Convenience and Necessity*, to operate the State of Maine Department of Transportation's (MDOT) portion of a rail line known as the Rockland Branch extending for approximately 51.76 miles between milepost 33.79, in Brunswick, ME, and milepost 85.55, in Rockland, ME (Rockland Branch). In addition, SHR will operate MDOT's approximately 33.60 miles of rail line known as the Lower Road extending between milepost 29.40, at Rock Junction, in Brunswick, and milepost 63.00 in Augusta, ME (Lower Road).

The Rockland Branch was owned by Maine Central Railroad Company (MEC) and approved for abandonment in *Maine Central Railroad Company—Abandonment—in Cumberland, Sagadahoc, Lincoln and Knox Counties, ME*, Docket No. AB-83 (Sub-No. 8) (ICC served Oct. 10, 1985). The Rockland Branch, as described above, was subsequently acquired by MDOT and has been operated by Maine Coast Railroad Corporation (MECO) pursuant to a modified rail certificate issued in *Maine Coast Railroad Corporation Modified Rail Certificate*, Finance Docket No. 31727 (ICC served Oct. 5, 1990). The Lower Road was owned by MEC and operated by Springfield Terminal Railway Company and approved for abandonment and discontinuance of service in *Maine Central Railroad Company and Springfield Terminal Railway—Abandonment and Discontinuance—in Cumberland, Sagadahoc and Kennebec Counties, ME*, Docket No. AB-83 (Sub-No. 9) (ICC served Jan. 8, 1990). The Lower Road was subsequently acquired by MDOT and has been operated by MECO pursuant to a modified rail

certificate issued in *Maine Coast Railroad Corporation Modified Rail Certificate*, Finance Docket No. 32271 (ICC served Apr. 22, 1993). On October 6, 2000, MECO filed with the Board, pursuant to 49 CFR 1150.24, its notice of intent to terminate service on the Rockland Branch and the Lower Road 60 days from the date of its notice.¹

Pursuant to a lease and operating agreement between MDOT and SHR (agreement), SHR will provide freight service over the Rockland Branch and the Lower Road beginning on or soon after December 6, 2000 and terminating on June 1, 2001.

The rail segments qualify for a modified certificate of public convenience and necessity. See *Common Carrier Status of States, State Agencies and Instrumentalities and Political Subdivisions*, Finance Docket No. 28990F (ICC served July 16, 1981).

A subsidy is involved. The agreement provides that SHR shall not suffer any financial loss and that MDOT will reimburse SHR the difference between SHR's costs and revenues through the term of the agreement. The agreement further provides that, should SHR's revenues exceed its costs, then no payments will be made by MDOT to SHR or by SHR to MDOT. SHR represents that it has obtained liability insurance coverage and that there are no preconditions for shippers to meet in order to receive rail service.

This notice will be served on the Association of American Railroads (Car Service Division) as agent for all railroads subscribing to the car-service and car-hire agreement: Association of American Railroads, 50 F Street, NW., Washington, DC 20001; and on the American Short Line and Regional Railroad Association: American Short Line and Regional Railroad Association, 1120 G Street, NW., Suite 520, Washington, DC 20005.

Decided: December 15, 2000.

By the Board, David M. Konschnik,
Director, Office of Proceedings.

Vernon A. Williams,
Secretary.

[FR Doc. 00-32717 Filed 12-21-00; 8:45 am]

BILLING CODE 4915-00-P

¹ In a related proceeding, the Board exempted SHR's acquisition of MECO's operating rights and incidental overhead trackage rights between milepost 27.5 and milepost 33.79 in Brunswick. See *Safe Handling Rail, Inc.—Operation Exemption—Maine Coast Railroad Corporation, Maine Central Railroad Company, Springfield Terminal Railway Company, and State of Maine Department of Transportation*, STB Finance Docket No. 33968 (STB served Dec. 15, 2000).

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Form 8861

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104-13(44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning Form 8861, Welfare-to-Work Credit.

DATES: Written comments should be received on or before February 20, 2001 to be assured of consideration.

ADDRESSES: Direct all written comments to Garrick R. Shear, Internal Revenue Service, room 5244, 1111 Constitution Avenue NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form and instructions should be directed to Larnice Mack, (202) 622-3179, Internal Revenue Service, room 5244, 1111 Constitution Avenue NW., Washington, DC 20224.

SUPPLEMENTARY INFORMATION:

Title: Welfare-to-Work Credit.

OMB Number: 1545-1569.

Form Number: 8861.

Abstract: Section 51A of the Internal Revenue Code allows employers an income tax credit of 35% of the first \$10,000 of first-year wages and 50% of the first \$10,000 of second-year wages paid to long-term family assistance recipients. Form 8861 is used to compute the credit.

Current Actions: There are no changes being made to the form at this time.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations and farms.

Estimated Number of Respondents: 500.

Estimated Time Per Respondent: 11 hr., 7 min.

Estimated Total Annual Burden Hours: 5,555.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information

unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: December 19, 2000.

Garrick R. Shear,

IRS Reports Clearance Officer.

[FR Doc. 00-32776 Filed 12-21-00; 8:45 am]

BILLING CODE 4830-01-P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Form 8716

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104-13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning Form 8716, Election To Have a Tax Year Other Than a Required Tax Year.

DATES: Written comments should be received on or before February 20, 2001 to be assured of consideration.

ADDRESSES: Direct all written comments to Garrick R. Shear, Internal Revenue Service, room 5244, 1111 Constitution Avenue NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form and instructions should be directed to Larnice Mack, (202) 622-3179, Internal Revenue Service, room 5244, 1111 Constitution Avenue NW., Washington, DC 20224.

SUPPLEMENTARY INFORMATION:

Title: Election To Have a Tax Year Other Than a Required Tax Year.

OMB Number: 1545-1036.

Form Number: Form 8716.

Abstract: Form 8716 is filed by partnerships, S corporations, and personal service corporations under Internal Revenue Code section 444(a) to elect to retain or to adopt a tax year that is not a required tax year. The form provides IRS with information to determine that the section 444(a) election is properly made and identifies the tax year to be retained, changed, or adopted.

Current Actions: There are no changes being made to the form at this time.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations and farms.

Estimated Number of Respondents: 40,000.

Estimated Time Per Respondent: 5 hr., 7 min.

Estimated Total Annual Burden Hours: 204,400.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the

information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: December 19, 2000.

Garrick R. Shear,

IRS Reports Clearance Officer.

[FR Doc. 00-32777 Filed 12-21-00; 8:45 am]

BILLING CODE 4830-01-U

DEPARTMENT OF THE TREASURY

Office of Thrift Supervision

Proposed Agency Information Collection Activities; Comment Request

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to comment on proposed and continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104-13. Today, the Office of Thrift Supervision within the Department of the Treasury solicits comments on the Application for Issuance of Subordinated Debt Securities/Notice for Issuance of Subordinated Debt or Mandatorily Redeemable Preferred Stock.

DATES: Submit written comments on or before February 22, 2001.

ADDRESSES: *Mail:* Send comments to Manager, Dissemination Branch, Information Management and Services Division, Office of Thrift Supervision, 1700 G Street, NW., Washington, DC 20552, Attention 1550-0030.

Delivery: Hand deliver comments to the Guard's Desk, East Lobby Entrance, 1700 G Street, NW., from 9:00 a.m. to 4:00 p.m. on business days, Attention 1550-0030

Facsimiles: Send facsimile transmissions to FAX Number (202) 906-7755, Attention 1550-0030; or (202) 906-6956 (if comments are over 25 pages).

E-Mail: Send e-mails to "public.info@ots.treas.gov", Attention

1550-0030, and include your name and telephone number.

Public Inspection: Interested persons may inspect comments at the Public Reference Room, 1700 G St. NW., from 10:00 a.m. until 4:00 p.m. on Tuesdays and Thursdays or obtain comments and/or an index of comments by facsimile by telephoning the Public Reference Room at (202) 906-5900 from 9:00 a.m. until 5:00 p.m. on business days. Comments and the related index will also be posted on the OTS Internet Site at "www.OTS.treas.gov".

FOR FURTHER INFORMATION CONTACT:

Nadine Washington, Supervision, Office of Thrift Supervision, 1700 G Street, NW., Washington, DC 20552, (202) 906-6706.

SUPPLEMENTARY INFORMATION:

Title: Application for Issuance of Subordinated Debt Securities/Notice for Issuance of Subordinated Debt or Mandatorily Redeemable Preferred Stock.

OMB Number: 1550-0030.

Form Number: OTS Form 1344 (Application) and OTS Form 1561 (Notice).

Abstract: The information provided to the OTS issued to determine if the proposed issuance of securities will benefit the thrift institution or create an unreasonable risk to the Savings Association Insurance Fund (SAIF).

Current Actions: OTS proposes to renew this information collection without revision.

Type of Review: Renewal.

Affected Public: Business or For Profit.

Estimated Number of Respondents: 4.

Estimated Time Per Respondent: 42 hours.

Estimated Total Annual Burden Hours: 168 hours.

Request for Comments

The OTS will summarize comments submitted in response to this notice or will include these comments in its request for OMB approval. All

comments will become a matter of public record. The OTS invites comment on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality; (d) ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or starting costs and costs of operation, maintenance, and purchase of services to provide information.

Dated: December 18, 2000.

John E. Werner,

Director, Information & Management Services Division.

[FR Doc. 00-32664 Filed 12-21-00; 8:45 am]

BILLING CODE 6720-01-P

Corrections

Federal Register

Vol. 65, No. 247

Friday, December 22, 2000

This section of the FEDERAL REGISTER contains editorial corrections of previously published Presidential, Rule, Proposed Rule, and Notice documents. These corrections are prepared by the Office of the Federal Register. Agency prepared corrections are issued as signed documents and appear in the appropriate document categories elsewhere in the issue.

FEDERAL COMMUNICATIONS COMMISSION

Notice of Public Information Collection(s) Being Reviewed by the Federal Communications Commission, Comments Requested

Correction

In notice document 00-30802 beginning on page 75701 in the issue of Monday, December 4, 2000, make the following correction:

On page 75701, in the second column, in the **DATES** section, in the second line, "January 3, 2001" should read "February 2, 2001."

[FR Doc. C0-30802 Filed 12-21-00; 8:45 am]

BILLING CODE 1505-01-D

NUCLEAR REGULATORY COMMISSION

10 CFR Part 32

RIN 3150-AG03

Requirements for Certain Generally Licensed Industrial Devices Containing Byproduct Material

Correction

In rule document 00-31873 beginning on page 79162 in the issue of Monday,

December 18, 2000, make the following correction:

§32.51a [Corrected]

On page 79189, in the third column, in §32.51a(d), in the second line, "(insert date 1 year after the effective date of this rule)" should read "February 19, 2002".

[FR Doc. C0-31873 Filed 12-21-00; 8:45 am]

BILLING CODE 1505-01-D

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 450

[Docket No. FAA 1999-6265; Amendment No. 450-1]

RIN 2120-AG76

Financial Responsibility Requirements for Licensed Reentry Activities

Correction

In rule document 00-22565 beginning on page 56670 in the issue of Tuesday, September 19, 2000, make the following correction:

§450.3 [Corrected]

1. On page 56700, in the first column, in §450.3(a), in the definition of *Maximum probable loss (MPL)*, in the paragraph designated as (1), in the third line, "participant's" should read "participants".

§450.9 [Corrected]

2. On page 56701, in the second column, in §450.9(f), in the second line, before "licensee" add "a".

§450.13 [Corrected]

3. On the same page, in the third column, in §450.13(a)(3), in the eighth

line, after "in" add "an". And in the 10th line, after "funds" remove the comma.

§450.15 [Corrected]

4. On page 56702, in the first column, in §450.15(a)(2), in the second line, "lest" should read "least".

5. On the same page, in the second column, in §450.15(b), in the third line, "all" should read "and".

6. On the same page, in the same column, in §450.15(c)(1)(ii), in the fourth line, "insures" should read "insurers". And in the ninth line, "an" should read "and".

§450.17 [Corrected]

7. On the same page, in the third column, in §450.17(d), in the 13th line, after "out" add "of".

8. On page 56704, in the first column, in the appendix A to part 450, in the paragraph designated as C.3., in the third line, "license" should read "licensed".

Appendix B to Part 450 [Corrected]

9. On page 56705, in the first column, in the appendix B to part 450, in the paragraph designated as (c), in the 18th line, after "responsibility" add "required". And in the 19th line, before "450.9(c)" add "§".

10. On the same page, in the same column, in the same appendix, in the last paragraph, in the 11th line, "form" should read "from".

11. On the same page, in the second column, in the same appendix, in the sixth line, "450.9(e)" should read "450.9(e))"

[FR Doc. C0-22565 Filed 12-21-00; 8:45 am]

BILLING CODE 1505-01-D



Federal Register

**Friday,
December 22, 2000**

Part II

Department of Energy

48 CFR Chapter 9

**Department of Energy Acquisition
Regulation; Rewrite of Regulations
Governing Management and Operating
Contracts; Final Rule**

DEPARTMENT OF ENERGY

48 CFR Chapter 9

RIN 1991-AB46; RIN 1991-AB49

Department of Energy Acquisition Regulation; Rewrite of Regulations Governing Management and Operating Contracts

AGENCY: Department of Energy.

ACTION: Final rule.

SUMMARY: The Department of Energy (DOE) amends its Acquisition Regulation to streamline the policies, procedures, provisions and clauses that are applicable to its management and operating contracts. This rulemaking eliminates coverage that is obsolete or that duplicates the Federal Acquisition Regulation (FAR), and retains only coverage that either implements or supplements the FAR for the award and administration of the Department's management and operating contracts. The rule also adds five new clauses and amends several existing clauses to promote uniform application of the Department's award and administration policies for management and operating contracts. Also, this final rule amends the Department's Acquisition Regulation regarding management and operating contract cost principles by adopting the Federal Acquisition Regulation cost principles, with some supplemental material. Finally, the Department is making technical and administrative changes.

EFFECTIVE DATE: This final rule is effective January 22, 2001.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

- I. Background
- II. Discussion of Public Comments
- III. Procedural Requirements
 - A. Review of Executive Order 12866
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I. Background

On March 13, 2000, the Department of Energy (DOE or Department) published

in the **Federal Register** (65 FR 13418) a Notice of Proposed Rulemaking to amend the Department of Energy Acquisition Regulation (DEAR) to streamline the policies, procedures, provisions and clauses that are applicable to its management and operating contracts. This Rulemaking was titled "Rewrite of Regulations Governing Management and Operating Contracts." On June 14, 2000, DOE published in the **Federal Register** (65 FR 37335) a related Notice of Proposed Rulemaking to amend the DEAR to delete those cost principles and related provisions of the DEAR that are applicable to its management and operating contracts that are adequately covered by the Federal Acquisition Regulation (FAR). This Rulemaking was titled "Changes to Department of Energy Cost Principles and Various Clauses." Today, DOE publishes a final rule based on these Notices of Proposed Rulemaking.

This rule rewrites DEAR Part 970, in its entirety, to streamline the policies, procedures, provisions and clauses that are applicable to the Department's management and operating (M&O) contracts. The rule eliminates coverage that is obsolete or that unnecessarily duplicates coverage contained in the FAR. The rule also updates and revises prescriptions and text of certain clauses to provide greater flexibility for DOE contracting personnel to make administrative modifications to the text of these clauses and to eliminate the need for commonly used deviations to such clauses. Five new clauses are included in the DEAR. The new clauses prescribe uniform Departmental policies concerning: (1) Cooperation between the Department and its contractors in disseminating information to the public; (2) technical direction provided to contractors by a designated contracting officer's representative; (3) collaboration to identify, evaluate, and institutionalize processes that will improve the effectiveness or efficiency of any aspect of contract performance, and collaboration regarding such improvements between the Department and other major site and facility management contractors; (4) implementation of FAR 35.017 regarding the establishment, use, review, and termination of Federally Funded Research and Development Centers which are sponsored by the Department; and (5) outreach to the local communities in which DOE conducts business.

Additionally, Part 970 is reorganized and renumbered so that the coverage corresponds, to the extent practicable, with the FAR part, subpart, section, and

subsection(s) being implemented or supplemented, as appropriate, in Part 970. Accordingly, technical and conforming amendments to DEAR part 970 and other DEAR parts are made. Among the renumbered provisions are the Financial Management clauses for management and operating contracts, which were published as a final rulemaking in the **Federal Register** (65 FR 21371) on April 21, 2000.

In preparing this Notice of Final Rulemaking, the Department has made a variety of technical changes, which, with one exception, do not warrant extended discussion. That exception is the coverage for Contractor Employee Travel Discounts, found at 48 CFR 951.7002 and 48 CFR 952.251-70, which has been updated to conform to mandatory GSA travel policy.

Contracting officers must apply these DEAR changes to solicitations issued on or after the effective date of this rule.

Contracting officers may, at their discretion, include these DEAR changes in solicitations issued before the effective date of this rule, provided award of the resulting contract(s) occurs on or after the effective date.

Contracting officers must apply these DEAR changes: to contracts extended in accordance with the Department's extend/compete policies and procedures (48 CFR 917.6, 48 CFR 970.1702-1(a), and internal guidance); and to options exercised under competitively awarded management and operating contracts (48 CFR 970.1702-1(b)).

Contracting officers may, after consulting with the Department of Energy Office of Procurement and Assistance Policy of the Office of Procurement and Assistance Management, apply these DEAR changes, with the exception of the changes to the cost principles and related clauses, to existing contracts.

Contracting officers should modify existing contracts to incorporate the following clauses within one year of the effective date of this rule: 952.204-75, Public Affairs; 952.215-70, Key Personnel; 970.5203-2, Performance Improvement and Collaboration; 970.5203-3, Contractor's Organization; 970.5226-3, Community Commitment; and 970.5235-1, Federally funded Research and Development Center Sponsoring Agreement.

II. Discussion of Public Comments

The major issues emerging from the public comments on the two proposed rules that led to this final rule (the "Rewrite of Regulations Governing Management and Operating Contracts" and the "Changes to Department of Energy Cost Principles and Various

Clauses”) are discussed separately below. DOE received other comments that were out of scope, speculative, or otherwise irrelevant. Consistent with applicable law, DOE is not responding to those comments.

Rewrite of Regulations Governing Management and Operating Contracts

Fourteen respondents submitted 43 comments covering 22 separate topics. However, some of these comments raised issues not listed as open for comment in the proposed rule. The Department is separately evaluating these comments for potential rulemaking actions in the future.

952.204–75 Public Affairs

Comment: Four respondents expressed dissatisfaction with proposed Public Affairs clause asserting its requirements were, among other things, unproductive, burdensome, ambiguous, and unworkable.

Response: To permit appropriate procedures at each activity that will maximize the effectiveness of the clause and minimize the burden on the Departments’ contractors, the Department has added the following language to paragraphs (a), (e), and (f) of the clause: “in accordance with procedures defined by the Contracting Officer.”

952.215–70 Key Personnel

Comment: Two respondents recommended DOE not require the contractor to obtain DOE’s approval before moving key personnel.

Response: While the Department deems it essential that it retain the right to approve movements of key personnel in most cases, it has amended paragraph (a) of the clause by adding language to permit a contractor to move key personnel if the contractor deems immediate removal or suspension of any member of its management team necessary to fulfill its obligation to maintain satisfactory standards of employee competency, conduct, and integrity under the clause at 48 CFR 970.5203–3, Contractor’s Organization. The Contractor must notify the contracting officer prior to or concurrently with such action.

952.242–70 Technical Direction

Comment: Two respondents expressed dissatisfaction with the clause’s asserted lack of congruence with contracts for basic research.

Response: The use of the clause is discretionary. Nevertheless, the Department has added to the clause prescription at 48 CFR 942.270–2 authorization to use a clause

“substantially the same as” the standard clause. Additionally, the Department has added to the clause at 48 CFR 952.242–70 a new paragraph (e)(3) that gives the contracting officer another option in responding to the contractor’s assertion of changed conditions. This option permits the contracting officer to advise the contractor in writing within a reasonable time not to proceed with the instruction or direction of the contracting officer’s representative.

970.0370/970.5203–2 Performance Improvement and Collaboration

Comment: One respondent recommended: (1) deleting the first and sixth sentences in paragraph (d) of 48 CFR 970.0370–1 because they were redundant with other coverage; and, (2) in performance-based management contracts, replacing the requirement in the first sentence of 48 CFR 970.5203–2(d) that the contractor obtain the contracting officer’s approval where necessary with a statement that the contract would define the requirement for the clause per DOE policy. Another respondent, while not objecting to the clause, urged that its use “* * * not lead to unnecessary implementation or oversight expenses for DOE or its contractors.”

Response: Regarding the first respondent’s recommendation, the Department does not agree that the first and sixth sentences in paragraph (d) of 48 CFR 970.0370–1 are redundant. They state the Department’s policy and expectations clearly. Nor does the Department agree that the suggested replacement in 48 CFR 970.5203–2(d) adds clarity; it would remove clear-cut direction regarding the contractor’s obligation to seek approval with a vague statement that requirements would be defined later. Regarding the second respondent’s recommendation, the Department shares the respondent’s hope that the clause will be implemented prudently.

970.2673–2/970.5226–3 Community Commitment

Comment: Seven respondents submitted comments on the proposed community commitment clause. The gist of the comments was that DOE was inappropriately changing existing policy for economic development initiatives for its major site and facility contracts. Some comments were supportive of the proposed clause and suggested additional language to expand or clarify the proposed language.

Response: The Department has decided not to adopt any of the respondents’ proposed changes, not because the Department disagrees in

principle with the changes, but because they are unnecessary. Some elaboration is appropriate.

In the past, a number of DOE’s competitive solicitations for major site and facility contracts included requirements that competitors propose specific economic development initiatives as a consideration in source selection. This type of selection factor was primarily used in association with sites and facilities that were undergoing major changes, such as downsizing or closure, and where the Department envisioned the contractor to have a major role in the change-over. In certain cases the contractor’s performance against the proposed economic development initiatives became a contract requirement subject to assessment in making fee determinations.

The use of economic development source selection factors was, however, neither a requirement of law, such as Section 3161 of the National Defense Authorization Act for Fiscal Year 1993, nor a part of DOE’s implementation of worker and community transition policies. The use of economic development contractor selection factors was, in short, not a Departmental policy, but rather an occasional practice related to specific considerations at the site or facility. Although DOE included source selection factors related to economic development in past competitive solicitations, DOE does not currently have appropriate applications for this practice. For the most part, our sites and facilities are stable in the sense that we do not envision radical mission changes or downsizing.

This does not mean that the Department has lost sight of the fact that the Department and its contractors need to be good neighbors. To reflect the Department’s policy, we are issuing a contract clause that will require each major site and facility contractor to conduct its business activities at the DOE facility in a manner that: (1) recognizes the diverse interests of the region and its stakeholders; (2) engages regional stakeholders in issues and concerns of mutual interest; and (3) recognizes that giving back to the community is a worthwhile business practice. This requirement has also been included in our most recent competitive contract awards. The use of such a contractual requirement provides a viable mechanism to ensure that DOE contractors are responsive to local interests.

The new clause does not preclude the Department from incorporating specific requirements in its contracts where such requirements fulfill or support DOE’s

mission at the site or facility. For example, DOE's major site and facility contracts will continue to require compliance with the Department's Section 3161 program to minimize the impact of mission changes on the contractor workforce and the affected community. Additionally, DOE may pursue economic development activities directly rather than through a contract mechanism. DOE will continue to assess the need for these activities on a case-by-case basis where such activities are in connection with the mission of the site or facility and can be accomplished consistent with the provisions of various appropriations laws and other regulations. However, DOE does not intend to use economic development requirements in solicitations and contracts where such requirements are unrelated to the specific mission at the site or facility.

DOE has a long-standing commitment to the regions and local communities in which it conducts business. The Department continues to recognize that its success in meeting critical mission needs is dependent on active support from state, regional and local governments, communities, and other organizations. DOE has demonstrated that commitment through outreach and partnering initiatives in a number of ways including: hiring preferences and preservation of benefits to employees of successor contractors; programs for ensuring worker safety and health; aggressive subcontracting programs for small businesses, small disadvantaged businesses, women-owned businesses, and HUB Zone businesses; small business mentoring programs; release of assets no longer needed by the Department to community reuse organizations; support to local educational institutions; and technology transfer programs.

The Department's commitment remains strong today, and it will continue pursuing opportunities to ensure that the Department is a productive and conscientious partner in the areas in which it conducts business. The Department recognizes and accepts its obligation to the people and communities surrounding DOE sites and facilities.

970.4501-1/970.5245-1 *Government Property*

Comment: One respondent suggested that DOE remove the definition of "managerial personnel" from the property clause, implying the definition should be in the "Definitions" clause of the contract.

Response: The Department does not agree that the suggested change would

be an improvement. The current property clause defines managerial personnel and other clauses use the definition by referencing it rather than repeating it. This has been a Department-wide practice since the implementation of contract reform. There would be no obvious benefit to changing this successful practice.

970.5203-3 *Contractor's Organization*

Comment: Seven respondents provided comments whose gist was an objection to the "new" right DOE is asserting to direct the removal of contractor employees for specified causes. The respondents raised numerous issues, such as legal complexities, recruiting difficulties, labor-management concerns, and employer-employee relationship concerns.

Response: The Department does not agree that this proposed clause is essentially a new right DOE is asserting. This right has always been standard language in the DEAR. DOE is simply removing the alternate language, which did permit contracting officers to not assert this right. Additionally, the FAR (at 48 CFR 52.236-5, Material and Workmanship) and case law have supported the Government's use of this contractual authority. The unique nature of a management and operating contracts makes it appropriate that the Government retain this right in this type of contract.

Notwithstanding the above, the Department recognizes that exercising this right is an action not to be taken lightly. Consequently, the Department has amended the proposed language by raising the approval authority for exercising this right to the Secretary of Energy. Further, the Department plans to provide guidance to its personnel to emphasize that they should only consider exercising this right if the contractor fails to fulfill its obligation under this clause to implement a process for maintaining satisfactory standards of employee competency, conduct, and integrity.

In addition to the change above, the Department also added an optional phrase to the clause's prescription (48 CFR 970.0371-9) that the chart discussed in paragraph (a) of the clause also include managerial personnel.

970.5235-1 *Federally Funded Research and Development Center Sponsoring Agreement*

Comment: Two respondents suggested editorial changes and questioned DOE's implementation of the FAR policy regarding Federally Funded Research and Development Center (FFRDCs),

alleging, for example, that the FAR mandates "long term relationships" while DOE's proposed language does not.

Response: The Department does not agree that its proposed language is in any way inconsistent with the FAR policy on FFRDCs. The comments infer meanings from the FAR language that are not warranted. Language in the FAR does not mandate "long term relationships" between agencies and FFRDCs, it simply encourages them. Current DOE policy provides for a potential 10-year relationship.

970.5244-1 *Contractor Purchasing System*

Comment: Two respondents commented on DOE's alternatives of using either the Contractor Purchasing System Review or the Balanced Score Card methodology for periodic appraisals of the Contractor's management of the purchasing function. One suggested choosing the alternative prior to the evaluation period. The other questioned the reintroduction of the formal Contractor Purchasing System Review as an alternative to the Balanced Score Card methodology.

Response: The Department disagrees that the alternative must be established prior to the evaluation period. The proposed clause requires the Contractor Purchasing System Review unless the contractor can obtain the contracting officer's approval to participate in the Balanced Score Card methodology. The Department also disagrees that it is "reintroducing" the formal Contractor Purchasing System Review. The current DEAR clause states DOE reserves the right to review/approve the contractor's purchasing system per FAR Subpart 44.3—the Contractor Purchasing System Review.

52.211-5 *Workmanship and Materials/ Material Requirements*

Comment: One respondent questioned DOE's intent in replacing the DEAR Workmanship and Materials clause at 48 CFR 970.5204-25 with the FAR Material Requirements clause at 48 CFR 52.211-5. The respondent asserted that the clauses were dissimilar.

Response: In its review of DEAR Part 970, the Department determined the requirements of the DEAR Workmanship and Materials clause were mostly subjective. The requirements, to the extent necessary, are more suitably enforced by other, less subjective parts of the contract such as work authorization directives. The clause requirement that only new materials be used is provided for in 48 CFR 52.211-5. The Department had

added a clause prescription at 48 CFR 970.1103-4. Additionally, the Department has added language to 48 CFR 970.0100 and 48 CFR 970.5200 to emphasize that management and operating contracts, as specialized government contracts, include both FAR and DEAR clauses.

52.236-8 Other Contracts

Comment: One respondent objected to DOE's adopting the standard FAR clause (48 CFR 52.236-8), Other Contracts, because it conflicts with DOE's current practice of holding a facility management contractor accountable regardless of who performs the work. The respondent recommended authorizing tailoring of the clause.

Response: The Department does not agree that there is a conflict or that the clause should permit tailoring. It appears the respondent is confusing two separate contractor responsibilities: one is managing its subcontractors; the other is cooperating with other prime contractors on site. DOE's current practice regarding a prime contractor managing its subcontractors (specified in the clause at 48 CFR 970.5223-1, Integration of Environment, Safety, and Health into Work Planning and

Execution) is to hold the contractor accountable regardless of who performs the work. DOE's current practice regarding cooperation among prime contractors is that the prime contractor must cooperate fully with other prime contractors (which is no different than the proposed practice required by the standard FAR clause). These two requirements are independent of each other.

Changes to Department of Energy Cost Principles and Various Clauses

Five respondents submitted 34 comments covering 24 separate topics.

The "Changes to Department of Energy Cost Principles and Various Clauses" proposed rule did not use the organization and numbering system that this final rule institutes. This new organization and numbering system, which was introduced in the "Rewrite of Regulations Governing Management and Operating Contracts" proposed rule, is reflected in the comprehensive conversion table for DEAR Part 970 that follows this section. That conversion table compares new citations, which appear in the final rule, to current citations.

To aid the reader in tracing from the "Changes to Department of Energy Cost Principles and Various Clauses" proposed rule to this final rule, the headings within the discussion of public comments section that follows are listed both with the current citation, which appeared in the proposed rule, and with the new (if there is one) citation, which appears in this final rule. The new citation appears in parentheses.

As an additional aid to the reader, the following mini-conversion table compares current citations, which appeared in the proposed rule, to new citations, which appear in this final rule, for the citations that meet the following criteria: (1) They were affected by the "Changes to Department of Energy Cost Principles and Various Clauses" proposed rule and they appear in this final rule; or (2) they are new citations and they appear in this final rule.

By using the following mini-conversion table and the comprehensive conversion table for DEAR Part 970 that follows this section, the reader should be able to follow the transition (from the current citations to the new citations) easily.

Current citation	New citation	Title
970.3100-1	970.3101-00-70	Scope of subpart.
970.3101-3	970.3102-3-70	Home Office Expenses.
970.3101-9	970.3101-9	Advance Agreements.
970.3101-10	970.3101-10	Cost Certification.
970.3102	970.3102-05	Application of Cost Principles.
970.3102-4	970.3102-05-4	Bonding Costs.
970.3102-6	970.3102-05-6	Compensation for Personal Services.
970.3102-18	970.3102-05-18	Independent research and development and bid and proposal costs.
970.3102-19	970.3102-05-19	Insurance and indemnification.
970.3102-22	970.3102-05-22	Lobbying and political activity costs.
970.3102-28	970.3102-05-28	Other business expenses.
970.3102-30	970-3102-05-30	Patent costs and technology transfer costs.
970.3102-46	970-3102-05-46	Travel Costs.
N/A	970.3102-05-47	Costs Related to Legal and Other Proceedings.
970.3102-53	970.3102-05-53	Preexisting Conditions.
N/A	970.3170	Contract Clause.
970.42	970.42	Contract Administration.
970.4207-1	970.4207-05-01	Contracting officer determination procedure.
N/A	970.4207-03-70	Contract clause.
970.4207-2	970.4207-03-02	Certificate of Costs.
970.5204-16	970.5232-2	Payments and advances.
970.5204-31	970.5228-1	Insurance-litigation and claims.
970.5204-XX	970.5242-1	970.3102-53

970.3101-1 (No New Citation) Objectives

Comment: One respondent commented that the proposed 48 CFR 970.3101-1 Objectives unnecessarily addresses deviations to the cost principles, since deviations are addressed at 48 CFR 970.5202 and in written Departmental procedures.

Response: The Department concurs and has deleted the coverage from the final rule.

970.3101-3 (970.3102-3-70) Home Office Expenses

Comment: Two respondents commented that the proposed coverage at 48 CFR 970.3101-3, Home Office Expenses, appeared at odds with the

policy articulated at 48 CFR 970.15404-4-2(b)(1), Special Considerations: Laboratory Management and Operation, which states in part that costs incurred in the operation of a laboratory that are allowable and allocable under the cost principles should be classified as direct or indirect charges to the contract and not included as proposed fee.

Response: The proposed coverage and the policy are not at odds. The proposed coverage requires the laboratory management contractor to classify allowable costs under the cost principles and other regulations as charges to the contract and not fee. This means that when the laboratory management contractor requests, per the regulation at 48 CFR 970.3101-3, that the contracting officer consider some home office expense allowable under the contract, the contractor must propose the expense as a charge to the contract and not fee. Nevertheless, to diminish the possibility of confusion, DOE has added the language “(but see 48 CFR 970.15404-1-3(b)(1) if the contract is for the management and operation of a laboratory)” to 48 CFR 970.3101-3(a)(3)(i). Additionally, we have added “(including 48 CFR 970.31)” after “regulations” to 48 CFR 970.15404-1-3(b)(1) to emphasize that the FAR cost principles, including home office expense, are supplemented by 48 CFR 970.31 in all M&O contracts.

Comment: One respondent asserted that conventional allocation bases are not always appropriate, since they presume significant investment in the operations. This respondent suggests that 48 CFR 970.3101-3 be revised to state that the nature of the M&O contracting environment creates a unique environment and conventional home office cost allocation bases may be inappropriate. Contracting officers should evaluate the contractor's specific circumstances and pursue an advance agreement covering the allowability of home office expenses.

Response: DOE fails to see where the policy at 48 CFR 970.3101-3 does not provide everything that the respondent seeks. The policy clearly recognizes that “the nature of the M&O contracting environment creates a unique environment.” And it clearly states that “conventional home office cost allocation bases may be inappropriate.” It also requires the HCA's approval for any contractor request to make some home office expense allowable under the contract. It is clear that under the policy at 48 CFR 970.3101-3, contracting officers will evaluate the contractor's specific circumstances.

Comment: One commenter claimed that proposed 48 CFR 970.3101-3(a) eliminates contracting officer discretion to make home office expenses fully allowable when circumstances warrant.

Response: While DOE agrees that the policy at 48 CFR 970.3101-3 precludes contracting officers from making home office expenses fully allowable, DOE disagrees that this “eliminates” any discretion that contracting officers

formerly held. The Department's policy as stated in the DEAR for many years has been that the contractor's fee generally provides adequate compensation for home office expense. Under the Department's policy, exceptions were allowed, but it included a requirement to recognize that some home office expense had been accounted for in the management and operating contractor's fee. The policy at 48 CFR 970.3101-3 simply continues the Department's traditional policy.

970.3101-9 (970.3101-9) Advance Agreements

Comment: Two respondents commented that they believed the intent of 48 CFR 970.3101-9, Advance Agreements, is to emphasize the non-inclusive nature of the list of potential advance agreement candidates. A respondent recommended replacing the language in the proposed rule with:

“At any time, in accordance with the contract terms and conditions, the contracting officer may pursue an advance agreement in connection with any cost item under the contract.”

Response: The Department concurs and has made the change as suggested.

970.3102-6 (970.3102-05-6) Compensation for Personal Services

Comment: Two respondents commented on the proposed coverage at 48 CFR 970.3102-6, Compensation. One stated that significant effort has been invested in streamlining personnel matters to reduce cost and administrative burden and a manageable personnel appendix was the result. The respondent recommended against a requirement that would revert to the burdensome personnel appendices of the past.

Response: There is no new language, and there are no new requirements. DOE sites and facilities should continue to use those policies and practices that have been jointly developed over the life of the contract.

970.3102-18 (970.3102-05-18) Independent Research and Development and Bid and Proposal Costs

Comment: Two responders commented that the proposed coverage at 48 CFR 970.3102-18, Independent Research and Development and Bid and Proposal Costs, should be clarified to distinguish between bid and proposal costs a contractor incurs to obtain new business in its non-FFRDC operations and preparation of proposal costs incurred by FFRDCs to perform work authorized by the sponsoring agency for others. Additionally, the respondents recommended that contracting officer-

approved Laboratory Directed Research and Development costs be specified as allowable costs notwithstanding any other treatment of IR&D.

Response: DOE concurs. The coverage has been rewritten to identify and distinguish between approved Laboratory Directed Research and Development costs and bid and proposal costs and those costs incurred under the rubric of the Department's various “reimbursable programs.”

970.3102-20 (no new citation) Interest and Other Financial Costs

Comment: One commenter pointed out that proposed 48 CFR 970.3102-20, Interest and other financial costs, is not necessary. The cost principles at 48 CFR 31.205-10 and 48 CFR 31.205-20 provide adequate coverage.

Response: DOE concurs and has deleted the proposed coverage.

970.3102-21 (no new citation) Fines and Penalties

Comment: The proposed rulemaking adopts the FAR coverage on fines and penalties. Both FAR and DEAR provide exceptions to fines or penalties when they are the result of (1) the terms and conditions of the contract, or (2) written direction of the contracting officer. However, the DEAR provides another exception not contained in the FAR coverage; when such a civil fine or penalty was imposed without regard to fault and could not have been avoided by the exercise of due care. The respondent recommended DOE retain this exception.

Response: The language applicable to the Department's contractors should be the same as that applied to other Federal contractors since this type of issue is not unique to the Department's contractors. There is already sufficient flexibility within the FAR cost principle to authorize reimbursement of this cost category when conditions warrant.

970.3102-46 (970.3102-05-46) Travel Costs

Comment: Though Congress has mandated separate travel requirements for DOE contractors (P.L. 106-60), one respondent stated that this should not be a barrier to the use of FAR language. FAR language could be incorporated into each contract and supplemented if the regulatory climate (reasonableness standard) and the statutory climate change.

Response: Although the respondent's proposed solution is one way of addressing the issue, the Department believes that the statutory direction should be implemented in the

regulation rather than on a contract-by-contract basis.

Comment: One commenter contended that the detailed description constrains the contractor from pursuing other travel reimbursement policies that may be more economical overall to the Government and still meet the intent of P.L. 106-60, Section 309.

Response: DOE disagrees. The deviation provisions contained in the DEAR permit the consideration of modifications to a cost principle where economies or efficiencies can be demonstrated (except for those cost principles statutorily mandated).

Comment: Two respondents commented that the cost principle should not be adopted, since the source of this requirement is appropriations law, not substantive law. The respondents recommended developing a clause that commits the contractor to abide by any applicable restrictions communicated by the contracting officer in providing appropriated funds to the contractor.

Response: DOE disagrees. The Department believes that the establishment of consistent, comprehensive policy direction is the appropriate course of action.

970.5204-13 (no new citation) Allowable Costs and Fixed-Fee

Comment: One commenter disagreed with the proposed deletion of this clause, arguing that contracting officers should be authorized to develop a local allowable cost clause that adapts the relevant portions of 48 CFR Part 31.

Response: DOE disagrees. The intent of this rulemaking is to eliminate

redundancy in the DEAR and bring the Department's cost reimbursement

practices in alignment with the rest of the federal government, except when a different practice is specifically warranted by the nature of the Department's activities. Local clauses are designed to address local issues, not those that are common throughout the Department.

970.5204-16 (970.5232-2) Payments and Advances

Comment: One respondent asserted that the proposed reference should be to 48 CFR part 31, not to 48 CFR subpart 31.2.

Response: DOE disagrees. The activities carried out under the Department's management and operating contracts have always been subject to the same cost principles, regardless of whether the entity performing the contract was a for-profit entity, a non-profit entity, or an educational institution. Now the cost principles will be those provided at 48 CFR Subpart 31.2.

970.5204-XX (970.5242-1) Penalties for Unallowable Costs

Comment: Paragraph (b) of the clause states “* * * the contracting officer shall assess a penalty * * *” but paragraph (e) states “The contracting officer may waive the penalty provision * * *”. A respondent recommended changing the “shall” to “may.”

Response: The language contained in the coverage is identical to that contained in statute, Section 2151(b) of Pub. L. 103-355.

31.205-30 (970.3102-05-30) Patent Costs

Comment: One commenter argued that use of only the FAR cost principle would adversely affect the Laboratories' ability to carry out DOE's and the Laboratories' technology transfer mission. The deletion of the entire 48 CFR 970.5204-13(d)(7) without a compensating fix to allow patent related costs is not acceptable.

Response: While DOE does not necessarily agree that the FAR cost principle is insufficient because of the importance of the technology transfer mission, DOE has added coverage at 48 CFR 970.3102-05-30 for Patent costs and technology transfer costs. The coverage distinguishes between contracts that include and contracts that do not include the clause at 48 CFR 970.5227-3, Technology Transfer Mission.

Part 970 Rewrite Conversion Table

The following conversion table shows how this rule reorganizes and rennumbers Part 970. (The table's “Current Citation” column reflects the DEAR as it was prior to: the “Financial Management Clauses for Management and Operating Contracts” final rule, 65 FR 21371, April 21, 2000; the Costs Associated with “Whistleblower Actions” final rule, 65 FR 62299, October 18, 2000; and the “Revision of Patent Regulations Relating to DOE Management and Operating Contracts” interim final rule, 65 FR 68932, November 15, 2000.)

New citation	Current citation	Title
970.01	N/A	Management and Operating Contract Regulatory System.
970.0100	970.0000	Scope of Part.
N/A	970.0001	[Reserved].
970.0103	N/A	Publication and Codification.
970.03	970.03 [Note: Current 970.03 is reserved]..	Improper Business Practices and Personal Conflicts of Interest.
970.0309	970.2274	Whistleblower Protection of Contractor Employees.
970.0309-1	970.2274-1(a)	Applicability.
970.0370	970.0901 (Title)	Management Controls and Improvements.
970.0370-1	970.0901(a), (b), and (c)	Policy.
970.0370-2	N/A	Contract Clause.
970.0371	970.2272 (Title)	Conduct of Employees of DOE Management and Operating Contractors.
970.0371-1	970.2272(a)	Scope of Section.
970.0371-2	970.2272(b)(1)	Applicability.
970.0371-3	N/A	Definition.
970.0371-4	970.2272(c)	Gratuities.
970.0371-5	970.2272(d)	Use of Privileged Information.
970.0371-6	970.2272(g)	Incompatibility Between Regular Duties and Private Interests.
970.0371-7	970.2272(e)	Outside Employment of Contractor Employees.
970.0371-8	970.2272(f)	Employee Disclosure Concerning Other Employment Services.
970.0371-9	970.2272(b)(2) and (3)	Contract Clause.
970.04	970.04	Administrative Matters.
970.0404	970.0404	Safeguarding Classified Information.
970.0404-1	970.0404-1	Definitions.
970.0404-2	970.0404-2	General.

New citation	Current citation	Title
970.0404-3	970.0404-3 (a) and (b)	Responsibilities of Contracting Officers.
970.0404-4	970.0404-4 (d)	Solicitation Provision and Contract Clauses.
N/A	970.0404-4 (a), (b) and (c)	[Reserved].
970.0407	970.0406	Contractor Records Retention.
970.0407-1	N/A	Applicability.
970.0407-1-1	970.0407	Alternate Retention Schedules.
970.0407-1-2	970.0407-1	Access to and Ownership of Records.
970.0407-1-3	970.0407-2	Contract Clause.
970.0470	970.0407-3	Department of Energy Directives.
970.0470-1	970.0470	General.
970.0470-2	970.0470-1	Contract Clause.
970.08	970.0470-2	Required Sources of Supplies and Services.
970.0801	970.08	Excess Personal Property.
970.0801-1	970.0801 (Title)	Policy.
970.0808	970.0801 (Text)	Acquisition of Printing.
970.0808-1	N/A	Scope of Section.
970.0808-2	N/A	Policy.
970.0808-3	N/A	Contract Clause.
970.09	970.09	Contractor Qualifications.
970.0905	970.0905	Organizational Conflicts of Interest.
970.0970	N/A	Performance Guarantees.
970.0970-1	970.0902(a), (b) and (c)	Determination of Responsibility.
970.0970-2	970.0902(d)	Solicitation Provision.
970.11	970.10	Describing Agency Needs
970.1100	N/A	Policy.
970.1100-1	970.1001	Performance-based Contracting.
970.1100-2	970.1002	Additional Considerations
970.1103-4	N/A	Contract Clause
970.15	970.15	Contracting by Negotiation.
970.1504	N/A	Contract Pricing.
970.1504-1	N/A	Price Analysis.
970.1504-1-1	970.15404-4	Fees for Management and Operating Contracts.
970.1504-1-2	970.15404-4-1	Fee Policy.
970.1504-1-3	970.15404-4-2	Special Considerations: Laboratory Management and Operation.
970.1504-1-4	970.15404-4-3	Types of Contracts and Fee Arrangements.
970.1504-1-5	970.15404-4-4	General Considerations and Techniques for Determining Fixed Fees.
970.1504-1-6	970.15404-4-5	Calculating Fixed Fee.
970.1504-1-7	970.15404-4-6	Fee Base.
970.1504-1-8	970.15404-4-7	Special Equipment Purchases.
970.1504-1-9	970.15404-4-8	Special Considerations: Cost-plus-award-fee.
970.1504-1-10	970.15404-4-9	Special Considerations: Fee Limitations.
970.1504-1-11	970.15404-4-10	Documentation.
970.1504-2	970.15405	Price Negotiation.
970.1504-3	N/A	Documentation.
970.1504-3-1	970.15406-2	Cost or Pricing Data.
970.1504-4	N/A	Special Cost or Pricing Areas.
970.1504-4-1	970.15407-2	Make-Or-Buy Plans.
970.1504-4-2	970.15407-2-1	Policy.
970.1504-4-3	970.15407-2-2	Requirements.
970.1504-5	970.15404-4-11	Solicitation Provision and Contract Clauses
970.15407-2-3	970.15407-2-3	
970.17	970.17	Special Contracting Methods
970.1706	N/A	Management and Operating Contracts.
970.1706-1	970.1702-1	Award, Renewal, and Extension.
970.1706-2	970.1702-2	Contract Clause.
970.19	970.19	Small, Small Disadvantaged and Women-owned Small Business Concerns
970.1907	N/A	Subcontracting with Small Business, Small Disadvantaged Business and Woman-owned Small Business Concerns.
970.1907-1	970.1901	Subcontracting Plan Requirements.
N/A	970.20	[Reserved]
970.22	970.22	Application of Labor Policies
970.2200	N/A	Scope of Subpart
970.2201	970.2201	Basic Labor Policies.
970.2201-1	N/A	Labor Relations.
970.2201-1-1	970.2201(a)	General.
970.2201-1-2	970.2201(b)	Policies.
970.2201-1-3	970.2201(b)(5)(ii)	Contract Clause.
970.2201-2	970.2275	Overtime Management
970.2201-2-1	970.2275-1	Policy.
970.2201-2-2	970.2275-2	Contract Clause.
N/A	970.2206	Walsh-Healey Public Contracts Act.

New citation	Current citation	Title
970.2204	N/A	Labor Standards for Contracts Involving Construction.
970.2204-1	N/A	Statutory and Regulatory Requirements.
970.2204-1-1	970.2273	Administrative Controls and Criteria for Application of the Davis-Bacon Act in Operational or Maintenance Activities.
970.2208	970.2208	Equal Employment Opportunity.
970.2210	970.2210	Service Contract Act.
970.2270	970.2270	Unemployment Compensation.
970.23	970.23	Environmental, Conservation, and Occupational Safety Programs
970.2303	970.2303	Hazardous Materials Identification and Material Safety.
970.2303-1	970.2303-1	General.
970.2303-2	970.2303-2	Clauses.
970.2304	970.2304	Use of Recovered/Recycled Materials.
970.2304-1	970.2304-1	General.
970.2304-2	970.2304-2	Contract Clause.
970.2305	970.2305	Workplace Substance Abuse Programs-Management and Operating Contracts.
970.2305-1	970.2305-1	General.
970.2305-2	970.2305-2	Applicability.
970.2305-3	970.2305-3	Definitions.
970.2305-4	970.2305-4	Solicitation Provision and Contract Clause.
970.2306	970.2305-5	Suspension of Payments, Termination of Contract, and Debarment and Suspension Actions.
N/A	970.25	Foreign Acquisition.
970.26	970.26	Other Socioeconomic Programs.
970.2670	970.2601 (Title)	Implementation of Section 3021 of the Energy Policy Act of 1992.
970.2670-1	970.2601(a)	Requirements.
970.2671	N/A	Diversity.
970.2671-1	970.2601(b)	Policy.
970.2671-2	970.2602-2(b)	Contract Clause.
970.2672	970.2602-1	Implementation of Section 3161 of the National Defense Authorization Act for Fiscal Year 1993.
970.2672-1	970.2602-1(a)	Policy.
970.2672-2	970.2602-1(b)	Requirements.
970.2672-3	970.2602-2(a)	Contract Clause.
970.2673	N/A	Regional Partnerships.
970.2673-1	N/A	Policy.
970.2673-2	N/A	Contract Clause.
970.27	970.27	Patents, Data, and Copyrights.
970.2701	970.2701 (Title)	General.
970.2701-1	970.2701 (Text)	Applicability.
970.2702	N/A	Patent related clauses.
970.2702-1	N/A	Authorization and consent.
970.2702-2	N/A	Notice and assistance regarding patent and copyright infringement.
970.2702-3	N/A	Patent indemnity.
970.2702-4	N/A	Royalties.
970.2702-5	N/A	Rights to proposal data.
970.2702-6	N/A	Notice of right to request patent waiver.
970.2703	970.2702 (Title)	Patent Rights.
970.2703-1	970.2702 (Text)	Purposes of patent rights clauses.
970.2703-2	970.2704	Patent rights clause provisions for management and operating contractors.
970.2704	N/A	Rights in Data.
970.2704-1	970.2705	General.
970.2704-2	970.2706	Procedures.
970.2704-3	970.2707	Contract Clauses.
970.2770	970.73	Technology Transfer.
970.2770-1	970.7310	General.
970.2770-2	970.7320	Policy.
970.2770-3	970.2703	Technology Transfer and Patent Rights.
970.2770-4	970.7330	Contract Clause.
970.28	970.28	Bonds and Insurance.
970.2803	N/A	Insurance.
970.2803-1	970.2271	Workers' Compensation Insurance.
970.2803-2	970.2830	Contract Clause.
970.29	970.29	Taxes.
970.2902	N/A	Federal Excise Taxes.
970.2902-1	970.2901	Exemptions from Federal Excise Taxes.
970.2903	N/A	State and Local Taxes.
970.2903-1	970.2902	Applicability of State and Local Taxes to the Government.
970.2904	N/A	Contract Clauses.
970.2904-1	970.2903	Management and Operating Contracts.
970.30	970.30	Cost Accounting Standards.
970.3002	970.3001	CAS Program Requirements.
970.3002-1	970.3001-1	Applicability.

New citation	Current citation	Title
N/A	970.3001-2	Limitations.
970.31	970.31	Contract Cost Principles and Procedures.
970.3101-00-70	970.3100	Scope of Subpart.
N/A	970.3100-1	Definitions.
N/A	970.3100-2	Responsibilities.
N/A	970.3100-3	Objectives.
970.3101-9	970.3101-6	Advance Agreements.
970.3101-10	N/A	Cost certification.
970.3102-3-70	N/A	Home Office Expenses.
N/A	970.3101-7	Cost Certification and Penalties on Unallowable Costs.
N/A	970.3101	General.
N/A	970.3101-1	Actual Cost Basis.
970.3102-05	970.3102	Application of Cost Principles.
N/A	970.3101-3	General Basis for Reimbursement of Costs.
N/A	970.3101-4	Cost Determination Based on Audit.
N/A	970.3101-5	Contractor's System of Accounting.
N/A	970.3101-2	Direct and Indirect Costs.
N/A	N/A	Selected Costs.
N/A	970.3102-19	Public Relations and Advertising.
970.3102-05-4	N/A	Bonding costs.
970.3102-05-6	970.3102-2	Compensation for Personal Services.
970.3102-05-18	N/A	Independent research and development and bid and proposal costs.
970.3102-05-19	N/A	Insurance and indemnification.
N/A	970.3102-3	Cost of Money.
N/A	970.3102-4	Depreciation.
N/A	970.3102-5	Employee Morale, Health, Welfare, Food Service, and Dormitory Costs.
N/A	970.3102-21	Fines, Penalties, and Mischarging Costs.
970.3102-05-22	970.3102-7	Lobbying and Political Activity Costs.
970.3102-05-28	N/A	Other business expenses.
970.3102-05-30	N/A	Patent costs and technology transfer costs.
N/A	970.3102-1	General and Administrative Expenses.
N/A	970.3102-12	Plant Reconversion Costs.
N/A	970.3102-13	Precontract Costs.
N/A	970.3102-9	Professional and Consultant Service Costs.
N/A	970.3102-16	Relocation Costs.
N/A	970.3102-8	Trade, Business and Professional Activity Costs.
970.3102-05-46	970.3102-17	Travel Costs.
970.3102-05-47	970.3102-20	Cost Related to Legal and Other Proceedings.
970.3102-05-53	N/A	Preexisting conditions.
N/A	970.3102-10	Overtime, Shift, and Holiday Premiums.
N/A	970.3102-11	Page Charges in Scientific Journals.
N/A	970.3102-14	Preparatory and Make-Ready Costs.
N/A	970.3102-6	Facilities (Plant and Equipment).
N/A	970.3102-18	Special Funds in the Construction Industry.
N/A	970.3102-15	Procurement: Subcontracts, Contractor-Affiliated Sources, and Leases.
970.3170	970.3103	Contract Clause.
970.32	970.32	Contract Financing
970.3200	970.3201	Policy.
970.3200-1	970.3272(a) and b	Reduction or Suspension of Advance, Partial, or Progress Payments.
970.3200-1-1	970.3272 (d)	Contract Clause.
970.3204	970.3202 (Title)	Advance Payments.
970.3204-1	970.3202 (Text)	Applicability.
N/A	970.3271	Special Bank Account Agreement.
970.3270	970.3270	Standard Financial Management Clauses.
970.34	970.70	Major System Acquisition.
970.3400	N/A	General Requirements.
970.3400-1	970.7000	Mission-oriented Solicitation.
970.35	N/A	Research and Development Contracting
970.3500	N/A	Scope of Subpart.
970.3501	N/A	Federally Funded Research and Development Centers.
970.3501-1	N/A	Sponsoring Agreements.
970.3501-2	N/A	Using an FFRDC.
970.3501-3	N/A	Reviewing FFRDC's.
970.3501-4	N/A	Contract Clause.
970.36	970.36	Construction and Architect-Engineer Contracts.
970.3605	N/A	Contract Clauses.
970.3605-1	970.5204-43	Other Contracts.
970.3605-2	970.3601	Special Construction Clause for Operating Contracts.
970.37	N/A	Facilities Management Contracting.
970.3770	970.72	Facilities Management.
970.3770-1	970.7201	Policy.
970.3770-2	970.7201	Contract Clause.

New citation	Current citation	Title
970.41	970.41	Acquisition of Utility Services.
970.4102	N/A	Acquiring Utility Services.
970.4102-1	970.4100	Policy.
970.42	N/A	Contract Administration.
970.4207-03-02	N/A	Certificate of costs.
970.4207-03-70	N/A	Contract clause.
970.4207-05-01	N/A	Contracting officer determination procedure.
970.43	N/A	Contract Modifications.
970.4302	N/A	Changes.
970.4302-1	N/A	Contract Clause.
970.44	970.71	Management and Operating Contractor Purchasing.
970.4400	N/A	Scope.
970.4401	N/A	Responsibilities.
970.4401-1	970.7102	General.
970.4401-2	970.7108	Review and Approval.
970.4401-3	970.7109	Advance Notification.
970.4402	N/A	Contractor Purchasing System.
970.4402-1	970.7101	Policy.
970.4402-2	970.7103	General Requirements.
970.4402-3	970.7105	Purchasing From Contractor-Affiliated Sources.
970.4402-4	970.7110	Nuclear Material Transfers.
970.4403	N/A	Contract Clause.
970.45	970.45	Government Property.
970.4501	N/A	General.
970.4501-1	970.4501	Contract Clause.
970.49	970.49	Termination of Contracts.
970.4905	N/A	Contract Termination Clause.
970.4905-1	970.4901 and 970.4902	Termination for Convenience of the Government and Default.
970.50	N/A	Extraordinary Contractual Actions.
970.5004	N/A	Residual Powers.
970.5004-1	N/A	Contract Clause.
970.5070	970.2870 (Title)	Indemnification.
970.5070-1	970.2870(a) and (b)	Scope and Applicability.
970.5070-2	970.2870(e)	General.
970.5070-3	970.2870(c) and (d)	Contract Clauses.
N/A	970.51	Use of Government Sources by Contractors.
970.52	970.52	Solicitation Provisions and Contract Clauses for Management and Operating Contracts.
970.5200	970.5201	Scope of Subpart.
N/A	970.5203	Modifications and Notes to Far Clauses.
970.5201	970.5204	Text of Provisions and Clauses.
970.5203-1	970.5204-20	Management Controls.
970.5203-2	N/A	Performance Improvement and Collaboration.
970.5203-3	970.5204-12	Contractor's Organization.
970.5204-1	970.5204-1	Counterintelligence.
970.5204-2	970.5204-78	Laws, Regulations, and DOE Directives.
970.5204-3	970.5204-79	Access to and Ownership of Records.
970.5208-1	970.5204-19	Printing.
970.5209-1	970.5204-89	Requirement for Guarantee of Performance.
970.5215-1	970.5204-54	Total Available Fee: Base Fee Amount and Performance Fee Amount.
970.5215-2	970.5204-76	Make-or-Buy Plan.
970.5215-3	970.5204-86	Conditional Payment of Fee, Profit, or Incentives.
970.5215-4	970.5204-87	Cost Reduction.
970.5215-5	970.5204-88	Limitation on Fee.
970.5222-1	970.5204-63	Collective Bargaining Agreements—Management and Operating Contracts.
970.5222-2	970.5204-80	Overtime Management.
970.5223-1	970.5204-2	Integration of Environment, Safety and Health into Work Planning and Execution.
970.5223-2	970.5204-39	Acquisition and Use of Environmentally Preferable Products and Services.
970.5223-3	970.5204-57	Agreement Regarding Workplace Substance Abuse Programs at DOE Facilities.
970.5223-4	970.5204-58	Workplace Substance Abuse Programs at DOE Sites.
970.5226-1	970.5204-81	Diversity Plan.
970.5226-2	970.5204-77	Workforce Restructuring under Section 3161 of the National Defense Authorization Act for Fiscal Year 1993.
970.5226-3	N/A	Community Commitment.
970.5227-1	970.5204-82	Rights in Data-Facilities.
970.5227-2	970.5204-83	Rights in Data-Technology Transfer
970.5227-3	970.5204-40	Technology Transfer Mission.
970.5227-4	N/A	Authorization and consent.
970.5227-5	N/A	Notice and assistance regarding patent and copyright infringement.

New citation	Current citation	Title
970.5227-6	N/A	Patent indemnity—subcontracts.
970.5227-7	N/A	Royalty information.
970.5227-8	N/A	Refund of royalties.
970.5227-9	N/A	Notice of right to request patent waiver.
970.5227-10	970.5204-71	Patent rights—management and operating contracts, nonprofit organization or small business firm contractor.
970.5227-11	970.5204-72	Patent rights—management and operating contracts, for-profit contractor, non-technology transfer.
970.5227-12	N/A	Patent rights—management and operating contracts, for-profit contractor, advance class waiver.
970.5228-1	970.5204-31	Insurance—Litigation and Claims.
970.5229-1	970.5204-23	State and Local Taxes.
N/A	970.5204-13	Allowable Costs and Fee (Management and Operating Contracts).
970.5231-4	970.5204-75	Preexisting Conditions.
970.5232-1	970.5204-85	Reduction or Suspension of Advance, Partial, or Progress Payments upon Finding of Substantial Evidence of Fraud.
970.5232-2	970.5204-16	Payments and Advances.
970.5232-3	970.5204-9	Accounts, Records, and Inspection.
970.5232-4	970.5204-15	Obligation of Funds.
970.5232-5	N/A	Liability with respect to cost accounting standards.
970.5232-6	N/A	Work for others funding authorization.
970.5232-7	N/A	Financial management system.
970.5232-8	N/A	Integrated accounting.
970.5235-1	N/A	Federally Funded Research and Development Center Sponsoring Agreement.
970.5236-1	970.5204-38	Government Facility Subcontract Approval.
N/A	970.5204-84	Waiver of Limitations on Severance Payments to Foreign Nationals.
970.5237-2	970.5204-60	Facilities Management.
970.5242-1	N/A	Penalties for unallowable costs.
970.5243-1	970.5204-11	Changes.
970.5244-1	970.5204-22	Contractor Purchasing System.
970.5245-1	970.5204-21	Property.
N/A	970.5204-3	Buy American Act" Construction Materials.
N/A	970.5204-4	New Mexico Gross Receipts and Compensating Tax.
N/A	970.5204-5	Disclosure of Information.
N/A	970.5204-6	Nuclear Hazards Indemnity.
N/A	970.5204-7	Protecting the Government's Interest When Subcontracting with Contractors Debarred, Suspended, or Proposed for Debarment.
N/A	970.5204-8	Indemnity Assurance to Architect-Engineer or Supplier Prior to Operation of a Nuclear Facility.
N/A	970.5204-10	Foreign Ownership, Control, or Influence over Contractors (FOCI).
N/A	970.5204-14	Allowable Costs and Fixed-fee (Support Contracts).
N/A	970.5204-25	Workmanship and Materials.
N/A	970.5204-27	Consultant or Other Comparable Employment Services of Contractor Employees.
N/A	970.5204-28	Assignment.
N/A	970.5204-29	Permits or Licenses.
N/A	970.5204-30	Notice of Labor Disputes.
N/A	970.5204-33	Priorities and Allocations.
N/A	970.5204-35	Controls in the National Interest (Unclassified Contracts with Educational Institutions).
N/A	970.5204-36	Preventing Conflicts of Interest in University Research.
N/A	970.5204-37	Statement of Work (Management and Operating Contracts).
N/A	970.5204-42	Key Personnel.
N/A	970.5204-43	Other Government Contractors.
N/A	970.5204-44	Flowdown of Contract Requirements to Subcontracts.
N/A	970.5204-45	Termination.
N/A	970.5204-52	Foreign Travel.
N/A	970.5204-53	Contractor Employee Travel Discounts.
952.203-70	970.5204-59	Whistleblower Protection for Contractor Employees.
N/A	970.5204-71	Patent Rights-nonprofit Management and Operating Contractors.
N/A	970.5204-72	Patent Rights-profit-making Management and Operating Contractors.
N/A	970.5204-73	Notice Regarding Options.
N/A	970.5204-74	Option to Extend the Term of the Contract.

III. Procedural Requirements

A. Review Under Executive Order 12866

Today's regulatory action has been determined not to be a "significant regulatory action" under Executive

Order 12866, "Regulatory Planning and Review," (58 FR 51735, October 4, 1993). Accordingly, today's action was not subject to review under the Executive Order by the Office of

Information and Regulatory Affairs of the Office of Management and Budget.

B. Review Under Executive Order 12988

With respect to the review of existing regulations and the promulgation of

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

C. Review Under the Regulatory Flexibility Act

This rule was reviewed under the Regulatory Flexibility Act of 1980, Pub. L. 96-354, which requires preparation of a regulatory flexibility analysis for any rule which is likely to have a significant economic impact on a substantial number of small entities. This rule would only apply to M&O contractors, which are all large entities. DOE certified that the rules that are formalized today will not have a significant economic impact on a substantial number of small entities and, therefore, no regulatory flexibility analysis has been prepared. DOE did not receive any comments on its certifications.

D. Review Under the Paperwork Reduction Act

No new information collection requirements subject to the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*, are imposed by today's regulatory action.

E. Review Under Executive Order 13132

Executive Order 13132 (64 FR 43255, August 4, 1999) imposes certain requirements on agencies formulating and implementing policies or regulations that preempt State law or that have federalism implications. Agencies are required to examine the constitutional and statutory authority supporting any action that would limit the policymaking discretion of the States and carefully assess the necessity for such actions. DOE has examined today's rule and has determined that it does not preempt State law and does not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. No further action is required by Executive Order 13132.

F. Review Under the National Environmental Policy Act

Pursuant to the Council on Environmental Quality Regulations (40 CFR Parts 1500-1508), the Department of Energy has established guidelines for its compliance with the provisions of the National Environmental Policy Act (NEPA) of 1969 (42 U.S.C. 4321 *et seq.*). Pursuant to appendix A of subpart D of 10 CFR part 1021, National Environmental Policy Act Implementing Procedures (57 FR 15122, 15152, April 24, 1992) (Categorical Exclusion A6), the Department of Energy has determined that this rule is categorically excluded from the need to prepare an environmental impact statement or environmental assessment.

G. Review Under the Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform Act of 1995 requires each Agency to assess the effects of Federal regulatory action on State, local, and tribal governments and the private sector. The Department has determined that today's regulatory action does not impose a Federal mandate on State, local, or tribal governments or on the private sector.

H. Review Under Small Business Regulatory Enforcement Fairness Act of 1996

As required by 5 U.S.C. 801, the Department of Energy will report to Congress promulgation of the rule prior to its effective date. The report will state that it has been determined that the rule is not a "major rule" as defined by 5 U.S.C. 804(3).

List of Subjects in 48 CFR Parts 901, 902, 903, 904, 909, 911, 915, 917, 922, 923, 927, 941, 942, 947, 951, 952, and 970.

Government procurement.

Issued in Washington, D.C. on November 30, 2000.

T.J. Glauthier,

Deputy Secretary, Department of Energy.

For the reasons set out in the preamble, Chapter 9 of Title 48 of the Code of Federal Regulations is amended as set forth below.

1. The authority citations for parts 901, 902, 903, 904, 909, 911, 915, 917, 922, 923, 941, 942, 947, 951, and 952 continue to read as follows:

Authority: 42 U.S.C. 7254; 40 U.S.C. 486(c); 50 U.S.C. 2401 *et seq.*

PART 901—FEDERAL ACQUISITION REGULATIONS SYSTEM

901.105 [Amended]

2. Section 901.105 is amended in the second sentence by revising "(see 48 CFR (DEAR) 970.5204-76)" to read "(see 48 CFR 970.5215-2)", and by revising "(see 48 CFR (DEAR) 970.5204-2)" to read "(see 48 CFR 970.5223-1)."

PART 902—DEFINITIONS OF WORDS AND TERMS

3. Section 902.200 is revised to read as follows:

902.200 Definitions clause.

As prescribed by 48 CFR Subpart 2.2, insert the clause at 48 CFR 52.202-1, Definitions, but modify the clause to limit the definition at paragraph (a) to encompass only the Secretary, Deputy Secretary, or Under Secretary of the Department of Energy, and the Chairman, Federal Energy Regulatory Commission. The contracting officer shall also add a paragraph at the end of the clause that defines "DOE" as meaning the United States Department of Energy and "FERC" as meaning the Federal Energy Regulatory Commission. Additional definitions may be included, provided they are consistent with the clause, the Federal Acquisition Regulation and this Department of Energy Acquisition Regulation.

PART 903—IMPROPER BUSINESS PRACTICES AND PERSONAL CONFLICTS OF INTEREST

4. Subpart 903.9 is added to read as follows:

Subpart 903.9—Whistleblower Protection for Contractor Employees

Sec.	
903.901	Scope.
903.902	Definition.
903.903	Applicability.
903.970	Remedies.
903.971	Contract clause.

Subpart 903.9—Whistleblower Protection for Contractor Employees

903.901 Scope.

This subpart implements the DOE Contractor Employee Protection Program as set forth at 10 CFR part 708. Part 708 establishes criteria and procedures for the investigation, hearing, and review of allegations from DOE contractor employees of employer reprisal resulting from employee disclosure of information to DOE, to Members of Congress, or to the contractor; employee participation in proceedings before Congress or pursuant to this subpart; or employee refusal to engage in illegal or dangerous activities, when such disclosure, participation, or refusal pertains to employer practices which the employee believes to be unsafe; to violate laws, rules, or regulations; or to involve fraud, mismanagement, waste, or abuse.

903.902 Definition.

Contractor, as used in this subpart, has the meaning contained in 10 CFR 708.2.

903.903 Applicability.

10 CFR part 708 is applicable to complaints of retaliation filed by employees of contractors, and subcontractors, performing work on behalf of DOE directly related to DOE-owned or leased facilities, if the complaint stems from a disclosure, participation, or refusal described in 10 CFR 708.5.

903.970 Remedies.

(a) Contractors found to have retaliated against an employee in reprisal for such disclosure, participation or refusal are required to provide relief in accordance with decisions issued under 10 CFR part 708.

(b) 10 CFR part 708 provides that for the purposes of the Contract Disputes Act (41 U.S.C. 605 and 606), a final decision issued pursuant to 10 CFR part 708 shall not be considered to be a claim by the Government against a contractor or a decision by the contracting officer subject to appeal. However, a contractor's disagreement and refusal to comply with a final decision could result in a contracting officer's decision to disallow certain costs or to terminate the contract for default. In such case, the contractor could file a claim under the Disputes

clause of the contract regarding the disallowance of cost or the termination of the contract.

903.971 Contract clause.

The contracting officer shall insert the clause at 952.203–70, Whistleblower Protection for Contractor Employees, in contracts that involve work to be done on behalf of DOE directly related to activities at DOE-owned or leased sites.

PART 904—ADMINISTRATIVE MATTERS

5. Subpart 904.72 is added to read as follows:

Subpart 904.72—Public Affairs

Sec.	
904.7200	Purpose.
904.7201	Contract clause.

Subpart 904.72—Public Affairs

904.7200 Purpose.

It is the policy of the Department of Energy to provide to the public and the news media, accurate and timely unclassified information on Departmental policies, programs, and activities. The Department's contractors share the responsibility for releasing unclassified information related to efforts under their contracts and must coordinate the release of unclassified information with the cognizant contracting officer and appropriate DOE Public Affairs personnel.

904.7201 Contract clause.

The contracting officer shall insert the clause at 952.204–75 in solicitations and contracts that require the contractor to release unclassified information related to efforts under its contract regarding DOE policies, programs, and activities.

PART 909—CONTRACTOR QUALIFICATIONS

909.104–1 [Amended]

6. Subsection 909.104–1 is amended by revising “48 CFR 970.5204–57” to read “48 CFR 970.5223–3.”

PART 911—DESCRIBING AGENCY NEEDS

7. Section 911.604 is amended by revising paragraphs (d) and (e) to read as follows:

911.604 Solicitation provision and contract clause.

* * * * *

(d) The contracting officer shall insert the provision at 952.211–70, Priorities and Allocations (Domestic Energy Supplies), with its Alternate I, in solicitations that may result in the

placement of rated orders for authorized energy programs, and in solicitations for all management and operating contracts.

(e) The contracting officer shall insert the clause at 952.211–71, Priorities and Allocations (Domestic Energy Supplies), with its Alternate I, if it is believed the contract involves a program the purpose of which is to maximize domestic energy supplies, and in all management and operating contracts.

PART 915—CONTRACTING BY NEGOTIATION

8. Subsection 915.408–70 is added to read as follows:

915.408–70 Solicitation provision and contract clause.

The contracting officer (after deleting “under the clause at 48 CFR 970.5203–3, Contractor's Organization” from paragraph (a) if not a management and operating contract) shall insert the clause at 48 CFR 952.215–70, Key Personnel, in contracts under which performance is largely dependent on the expertise of specific key personnel.

PART 917—SPECIAL CONTRACTING METHODS

9. Section 917.600 is revised to read as follows:

917.600 Scope of subpart.

(a) This subpart implements 48 CFR subpart 17.6, Management and Operating Contracts. Departmental policies, procedures, provisions and clauses to be used in the award and administration of management and operating contracts that either implement or supplement the Federal Acquisition Regulation and parts 901 through 952 of this chapter are contained in 48 CFR part 970.

(b) The requirements of this subpart apply to any Department of Energy management and operating contract, including performance-based management contracts as defined in 48 CFR 917.601. References in this subpart to “management and operating contracts” include performance-based management contracts.

10. Section 917.601 is amended by revising the definition of performance-based contracting as follows:

917.601 Definitions.

Performance-based contracting has the meaning contained in 48 CFR 37.101.

* * * * *

11. Section 917.602 is revised to read as follows:

917.602 Policy.

(a) The use of a management and operating contract must be authorized by the Secretary, Deputy Secretary or Under Secretary.

(b) It is the policy of the Department of Energy to provide for full and open competition in the award of management and operating contracts, including performance-based management contracts.

(c) A management and operating contract may be awarded or extended at the completion of its term without providing for full and open competition only when such award or extension is justified under one of the statutory authorities identified in 48 CFR 6.302 and only when authorized by the Head of the Agency. Documentation and processing requirements for justifications for the use of other than full and open competition shall be accomplished in accordance with internal agency procedures

917.604 and 917.605 [Removed]

12. Sections 917.604 and 917.605 are removed.

PART 922—APPLICATION OF LABOR LAWS TO GOVERNMENT ACQUISITION**922.71 [Removed]**

13. Subpart 922.71 is removed.

PART 923—ENVIRONMENT, CONSERVATION, OCCUPATIONAL SAFETY AND DRUG-FREE WORKPLACE**923.570-2 [Amended]**

14. Subsection 923.570-2 is amended in paragraph (a) by revising “48 CFR 970.5204-57” to read “48 CFR 970.5223-3”; and in paragraph (b) by revising “970.5204-58” to read “48 CFR 970.5223-4.”

923.570-3 [Amended]

15. Subsection 923.570-3 is amended in paragraph (a) by revising “970.5204-58” to read “48 CFR 970.5223-4”, and in paragraph (b)(2) by revising “970.5204-57” to read “970.5223-3.”

PART 927—PATENTS, DATA, AND COPYRIGHTS

16. The authority citation for part 927 continues to read as follows:

Authority: Atomic Energy Act of 1954, as amended (42 U.S.C. 2168, 2182, 2201); Federal Nonnuclear Energy Research and Development Act of 1974 (42 U.S.C. 5908); Department of Energy National Security and Military Applications of Nuclear Energy Authorization Act of 1987 (42 U.S.C. 7261a.); Department of Energy Organization Act (42

U.S.C. 7101 *et seq.*); National Nuclear Security Administration Act (50 U.S.C. 4201 *et seq.*)

927.303 [Amended]

17. Paragraph (a)(3) of section 927.303 is amended by revising “970.5204-71 or 970.5204-72” to read “970.5227-10, 970.5227-11, or 970.5227-12.”

927.402-1 [Amended]

18. Subsection 927.402-1 is amended in paragraph (b) by revising “(see 970.2705)” to read “(see 48 CFR 970.2704)”, and by revising “970.5204-82” to read “48 CFR 970.5227-1.”

927.404 [Amended]

19. Section 927.404 is amended in paragraph (g)(4) by revising “970.5204-82” to read “48 CFR 970.5227-2.”

927.409 [Amended]

20. Section 927.409 is amended in paragraph (a)(2)(vi) by revising “(See 970.2705)” to read “(see 48 CFR 970.2704).”

PART 935—RESEARCH AND DEVELOPMENT CONTRACTING**935.070 [Removed]**

21. Section 935.070 is removed.

PART 941—ACQUISITION OF UTILITY SERVICES

22. Subsection 941.201-71 is amended by revising “48 CFR 970.0803” to read “48 CFR 970.4102-1.”

PART 942—CONTRACT ADMINISTRATION

23. Subpart 942.2 is added as follows:

Subpart 942.2—Contract Administration Services

Sec.

942.270-1 Contracting Officer's Representatives
942.270-2 Contract Clause

Subpart 942.2—Contract Administration Services**942.270-1 Contracting Officer's Representatives.**

In accordance with internal agency procedures, a contracting officer may designate other qualified personnel to be the Contracting Officer's Representative (COR) for the purpose of performing certain technical functions in administering a contract. These functions include, but are not limited to, technical monitoring, inspection, approval of shop drawings, testing, and approval of samples. The COR acts

solely as a technical representative of the contracting officer and is not authorized to perform any function that results in a change in the scope, price, terms or conditions of the contract. COR designations must be made in writing by the contracting officer, and shall identify the responsibilities and limitations of the designation. A copy of the COR designation must be furnished to the contractor and the contract administration office.

942.270-2 Contract Clause.

The clause at 952.242-70, or a clause substantially the same, may be inserted in solicitations and contracts when a designated Contracting Officer's Representative will issue technical direction to the contractor under the contract.

PART 947—TRANSPORTATION

24. Subpart 947.70 is added to read as follows:

Subpart 947.70—Foreign Travel

Sec.

947.7000 [Reserved]
947.7001 Policy.
947.7002 Contract clause.

Subpart 947.70—Foreign Travel**947.7000 [Reserved]****947.7001 Policy.**

Contractor foreign travel shall be conducted pursuant to the requirements contained in DOE Order 551.1, Official Foreign Travel, or any subsequent version of the order in effect at the time of award.

947.7002 Contract clause.

When foreign travel may be required under the contract, the contracting officer shall insert the clause at 48 CFR 952.247-70, Foreign Travel.

PART 951—USE OF GOVERNMENT SOURCES BY CONTRACTORS

25. Subpart 951.70 is revised to read as follows:

Subpart 951.70—Contractor Employee Travel Discounts**951.7002 Responsibilities.**

The contracting officer shall insert the clause at 952.251-70, Contractor employee travel discounts, in all cost-reimbursable solicitations and contracts when significant costs for rail travel, car rental, or lodging will be required to perform the contract. The contracting officer may furnish the contractor with appropriate identification letters.

PART 952—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

26. Section 952.203–70 is added to read as follows:

952.203–70 Whistleblower Protection for Contractor Employees.

As prescribed in 48 CFR 903.971, insert the following clause:

Whistleblower Protection for Contractor Employees (DEC 2000)

(a) The contractor shall comply with the requirements of “DOE Contractor Employee Protection Program” at 10 CFR part 708 for work performed on behalf of DOE directly related to activities at DOE-owned or -leased sites.

(b) The contractor shall insert or have inserted the substance of this clause, including this paragraph (b), in subcontracts at all tiers, for subcontracts involving work performed on behalf of DOE directly related to activities at DOE-owned or leased sites.

(End of Clause)

27. Section 952.204–75 is added as follows:

952.204–75 Public Affairs.

As prescribed in 48 CFR 904.7201, insert the following clause.

Public Affairs (DEC 2000)

(a) The Contractor must cooperate with the Department in releasing unclassified information to the public and news media regarding DOE policies, programs, and activities relating to its effort under the contract. The responsibilities under this clause must be accomplished through coordination with the Contracting Officer and appropriate DOE public affairs personnel in accordance with procedures defined by the Contracting Officer.

(b) The Contractor is responsible for the development, planning, and coordination of proactive approaches for the timely dissemination of unclassified information regarding DOE activities onsite and offsite, including, but not limited to, operations and programs. Proactive public affairs programs may utilize a variety of communication media, including public workshops, meetings or hearings, open houses, newsletters, press releases, conferences, audio/visual presentations, speeches, forums, tours, and other appropriate stakeholder interactions.

(c) The Contractor’s internal procedures must ensure that all releases of information to the public and news media are coordinated through, and approved by, a management official at an appropriate level within the Contractor’s organization.

(d) The Contractor must comply with DOE procedures for obtaining advance clearances on oral, written, and audio/visual informational material prepared for public dissemination or use.

(e) Unless prohibited by law, and in accordance with procedures defined by the Contracting Officer, the Contractor must notify the Contracting Officer and appropriate DOE public affairs personnel of

communications or contacts with Members of Congress relating to the effort performed under the contract.

(f) In accordance with procedures defined by the Contracting Officer, the Contractor must notify the Contracting Officer and appropriate DOE public affairs personnel of activities or situations that may attract regional or national news media attention and of non-routine inquiries from national news media relating to the effort performed under the contract.

(g) In releases of information to the public and news media, the Contractor must fully and accurately identify the Contractor’s relationship to the Department and fully and accurately credit the Department for its role in funding programs and projects resulting in scientific, technical, and other achievements.

(End of Clause)

28. Section 952.215–70 is added as follows:

952.215–70 Key Personnel.

As prescribed in 48 CFR 915.408–70, the contracting officer shall insert the following clause:

Key Personnel (DEC 2000)

(a) The personnel listed below or elsewhere in this contract [Insert cross-reference, if applicable] are considered essential to the work being performed under this contract. Before removing, replacing, or diverting any of the listed or specified personnel, the Contractor must: (1) Notify the Contracting Officer reasonably in advance; (2) submit justification (including proposed substitutions) in sufficient detail to permit evaluation of the impact on this contract; and (3) obtain the Contracting Officer’s written approval. Notwithstanding the foregoing, if the Contractor deems immediate removal or suspension of any member of its management team is necessary to fulfill its obligation to maintain satisfactory standards of employee competency, conduct, and integrity under the clause at 48 CFR 970.5203–3, Contractor’s Organization, the Contractor may remove or suspend such person at once, although the Contractor must notify Contracting Officer prior to or concurrently with such action.

(b) The list of personnel may, with the consent of the contracting parties, be amended from time to time during the course of the contract to add or delete personnel.

[Insert List of Key Personnel unless listed elsewhere in the contract]

(End of clause)

952.222–70 [Removed]

29. Section 952.222–70 is removed.

952.223–71 [Amended]

30. Section 952.223–71 is amended by revising “970.5204–2” to read “48 CFR 970.5223–1.”

31. Section 952.242–70 is added as follows:

952.242–70 Technical Direction.

As prescribed in 48 CFR 942.270–2, insert the following clause.

Technical Direction (DEC 2000)

(a) Performance of the work under this contract shall be subject to the technical direction of the DOE Contracting Officer’s Representative (COR). The term “technical direction” is defined to include, without limitation:

(1) Providing direction to the contractor that redirects contract effort, shift work emphasis between work areas or tasks, require pursuit of certain lines of inquiry, fill in details, or otherwise serve to accomplish the contractual Statement of Work.

(2) Providing written information to the contractor that assists in interpreting drawings, specifications, or technical portions of the work description.

(3) Reviewing and, where required by the contract, approving, technical reports, drawings, specifications, and technical information to be delivered by the contractor to the Government.

(b) The contractor will receive a copy of the written COR designation from the contracting officer. It will specify the extent of the COR’s authority to act on behalf of the contracting officer.

(c) Technical direction must be within the scope of work stated in the contract. The COR does not have the authority to, and may not, issue any technical direction that:

(1) Constitutes an assignment of additional work outside the Statement of Work;

(2) Constitutes a change as defined in the contract clause entitled “Changes;”

(3) In any manner causes an increase or decrease in the total estimated contract cost, the fee (if any), or the time required for contract performance;

(4) Changes any of the expressed terms, conditions or specifications of the contract; or

(5) Interferes with the contractor’s right to perform the terms and conditions of the contract.

(d) All technical direction shall be issued in writing by the COR.

(e) The contractor must proceed promptly with the performance of technical direction duly issued by the COR in the manner prescribed by this clause and within its authority under the provisions of this clause. If, in the opinion of the contractor, any instruction or direction by the COR falls within one of the categories defined in (c)(1) through (c)(5) of this clause, the contractor must not proceed and must notify the Contracting Officer in writing within five (5) working days after receipt of any such instruction or direction and must request the Contracting Officer to modify the contract accordingly. Upon receiving the notification from the contractor, the Contracting Officer must:

(1) Advise the contractor in writing within thirty (30) days after receipt of the contractor’s letter that the technical direction is within the scope of the contract effort and does not constitute a change under the Changes clause of the contract;

(2) Advise the contractor in writing within a reasonable time that the Government will issue a written change order; or

(3) Advise the contractor in writing within a reasonable time not to proceed with the instruction or direction of the COR.

(f) A failure of the contractor and Contracting Officer either to agree that the technical direction is within the scope of the contract or to agree upon the contract action to be taken with respect to the technical direction will be subject to the provisions of the clause entitled "Disputes."

(End of Clause)

32. Section 952.247-70 is revised to read as follows:

952.247-70 Foreign travel.

As prescribed in 48 CFR 947.7002, insert the following clause:

Foreign Travel (DEC 2000)

Contractor foreign travel shall be conducted pursuant to the requirements contained in DOE Order 551.1, Official Foreign Travel, or any subsequent version of the order in effect at the time of award.

(End of Clause)

952.250-70 [Amended]

33. Section 952.250-70 is amended in paragraph (h) by revising "Audit and records—negotiation", to read "Accounts, records, and inspection."

34. Section 952.251-70 is revised to read as follows:

952.251-70 Contractor employee travel discounts.

As prescribed in 48 CFR 951.70, insert the following clause.

Contractor Employee Travel Discounts (DEC 2000)

(a) The contractor shall take advantage of travel discounts offered to Federal contractor employee travelers by AMTRAK, hotels, motels, or car rental companies, when use of such discounts would result in lower overall trip costs and the discounted services are reasonably available. Vendors providing these services may require the contractor employee to furnish them a letter of identification signed by the authorized contracting officer.

(b) Contracted airlines. Contractors are not eligible for GSA contract city pair fares.

(c) Discount rail service. AMTRAK voluntarily offers discounts to Federal travelers on official business and sometimes extends those discounts to Federal contractor employees.

(d) Hotels/motels. Many lodging providers extend their discount rates for Federal employees to Federal contractor employees.

(e) Car rentals. The Military Traffic Management Command (MTMC) of the Department of Defense negotiates rate agreements with car rental companies that are available to Federal travelers on official business. Some car rental companies extend those discounts to Federal contractor employees.

(f) Obtaining travel discounts.

(1) To determine which vendors offer discounts to Government contractors, the contractor may review commercial publications such as the Official Airline

guides Official Traveler, Innovata, or National Telecommunications. The contractor may also obtain this information from GSA contract Travel Management Centers or the Department of Defense's Commercial Travel Offices.

(2) The vendor providing the service may require the Government contractor to furnish a letter signed by the contracting officer. The following illustrates a standard letter of identification.

OFFICIAL AGENCY LETTERHEAD

TO: Participating Vendor

SUBJECT: OFFICIAL TRAVEL OF
GOVERNMENT CONTRACTOR

(FULL NAME OF TRAVELER), the bearer of this letter is an employee of (COMPANY NAME) which has a contract with this agency under Government contract (CONTRACT NUMBER). During the period of the contract (GIVE DATES), AND WITH THE APPROVAL OF THE CONTRACT VENDOR, the employee is eligible and authorized to use available travel discount rates in accordance with Government contracts and/or agreements. Government Contract City Pair fares are not available to Contractors.

SIGNATURE, Title and telephone number of Contracting Officer

35. The authority citation for Part 970 continues to read as follows:

Authority: Sec. 161 of the Atomic Energy Act of 1954 (42 U.S.C. 2201), sec. 644 of the Department of Energy Organization Act (42 U.S.C. 7101, *et seq.*), National Nuclear Security Agency (50 U.S.C. 2401 *et seq.*)

36. Part 970 is revised to read as follows:

PART 970—DOE MANAGEMENT AND OPERATING CONTRACTS

Sec.

Subpart 970.01—Management and Operating Contract Regulatory System

970.0100 Scope of part.

970.0103 Publication and codification.

Subpart 970.03—Improper Business Practices and Personal Conflicts of Interest

970.0309 Whistleblower protection of contractor employees.

970.0309-1 Applicability.

970.0370 Management controls and improvements.

970.0370-1 Policy.

970.0370-2 Contract clause.

970.0371 Conduct of employees of DOE management and operating contractors.

970.0371-1 Scope of section.

970.0371-2 Applicability.

970.0371-3 Definition.

970.0371-4 Gratuities.

970.0371-5 Use of privileged information.

970.0371-6 Incompatibility between regular duties and private interests.

970.0371-7 Outside employment of contractor employees.

970.0371-8 Employee disclosure concerning other employment services.

970.0371-9 Contract clause.

Subpart 970.04—Administrative Matters

970.0404 Safeguarding classified information.

970.0404-1 Definitions.

970.0404-2 General.

970.0404-3 Responsibilities of contracting officers.

970.0404-4 Solicitation provision and contract clauses.

970.0407 Contractor records retention.

970.0407-1 Applicability.

970.0407-1-1 Alternate retention schedules.

970.0407-1-2 Access to and ownership of records.

970.0407-1-3 Contract clause.

970.0470 Department of Energy Directives.

970.0470-1 General.

970.0470-2 Contract clause.

Subpart 970.08—Required Sources of Supplies and Services

970.0801 Excess personal property.

970.0801-1 Policy.

970.0808 Acquisition of printing.

970.0808-1 Scope of section.

970.0808-2 Policy.

970.0808-3 Contract clause.

Subpart 970.09—Contractor Qualifications

970.0905 Organizational conflicts of interest.

970.0970 Performance guarantees.

970.0970-1 Determination of responsibility.

970.0970-2 Solicitation provision.

Subpart 970.11—Describing Agency Needs

970.1100 Policy.

970.1100-1 Performance-based contracting.

970.1100-2 Additional considerations.

970.1103-4 Contract clause.

Subpart 970.15—Contracting by Negotiation

970.1504 Contract pricing.

970.1504-1 Price analysis

970.1504-1-1 Fees for management and operating contracts.

970.1504-1-2 Fee policy.

970.1504-1-3 Special considerations: Laboratory management and operation.

970.1504-1-4 Types of contracts and fee arrangements.

970.1504-1-5 General considerations and techniques for determining fixed fees.

970.1504-1-6 Calculating fixed fee.

970.1504-1-7 Fee base.

970.1504-1-8 Special equipment purchases.

970.1504-1-9 Special considerations: Cost-plus-award-fee.

970.1504-1-10 Special considerations: Fee limitations.

970.1504-1-11 Documentation.

970.1504-2 Price negotiation.

970.1504-3 Documentation.

970.1504-3-1 Cost or pricing data.

970.1504-4 Special cost or pricing areas.

970.1504-4-1 Make-or-buy plans.

970.1504-4-2 Policy.

970.1504-4-3 Requirements.

970.1504-5 Solicitation provision contract clauses.

Subpart 970.17—Special Contracting Methods

970.1706 Management and operating contracts.

- 970.1706-1 Award, renewal, and extension.
970.1706-2 Contract clause.

Subpart 970.19—Small, Small Disadvantaged and Women-Owned Small Business Concerns

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Subpart 970.01—Management and Operating Contract Regulatory System**970.0100 Scope of part.**

This part provides Departmental policies, procedures, provisions, and clauses that implement and supplement the Federal Acquisition Regulation (FAR) and other parts of the Department of Energy Acquisition Regulation (DEAR) for the award and administration of the Department's management and operating contracts, as defined at 48 CFR subpart 17.6. The FAR and other parts of the DEAR apply to management and operating contracts. See 48 CFR 970.5200 for guidance regarding which provisions and clauses (from FAR, DEAR Part 970, or other parts of the DEAR) to include in management and operating contracts.

970.0103 Publication and codification.

(a) *Organization of Part 970.* (1) To the extent possible, the titles and text of the subparts, sections, and subsections of this part are numbered to correspond with related material that is contained in the FAR.

(2) The number to the left of the decimal point represents the DEAR part number (*i.e.*, 970). The numbers to the right of the decimal point and to the left of the dash represent, in order, the DEAR subpart (first two digits), and the DEAR section number (second two digits). The numbers to the right of the dash represent the DEAR subsection. A second dash may follow the DEAR subsection number. As applicable, numbers to the right of the second dash represent subordinate subsections.

(3) To the extent practicable, the subpart number corresponds with the FAR part which contains related coverage, and the section number corresponds with the FAR subpart which contains related coverage (*e.g.*, the coverage contained in DEAR 970.0309 corresponds with material contained in FAR 3.9).

(4) Where the FAR does not contain related coverage on a particular subject, the DEAR section number will be numbered using numbers of 70 and up (*e.g.*, 970.0370).

(b) *Special Note Regarding Clause Numbering.* The section number for clauses prescribed in part 970 are numbered to correspond with the subpart in which the clause is prescribed (*e.g.*, 970.5203-1 is prescribed for use at subpart 970.03).

Subpart 970.03—Improper Business Practices and Personal Conflicts of Interest**970.0309 Whistleblower Protection of Contractor Employees.****970.0309-1 Applicability.**

The contracting officer shall refer to 48 CFR subpart 903.9 regarding the applicability of the DOE Employee Protection Program to management and operating contracts.

970.0370 Management Controls and Improvements.**970.0370-1 Policy.**

(a) Management and operating contractors shall develop and maintain systems of management and quality control to discourage waste, fraud and abuse; and to ensure that components, products, and services that are provided to DOE satisfy the contractor's obligations under the contract.

(b) As a part of the required overall management structure, the contractor must maintain management control systems which, in compliance with the requirements of the clause at 48 CFR 970.5203-1:

(1) Are documented and satisfactory to DOE;

(2) Ensure that all levels of management are accountable for effective management systems and internal controls within their areas of assigned responsibility;

(3) Cover both programmatic and administrative functions;

(4) Provide reasonable assurance that Government resources are safeguarded against theft, fraud, waste, and unauthorized use;

(5) Promote efficient and effective operations;

(6) Ensure that all obligations and costs incurred are in compliance with

the intended purposes and the terms and conditions of the contract;

(7) Properly record, manage, and report all revenues, expenditures, transactions and assets;

(8) Maintain financial, statistical and other reports necessary to maintain accurate, reliable, and timely accountability and management controls;

(9) Are periodically reviewed to ensure that the systems provide reasonable assurance that the objectives of the system are being accomplished and that these controls are working effectively;

(10) Are in accordance with the Comptroller General's standards for internal controls, as set forth in the General Accounting Office Policy and Procedures Manual For Guidance To Federal Agencies, (Oct 1984), as amended.

(c) Management and operating contractors shall also develop and maintain a baseline program of quality assurance that will implement documented performance and quality standards, and management controls and assessment techniques to ensure components, services, and products meet DOE's, design criteria and other governing and applicable specifications.

(d) DOE expects all its contractors to seek to identify improvements in any aspect of performance. Management and operating contracts are very large and complex; therefore, the opportunities to identify changes in performance that will increase the effectiveness or efficiency of contract performance are more prevalent than under other contracts. The clause at 48 CFR 970.5203-2 requires DOE management and operating contractors to affirmatively seek to identify, evaluate, and institute, where appropriate, processes that will improve the effectiveness or efficiency of any aspect of contract performance. It further requires the contractor to communicate any such improvements to DOE, other management and operating contractors, and DOE major facilities contractors. The contractor is required to participate in efforts by those contractors to address common problems or the institution of improvements. It allows the contractor to enlist the aid of the DOE contracting officer where necessary to institute or communicate the improvements. The obligations under the clause in no way affect the contractor's obligations under other provisions of the contract to notify or acquire the approval of the contracting officer.

970.0370-2 Contract clause.

(a) The contracting officer shall insert the clause at 970.5203-1, Management Controls, in all management and operating contracts.

(b) The contracting officer shall insert the clause at 970.5203-2, Performance Improvement and Collaboration, in all management and operating contracts.

970.0371 Conduct of employees of DOE management and operating contractors.

970.0371-1 Scope of section.

This section establishes the policies for maintaining satisfactory standards of conduct on the part of individuals employed by DOE management and operating contractors.

970.0371-2 Applicability.

The policies in this section are applicable to all DOE management and operating contractors.

970.0371-3 Definition.

Employees, as used in this section, are defined to mean individuals employed by the contractor, both full and part-time, who are assigned to work under a DOE management and operating contract.

970.0371-4 Gratuities.

Employees of a management and operating contractor shall not, under circumstances which might reasonably be interpreted as an attempt to influence the recipients in the conduct of their duties, accept any gratuity or special favor from individuals or organizations with whom the contractor is doing business, or proposing to do business, in accomplishing the work under the contract. Reference is made to the requirements prescribed in 48 CFR 3.502.

970.0371-5 Use of privileged information.

Management and operating contractor employees shall not use privileged information for personal gain, or make other improper use of privileged information which is acquired in connection with their employment on contract work. For the purposes of this subsection, the term "privileged information" includes but is not limited to, unpublished information relating to technological and scientific developments; medical, personnel, or security records of individuals; anticipated materials' requirements or pricing action; possible new sites for DOE program operations; internal DOE decisions; policy development; and knowledge of selections of contractors or subcontractors in advance of official announcement.

970.0371-6 Incompatibility between regular duties and private interests.

(a) Employees of a management and operating contractor shall not be permitted to make or influence any decisions on behalf of the contractor which directly or indirectly affect the interest of the Government, if the employee's personal concern in the matter may be incompatible with the interest of the Government. For example: An employee of a contractor will not negotiate, or influence the award of, a subcontract with a company in which the individual has an employment relationship or significant financial interest; and an employee of a contractor will not be assigned the preparation of an evaluation for DOE or for any DOE contractor of some technical aspect of the work of another organization with which the individual has an employment relationship, or significant financial interest, or which is a competitor of an organization (other than the contractor who is the individual's regular employer) in which the individual has an employment relationship or significant financial interest.

(b) The contractor shall be responsible for informing employees that they are expected to disclose any incompatibilities between duties performed for the contractor and their private interests and to refer undecided questions to the contractor.

970.0371-7 Outside employment of contractor employees.

Employees of a management and operating contractor are entitled to the same rights and privileges with respect to outside employment as other citizens. Therefore, there is no general prohibition against contractor employees having outside employment. However, no employee of a contractor performing work on a full or part-time basis under a DOE management and operating contract may engage in employment outside official hours of duty or while on leave if such employment will:

(a) In any manner interfere with the proper and effective performance of the duties of the position;

(b) Appear to create a conflict-of-interest situation, or

(c) Appear to subject DOE or the contractor to public criticism or embarrassment.

970.0371-8 Employee disclosure concerning other employment services.

(a) Management and operating contractors are responsible for requiring its employees to file with the contractor, a written disclosure statement

concerning outside employment services which involve the use of information in the area of the employee's employment with the contractor. The disclosure shall contain such information concerning the outside employment as the contractor may prescribe. As a minimum, the employee's disclosure shall:

(1) Acknowledge that the employee has read and is familiar with:

(i) The requirements and restrictions prescribed in this section,

(ii) DOE publication entitled, "Reporting Results of Scientific and Technical Work Funded by DOE", and

(iii) The requirements of the contractor's contract with DOE relating to patents.

(2) Include information concerning any rate of remuneration significantly in excess of the employee's regular rate of remuneration;

(3) Identify any actual or potential conflicts with DOE's policies regarding conduct of employees of DOE's contractors set forth in this section;

(4) Address any potential impacts that such employment may have on the contractor's responsibility to report fully and promptly to DOE all significant research and development information; and

(5) Identify any potential conflicts such employment may have with the patent provisions of the contractor's contract with DOE.

(b) The contractor shall provide a copy of all disclosures to the contracting officer.

970.0371-9 Contract clause.

The contracting officer shall insert the clause at 970.5203-3, Contractor's Organization, in all management and operating contracts. The approval authority of the Secretary of Energy required in paragraph (c) may not be delegated. In paragraph (a) the words "and managerial personnel (see 48 CFR 970.5245-1(j))" may be inserted after "(see 48 CFR 952.215-70)".

Subpart 970.04—Administrative Matters

970.0404 Safeguarding classified information.

970.0404-1 Definitions.

Classified Information means any information or material that is owned by or produced for, or is under the control of the United States Government, and determined pursuant to provisions of Executive Order 12356 of April 2, 1982 (3 CFR, 1982 Comp., p. 166), or prior orders, or as authorized under the Atomic Energy Act of 1954, as amended, to require protection against

unauthorized disclosure, and is so designated.

Counterintelligence means information gathered and activities conducted to protect against espionage, other intelligence activities, sabotage, or assassinations conducted for or on behalf of foreign powers, organizations or persons, or international terrorist activities, but not including personnel, physical, document or communication security programs.

Restricted data means data which is defined, in section 11, of the Atomic Energy Act of 1954, as amended, as "all data concerning:

(1) Design, manufacture, or utilization of atomic weapons;

(2) The production of special nuclear material; or

(3) The use of special nuclear material in the production of energy, but shall not include data declassified or removed from the Restricted Data category pursuant to section 142."

970.0404-2 General.

(a) The basis of DOE's security requirements is the Atomic Energy Act of 1954, as amended.

(b) DOE regulations concerning national security information are codified at 10 CFR parts 1045 and 710. Supplemental security material is found in the DOE Directives system. Foreign ownership, control, or influence over contractors as it relates to security is discussed at 48 CFR 904.70 also applies to management and operating contracts. Regulations pertaining to the protection of restricted data are found under 10 CFR part 1016.

(c) Statutory requirements to be observed in connection with the release of Restricted Data to foreign governments are contained in the Atomic Energy Act of 1954, Sections 141 and 144 (42 U.S.C. 2161 and 2164).

(d) Section 148 of the Atomic Energy Act (42 U.S.C. 2168) prohibits the unauthorized dissemination of unclassified nuclear information with respect to the atomic energy defense programs pertaining to:

(1) The design of production facilities or utilization facilities;

(2) Security measures (including security plans, procedures, and equipment) for the physical protection of:

(i) Production or utilization facilities,

(ii) Nuclear material contained in such facilities, or

(iii) Nuclear materials in transit; or

(3) The design, manufacture, or utilization of any atomic weapon or component if the design, manufacture, or utilization of such weapon or component was contained in any

information declassified or removed from the Restricted Data category pursuant to section 142 of the Atomic Energy Act (42 U.S.C. 2162).

(e) Executive Order 12333, United States Intelligence Activities, provides for the organization and control of United States foreign intelligence and counterintelligence activities. In accordance with this Executive Order, DOE has established a counterintelligence program which is described in DOE Order 5670.3 (as amended). All DOE elements, including management and operating contractors and other contractors managing DOE-owned facilities which require access authorizations, should undertake the necessary precautions to ensure that DOE and covered contractor personnel, programs and resources are properly protected from foreign intelligence threats and activities.

970.0404-3 Responsibilities of contracting officers.

(a) If access to Restricted Data may be required during the solicitation process for a management and operating contract, security clearances shall be obtained in accordance with applicable DOE Directives in the safeguards and security series.

(b) Management and operating contracts which may require the processing or storage of Restricted Data or Special Nuclear Material require application of the applicable DOE Directives in the safeguards and security series.

(c) The contracting officer shall refer to 48 CFR 904.71 for guidance concerning the prohibition on award of a DOE contract under a national security program to a company owned by an entity controlled by a foreign government when access to proscribed information is required to perform the contract.

970.0404-4 Solicitation provision and contract clauses.

(a) The contracting officer shall insert the clause at 970.5204-1, Counterintelligence, into all management and operating contracts and other contracts for the management of DOE-owned facilities which include the security and classification/declassification clauses.

(b) The contracting officer shall refer to 48 CFR 904.404 and 48 CFR 904.7103 for the prescription of solicitation provisions and contract clauses relating to safeguarding classified information and foreign ownership, control, or influence over contractors.

970.0407 Contractor records retention.**970.0407-1 Applicability.****970.0407-1-1 Alternate retention schedules.**

Records produced under the Department's contracts involving management and operation responsibilities relative to DOE-owned or -leased facilities are to be retained and disposed of in accordance with the guidance contained in DOE G 1324.5B, Records Management Program and DOE Records Schedules (see current version), rather than those set forth at 48 CFR subpart 4.7, Contractor Records Retention.

970.0407-1-2 Access to and ownership of records.

Contracting officers may agree to contractor ownership of certain categories of records designated in the instruction contained in paragraph (b) of the clause at 48 CFR 970.5204-3, Access to and Ownership of Records, provided the Government's rights to inspect, copy, and audit these records are not limited. These rights must be retained by the Government in order to carry out the Department's statutory responsibilities required by the Atomic Energy Act and other statutes for oversight of its contractors, including compliance with the Department's health, safety and reporting requirements, and protection of the public interest.

970.0407-1-3 Contract clause.

The contracting officer shall insert the clause at 48 CFR 970.5204-3, Access to and Ownership of Records, in management and operating contracts.

970.0470 Department of Energy Directives.**970.0470-1 General.**

(a) The contractor is required to comply with the requirements of applicable Federal, State and local laws and regulations, unless relief has been granted by the appropriate authority. For informational purposes, the contracting officer may append the contract with a list of applicable laws or regulations (see 970.5204-2, Laws, Regulations, and DOE Directives, paragraph (a)).

(b) The Department of Energy Directives System is a system of instructions, including orders, notices, manuals, guides, and standards, for Departmental elements. In certain circumstances, requirements contained in these directives may apply to a contractor through operation of a contract clause. Program and requirements personnel are responsible for identifying requirements in the

Directives System which are applicable to a contract, and for developing a list of applicable requirements and providing it to the contracting officer for inclusion in the contract.

(c) Where directives requirements are established using either the Standards/Requirements Identification Process or the Work Smart Standards Process, the applicable process should also be used to establish the environment, safety, and health portion of the list identified in paragraph (b) of this section.

(d) Environmental, safety, and health (ES&H) requirements appropriate for work conducted under a management and operating contract may be determined by a DOE approved process to evaluate the work and the associated hazards, and identify an appropriately tailored set of standards, practices, and controls, such as a tailoring process included in a DOE approved Safety Management System implemented under 48 CFR 970.5223-1, Integration of Environment, Safety, and Health into Work Planning and Execution. When such a process is used, the contracting officer shall ensure that the set of tailored requirements, as approved by DOE pursuant to the process, is incorporated into the list identified in paragraph (b) of this section. These requirements shall supersede, in whole or in part, the contractual environmental, safety, and health requirements previously made applicable to the contract by List B. If the tailored set of requirements identifies an alternative requirement which varies from an ES&H requirement of an otherwise applicable law or regulation, the contractor must request an exemption or other appropriate regulatory relief that may be specified in the governing regulation.

970.0470-2 Contract clause.

The contracting officer shall insert the clause at DEAR 970.5204-2, Laws, Regulations, and DOE Directives, in management and operating contracts. The contracting officer may modify the clause to indicate the location in the contract of List A, List B, or both.

Subpart 970.08—Required sources of supplies and services**970.0801 Excess personal property.****970.0801-1 Policy.**

The provisions of 48 CFR subpart 8.1 (Federal Acquisition Regulation), 41 CFR 101-43 (Federal Property Management Regulation), and 41 CFR 109-43 (DOE Property Management Regulation) apply to DOE's management and operating contracts.

970.0808 Acquisition of printing.**970.0808-1 Scope of section.**

This section prescribes the Department's policy concerning duplicating or printing services which may be required in the performance of management and operating contracts.

970.0808-2 Policy.

Management and operating contractors shall provide or secure duplication and printing services in accordance with the Government Printing and Binding Regulations, Title 44 of the U.S. Code, and applicable DOE Directives.

970.0808-3 Contract clause.

The contracting officer shall insert the clause at 970.5208-1, Printing, in all management and operating contracts.

Subpart 970.09—Contractor qualifications**970.0905 Organizational conflicts of interest.**

Management and operating contracts shall contain an organizational conflict of interest clause substantially similar to the clause at 48 CFR 952.209-72, Organizational Conflicts of Interest, and which is appropriate to the statement of work of the individual contract. In addition, the contracting officer shall assure that the clause contains appropriate restraints on intra-corporate relations between the contractor's organization and personnel operating the Department's facility and its parent corporate body and affiliates. Such restraints shall include personnel access to the facility, technical transfer of information from the facility, and the availability from the facility of other advantages flowing from performance of the contract. The contracting officer is responsible for ensuring that M&O contractors adopt policies and procedures in the award of subcontracts that will meet the Department's need to safeguard against a biased work product and an unfair competitive advantage. To this end, the organizational conflicts of interest clause in management and operating contracts shall include Alternate I.

970.0970 Performance guarantees.**970.0970-1 Determination of responsibility.**

(a) In the award of a management and operating contract, the contracting officer shall determine that the prospective contractor is a responsible contractor and is capable of providing all necessary financial, personnel, and other resources in performance of the contract.

(b) DOE contracts with entities that have been created solely for the purpose of performing a specific management and operating contract. Generally, such newly created entities will have very limited financial and other resources. In such instances, when making the determination of responsibility required under this section, the contracting officer may evaluate the financial resources of other entities only to the extent that those entities are legally bound, jointly and severally if more than one, by means of a performance guarantee or other equivalent enforceable commitment to supply the necessary resources to the prospective contractor and to assume all contractual obligations of the prospective contractor. A performance guarantee should be the means used unless an equivalent degree of commitment can be obtained by an alternative means.

(c) The guaranteeing corporate entity(ies) must be found to have sufficient resources in order to satisfy its guarantee.

970.0970-2 Solicitation provision.

The contracting officer shall insert the provision at 48 CFR 970.5209-1, Requirement for Guarantee of Performance, in solicitations when the awardee will be required to be organized solely for performance of the requirement.

Subpart 970.11—Describing Agency Needs

970.1100 Policy.

970.1100-1 Performance-based contracting.

(a) It is the policy of the Department of Energy to use, to the maximum extent practicable, performance-based contracting methods in its management and operating contracts. Office of Federal Procurement Policy Letter 91-2 provides guidance concerning the development and use of performance-based contracting concepts and methodologies that may be generally applied to management and operating contracts. Performance-based contracts: Describe performance requirements in terms of results rather than methods of accomplishing the work; use measurable (*i.e.*, terms of quality, timeliness, quantity) performance standards and objectives and quality assurance surveillance plans; provide performance incentives (positive or negative) where appropriate; and specify procedures for award or incentive fee reduction when work activities are not performed or do not meet contract requirements.

(b) The use of performance-based statements of work, where feasible, is

the preferred method for establishing work requirements. Such statements of work and other documents used to establish work requirements (such as work authorization directives) should describe performance requirements and expectations in terms of outcome, results, or final work products, as opposed to methods, processes, or design.

(c) Contract performance requirements and expectations should be consistent with the Department's strategic planning goals and objectives, as made applicable to the site or facility through Departmental programmatic and financial planning processes. Measurable performance criteria, objective measures, and where appropriate, performance incentives, shall be structured to correspond to the performance requirements established in the statement of work and other documents used to establish work requirements.

(d) Quality assurance surveillance plans shall be developed to facilitate the assessment of contractor performance and ensure the appropriateness of any award or incentive fee payment. Such plans shall be tailored to the contract performance objectives, criteria, and measures, and shall, to the maximum extent practicable, focus on the level of performance required by the performance objectives rather than the methodology used by the contractor to achieve that level of performance.

970.1100-2 Additional considerations.

(a) While it is not feasible to set forth standard language which would apply to every contract situation, language must be designed for inclusion in a management and operating contract to describe clearly the work being undertaken; the controls, as appropriate, to be exercised by DOE over the performance of that work; and the relationship contemplated between the parties.

(b) The language shall also include the following with respect to subcontracting performance of the work described pursuant to paragraph (a) of this section: "The contractor shall, when directed by DOE and may, but only when authorized by DOE, enter into subcontracts for the performance of any part of the work under this clause."

(c) The provisions required in paragraphs (a) and (b) of this section shall be set forth in the statement of work of the contract.

970.1103-4 Contract clause.

Insert the clause at 48 CFR 52.211-5, Material Requirements, in solicitations and contracts.

Subpart 970.15—Contracting by Negotiation

970.1504 Contract pricing.

970.1504-1 Price analysis.

970.1504-1-1 Fees for management and operating contracts.

This subsection sets forth the Department's policies on fees for management and operating contracts and may be applied to other contracts as determined by the Procurement Executive, or designee.

970.1504-1-2 Fee policy.

(a) DOE management and operating contractors may be paid a fee in accordance with the requirements of this subsection.

(b) There are three basic principles underlying the Department's fee policy:

(1) The amount of available fee should reflect the financial risk assumed by the contractor.

(2) It is the policy of the Department, when work elements cannot be fixed price, incentive fees (including award fees) tied to objective measures should be used to the maximum extent appropriate.

(3) When work elements cannot be fixed price and award fees are employed, they should be tied to either objective or subjective measures. Each measure should, to the maximum extent appropriate, be directly tied to a specific portion of the fee pool.

(c) Fee objectives and amounts are to be determined for each contract. Standard fees or across-the-board fee agreements will not be used or made. Due to the nature of funding management and operating contracts, it is anticipated that fee shall be established in accordance with the annual funding cycle; however, with the prior approval of the Procurement Executive, or designee, a longer period may be used where necessary to incentivize performance objectives that span funding cycles or to optimize cost reduction efforts.

(d) Annual fee amounts shall be established in accordance with this subsection. Annual amounts shall not exceed maximum amounts derived from the appropriate fee schedule (and Classification Factor, if applicable) unless approved in advance by the Procurement Executive, or designee. In no event shall any fee exceed statutory limits imposed by 41 U.S.C. 254(b).

(e)(1) Contracting Officers shall include negative fee incentives in contracts when appropriate. A negative fee incentive is one in which the contractor will not be paid the full target fee amount when the actual

performance level falls below the target level established in the contract.

(2) Negative fee incentives may only be used when:

(i) A target level of performance can be established, which the contractor can reasonably be expected to reach;

(ii) The value of the negative incentive is commensurate with the lower level of performance and any additional administrative costs;

(iii) Factors likely to prevent attainment of the target level of performance are clearly within the control of the contractor; and

(iv) The contract indicates clearly a level below which performance is not acceptable.

(f) Prior to the issuance of a competitive solicitation or the initiation of negotiations for an extension of an existing contract, the HCA shall coordinate the maximum available fee, as allowed by 48 CFR 970.1504-1-1, and the fee amount targeted for negotiation, if less, with the Procurement Executive, or designee. Solicitations shall identify maximum available fee under the contract and may invite offerors to propose fee less than the maximum available.

(g) When a contract subject to this subsection requires a contractor to use its own facilities or equipment, or other resources to make its own cost investment for contract performance, (e.g., when there is no letter-of-credit financing) consideration may be given, subject to approval by the Procurement Executive, or designee, to increasing the total available fee amount above that otherwise provided by this subsection.

(h) Multiple fee arrangements should be used in accordance with 48 CFR 970.1504-1-4.

970.1504-1-3 Special considerations: Laboratory management and operation.

(a) For the management and operation of a laboratory, the contracting officer shall consider whether any fee is appropriate. Considerations should include:

(1) The nature and extent of financial or other liability or risk assumed or to be assumed under the contract;

(2) The proportion of retained earnings (as established under generally accepted accounting methods) that are utilized to fund the performance of work related to the DOE contracted effort;

(3) Facilities capital or capital equipment acquisition plans;

(4) Other funding needs, to include contingency funding, working capital funding, and provision for funding unreimbursed costs deemed ordinary and necessary;

(5) The utility of fee as a performance incentive; and

(6) The need for fee to attract qualified contractors, organizations, and institutions.

(b) In the event fee is considered appropriate, the contracting officer shall determine the amount of fee in accordance with this subsection.

(1) Costs incurred in the operation of a laboratory that are allowable and allocable under the cost principles (*i.e.*, commercial using 48 CFR 31.2, nonprofit using OMB Circular A-122, or university-affiliated using OMB Circular A-21), regulations (including 48 CFR 970.31), or statutes applicable to the operating contractor should be classified as direct or indirect (overhead or G&A) charges to the contract and not included as proposed fee. Exceptions must be approved by the Procurement Executive, or designee.

(2) Except as specified in 48 CFR 970.1504-1-3(c)(3), the maximum total amount of fee shall be calculated in accordance with 48 CFR 970.1504-1-5 or 48 CFR 970.1504-1-9, as appropriate. The total amount of fee under any laboratory management and operating contract or other designated contract shall not exceed, and may be significantly less than, the result of that calculation. In determining the total amount of fee, the contracting officer shall consider the evaluation of the factors in paragraph (a) of this subsection as well as any benefits the laboratory operator will receive due to its tax status.

(c) In the event fee is considered appropriate, the contracting officer shall establish the type of fee arrangement in accordance with this subsection.

(1) The amount of fee may be established as total available fee with a base fee portion and a performance fee portion. Base fee, if any, shall be an amount in recognition of the risk of financial liability assumed by the contractor and shall not exceed the cost risk associated with those liabilities or the amount calculated in accordance with 48 CFR 970.1504-1-5, whichever is less. The total available fee, excepting any base fee, shall normally be associated with performance at or above the target level of performance as defined by the contract. If performance in either of the two general work categories appropriate for laboratories (science/technology and support) is rated at less than the target level of performance, the total amount of the available fee shall be subject to downward adjustment. Such downward adjustment shall be subject to the terms of the clause at 48 CFR 970.5215-3,

Conditional Payment of Fee, Profit, or Incentives, if contained in the contract.

(2) The amount of fee may be established as a fixed fee in recognition of the risk of financial liability to be assumed by the contractor, with such fixed fee amount not exceeding the cost risk associated with the liabilities assumed or the amount of fee calculated in accordance with 48 CFR 970.1504-1-5, whichever is less.

(3) If the fixed fee or total available fee exceeds 75% of the fee that would be calculated per 48 CFR 970.1504-1-5 or 48 CFR 970.1504-1-9; or if a fee arrangement other than one of those set forth in paragraphs (c) (1) or (2) of this subsection is considered appropriate, the approval of the Procurement Executive, or designee, shall be obtained prior to its use.

(4) Fee, if any, as well as the type of fee arrangement, will normally be established for the life of the contract. It will be established at time of award, as part of the extend/compete decision, at the time of option exercise, or at such other time as the parties can mutually reach agreement, *e.g.*, negotiations. Such agreement shall require the approval of the Procurement Executive, or designee.

(5) Fee established for longer than one year shall be subject to adjustment in the event of a significant change (greater than +/-10% or a lesser amount if appropriate) to the budget or work scope.

(6) Retained earnings (reserves) shall be identified and a plan for their use and disposition developed.

(7) The use of retained earnings as a result of performance of laboratory management and operation may be restricted if the operator is an educational institution.

970.1504-1-4 Types of contracts and fee arrangements.

(a) Contract types and fee arrangements suitable for management and operating contracts may include cost, cost-plus-fixed-fee, cost-plus-award-fee, cost-plus-incentive-fee, fixed-price incentive, firm-fixed-price or any combination thereof (see 48 CFR 16.1). In accordance with 48 CFR 970.1504-1-2(b)(1), the fee arrangement chosen for each work element should reflect the financial risk for project failure that contractors are willing to accept. Contracting officials shall structure each contract and the elements of the work in such a manner that the risk is manageable and, therefore, assumable by the contractor.

(b) Consistent with the concept of a performance-based management contract, those contract types which incentivize performance and cost

control are preferred over a cost-plus-fixed-fee arrangement. Accordingly, a cost-plus-fixed-fee contract in instances other than those set forth in 48 CFR 970.1504-1-3(c)(2) may only be used when approved in advance by the Procurement Executive, or designee.

(c) A cost-plus-award-fee contract is generally the appropriate contract type for a management and operating contract.

(1) Where work cannot be adequately defined to the point that a fixed price contract is acceptable, the attainment of acquisition objectives generally will be enhanced by using a cost-plus-award-fee contract or other incentive fee arrangement to effectively motivate the contractor to superior performance and to provide the Department with flexibility to evaluate actual performance and the conditions under which it was achieved.

(2) The construct of fee for a cost-plus-award-fee management and operating contract is that total available fee will equal a base fee amount and a performance fee amount. The total available fee amount including the performance fee amount the contractor may earn, in whole or in part during performance, shall be established annually (or as otherwise agreed to by the parties and approved by the Procurement Executive, or designee), in an amount sufficient to motivate performance excellence.

(3) However, consistent with concepts of performance-based contracting, it is Departmental policy to place fee at risk based on performance. Accordingly, a base fee amount will be available only when approved in advance by the Procurement Executive, or designee, except as permitted in 48 CFR 970.1504-1-3(c)(1). Any base fee amount shall be fixed, expressed as a percent of the total available fee at inception of the contract, and shall not exceed that percent during the life of the contract.

(4) The performance fee amount may consist of an objective fee component and a subjective fee component. Objective performance measures, when appropriately applied, provide greater incentives for superior performance than do subjective performance measures and should be used to the maximum extent appropriate. Subjective measures should be used when it is not feasible to devise effective predetermined objective measures applicable to cost, technical performance, or schedule for particular work elements.

(d) Consistent with performance-based contracting concepts, performance objectives and measures

related to performance fee should be as clearly defined as possible and, where feasible, expressed in terms of desired performance results or outcomes. Specific measures for determining performance achievement should be used. The contract should identify the amount and allocation of fee to each performance result or outcome.

(e) Because the nature and complexity of the work performed under a management and operating contract may be varied, opportunities may exist to utilize multiple contract types and fee arrangements. Consistent with paragraph (a) of this subsection and 48 CFR 16.1, the contracting officer should apply that contract type or fee arrangement most appropriate to the work component. However, multiple contract types or fee arrangements:

(1) Must conform to the requirements of 48 CFR part 915 and 48 CFR parts 15 and 16, and

(2) Where appropriate to the type, must be supported by:

(i) Negotiated costs subject to the requirements of the Truth in Negotiations Act,

(ii) A pre-negotiation memorandum, and

(iii) A plan describing how each contract type or fee arrangement will be administered.

(f) Cost reduction incentives are addressed in the clause at 48 CFR 970.5215-4, Cost Reduction. This clause provides for incentives for quantifiable cost reductions associated with contractor proposed changes to a design, process, or method that has an established cost, technical, and schedule baseline, is defined, and is subject to a formal control procedure. The clause is to be included in management and operating contracts as appropriate. Proposed changes must be: Initiated by the contractor, innovative, applied to a specific project or program, and not otherwise included in an incentive under the contract. Such cost reduction incentives do not constitute fee and are not subject to statutory or regulatory fee limitations; however, they are subject to all appropriate requirements set forth in this subpart.

(g) Operations and field offices shall take the lead in developing and implementing the most appropriate pricing arrangement or cost reduction incentive for the requirements. Pricing arrangements which provide incentives for performance and cost control are preferred over those that do not. The operations and field offices are to ensure that the necessary resources and infrastructure exist within both the contractor's and government's organizations to prepare, evaluate, and

administer the pricing arrangement or cost reduction incentive prior to its implementation.

970.1504-1-5 General considerations and techniques for determining fixed fees.

(a) The Department's fee policy recognizes that fee is remuneration to contractors for the entrepreneurial function of organizing and managing resources, the use of their resources (including capital resources), and, as appropriate, their assumption of the risk that some incurred costs (operating and capital) may not be reimbursed.

(b) Use of a purely cost-based structured approach for determining fee objectives and amounts for DOE management and operating contracts is inappropriate considering the limited level of contractor cost, capital goods, and operating capital outlays for performance of such contracts. Instead of being solely cost-based, the desirable approach calls for a structure that allows evaluation of the following eight significant factors, as outlined in order of importance, and the assignment of appropriate fee values (subject to the limitations on fixed fee in 48 CFR 970.1504-1-6):

(1) The presence or absence of financial risk, including the type and terms of the contract;

(2) The relative difficulty of work, including specific performance objectives, environment, safety and health concerns, and the technical and administrative knowledge, and skill necessary for work accomplishment and experience;

(3) Management risk relating to performance, including:

(i) Composite risk and complexity of principal work tasks required to do the job;

(ii) Labor intensity of the job;

(iii) Special control problems; and

(iv) Advance planning, forecasting and other such requirements;

(4) Degree and amount of contract work required to be performed by and with the contractor's own resources, as compared to the nature and degree of subcontracting and the relative complexity of subcontracted efforts, subcontractor management and integration;

(5) Size and operation (number of locations, plants, differing operations, etc.);

(6) Influence of alternative investment opportunities available to the contractor (*i.e.*, the extent to which undertaking a task for the Government displaces a contractor's opportunity to make a profit with the same staff and equipment in some other field of activity);

(7) Benefits which may accrue to the contractor from gaining experience and

knowledge of how to do something, from establishing or enhancing a reputation, or from having the opportunity to hold or expand a staff whose loyalties are primarily to the contractor; and

(8) Other special considerations, including support of Government programs such as those relating to small and minority business subcontracting, energy conservation, etc.

(c) The total fee objective for a particular annual fixed fee negotiation is

established by evaluating the factors in this subsection, assigning fee values to them, and totaling the resulting amounts (subject to limitations on total fixed fee in 48 CFR 970.1504-1-6).

970.1504-1-6 Calculating fixed fee.

(a) In recognition of the complexities of the fee determination process, and to assist in promoting a reasonable degree of consistency and uniformity in its application, the following fee schedules set forth the maximum amounts of fee that contracting activities are allowed to

award for a particular fixed fee transaction calculated annually.

(b) Fee schedules representing the maximum allowable annual fixed fee available under management and operating contracts have been established for the following management and operating contract efforts:

- (1) Production;
 - (2) Research and Development; and
 - (3) Environmental Management.
- (c) The schedules are:

PRODUCTION EFFORTS

Fee base (dollars)	Fee (dollars)	Fee (percent)	Incr. (percent)
Up to \$1 Million			7.66
1,000,000	\$76,580	7.66	6.78
3,000,000	212,236	7.07	6.07
5,000,000	333,670	6.67	4.90
10,000,000	578,726	5.79	4.24
15,000,000	790,962	5.27	3.71
25,000,000	1,161,828	4.65	3.35
40,000,000	1,663,974	4.16	2.92
60,000,000	2,247,076	3.75	2.57
80,000,000	2,761,256	3.45	2.34
100,000,000	3,229,488	3.23	1.45
150,000,000	3,952,622	2.64	1.12
200,000,000	4,510,562	2.26	0.61
300,000,000	5,117,732	1.71	0.53
400,000,000	5,647,228	1.41	0.45
500,000,000	6,097,956	1.22	
Over \$500 Million	6,097,956		0.45

RESEARCH AND DEVELOPMENT EFFORTS

Fee base (dollars)	Fee (dollars)	Fee (percent)	Incr. (percent)
Up to \$1 Million			8.42
1,000,000	84,238	8.42	7.00
3,000,000	224,270	7.48	6.84
5,000,000	361,020	7.22	6.21
10,000,000	671,716	6.72	5.71
15,000,000	957,250	6.38	4.85
25,000,000	1,441,892	5.77	4.22
40,000,000	2,075,318	5.19	3.69
60,000,000	2,813,768	4.69	3.27
80,000,000	3,467,980	4.33	2.69
100,000,000	4,006,228	4.01	1.69
150,000,000	4,850,796	3.23	1.14
200,000,000	5,420,770	2.71	0.66
300,000,000	6,083,734	2.03	0.58
400,000,000	6,667,930	1.67	0.50
500,000,000	7,172,264	1.43	
Over \$500 Million	7,172,264		0.50

ENVIRONMENTAL MANAGEMENT EFFORTS

Fee base (dollars)	Fee (dollars)	Fee (percent)	Incr. (percent)
Up to \$1 Million			7.33
\$1,000,000	73,298	7.33	6.49
3,000,000	203,120	6.77	5.95
5,000,000	322,118	6.44	5.40
10,000,000	592,348	5.92	4.83
15,000,000	833,654	5.56	4.03
25,000,000	1,236,340	4.95	3.44
40,000,000	1,752,960	4.38	3.29
60,000,000	2,411,890	4.02	3.10
80,000,000	3,032,844	3.79	2.49

ENVIRONMENTAL MANAGEMENT EFFORTS—Continued

Fee base (dollars)	Fee (dollars)	Fee (percent)	Incr. (percent)
100,000,000	3,530,679	3.53	1.90
150,000,000	4,479,366	2.99	1.48
200,000,000	5,219,924	2.61	1.12
300,000,000	6,337,250	2.11	0.88
400,000,000	7,219,046	1.80	0.75
500,000,000	7,972,396	1.59	0.58
750,000,000	9,423,463	1.26	0.55
1,000,000,000	10,786,788	1.08	
Over \$1.0 billion	10,786,788		0.55

970.1504-1-7 Fee Base.

(a) The fee base is an estimate of necessary allowable costs, with some exclusions. It is used in the fee schedules to determine the maximum annual fee for a fixed fee contract. That portion of the fee base that represents the cost of the Production, Research and Development, or Environmental Management work to be performed, shall be exclusive of the cost of source and special nuclear materials; estimated costs of land, buildings and facilities whether to be leased, purchased or constructed; depreciation of Government facilities; and any estimate of effort for which a separate fee is to be negotiated.

(b) Such portion of the fee base, in addition to the adjustments in paragraph (a) of this subsection, shall exclude:

(1) Any part of the estimated cost of capital equipment (other than special equipment) which the contractor procures by subcontract or other similar costs which is of such magnitude or nature as to distort the technical and management effort actually required of the contractor;

(2) At least 20% of the estimated cost or price of subcontracts and other major contractor procurements;

(3) Up to 100% of the estimated cost or price of subcontracts and other major contractor procurements if they are of a magnitude or nature as to distort the technical and management effort actually required of the contractor;

(4) Special equipment as defined in 48 CFR 970.1504-1-8;

(5) Estimated cost of Government-furnished property, services and equipment;

(6) All estimates of costs not directly incurred by or reimbursed to the operating contractor;

(7) Estimates of home office or corporate general and administrative expenses that shall be reimbursed through the contract;

(8) Estimates of any independent research and development cost or bid and proposal expenses that may be approved under the contract;

(9) Any cost of work funded with uncosted balances previously included in a fee base of this or any other contract performed by the contractor;

(10) Cost of rework attributable to the contractor; and

(11) State taxes.

(c) In calculating the annual fee amounts associated with the Production, Research and Development, or Environmental Management work to be performed, the fee base is to be allocated to the category reflecting the work to be performed and the appropriate fee schedule utilized.

(d) The portion of the fee base associated with the Production, Research and Development, or Environmental Management work to be performed and the associated schedules in this part are not intended to reflect the portion of the fee base or related compensation for unusual architect-engineer, construction services, or special equipment provided by the management and operating contractor. Architect-engineer and construction services are normally covered by special agreements based on the policies applying to architect-engineer or construction contracts. Fees paid for such services shall be calculated using the provisions of 48 CFR 91504-1-5 relating to architect-engineer or construction fees and shall be in addition to the operating fees calculated for the Production, Research and Development, or Environmental Management work to be performed. Special equipment purchases shall be addressed in accordance with the provisions of 48 CFR 970.1504-1-8 relating to special equipment.

(e) No schedule set forth in 48 CFR 915.404-4-71-5 or 48 CFR 970.1504-1-6 shall be used more than once in the determination of the fee amount for an annual period, unless prior approval of the Procurement Executive, or designee, is obtained.

970.1504-1-8 Special equipment purchases.

(a) Special equipment is sometimes procured in conjunction with

management and operating contracts.

When a contractor procures special equipment, the DOE negotiating official shall determine separate fees for the equipment which shall not exceed the maximum fee allowable as established using the schedule in 48 CFR 915.404-4-71-5(h).

(b) In determining appropriate fees, factors such as complexity of equipment, ratio of procurement transactions to volume of equipment to be purchased and completeness of services should be considered. Where possible, the reasonableness of the fees should be checked by their relationship to actual costs of comparable procurement services.

(c) For purposes of this subsection, special equipment is equipment for which the purchase price is of such a magnitude compared to the cost of installation as to distort the amount of technical direction and management effort required of the contractor. Special equipment is of a nature that requires less management attention. When a contractor procures special equipment, the DOE negotiating official shall determine separate fees for the equipment using the schedule in 48 CFR 915.404-4-71-5(h). The determination of specific items of equipment in this category requires application of judgment and careful study of the circumstances involved in each project. This category of equipment would generally include:

(1) Major items of prefabricated process or research equipment; and

(2) Major items of preassembled equipment such as packaged boilers, generators, machine tools, and large electrical equipment. In some cases, it would also include special apparatus or devices such as reactor vessels and reactor charging machines.

970.1504-1-9 Special considerations: Cost-plus-award-fee.

(a) When a management and operating contract is to be awarded on a cost-plus-award-fee basis, several special considerations are appropriate.

(b) All annual performance incentives identified under these contracts are funded from the annual total available fee, which consists of a base fee amount (which may be zero) and a performance fee amount (which typically will consist of an incentive fee component for objective performance requirements, an award fee component for subjective performance requirements, or both).

(c) The annual total available fee for the contract shall equal the product of the fee(s) that would have been calculated for an annual fixed fee contract and the classification factor(s) most appropriate for the facility/task. If more than one fee schedule is applicable to the contract, the annual total available fee shall be the sum of the available fees derived proportionately from each fee schedule; consideration of significant factors applicable to each fee schedule; and application of a Classification Factor(s) most appropriate for the work.

(d) Classification Factors applied to each Facility/Task Category are:

Facility/task category	Classification factor
A	3.0
B	2.5
C	2.0
D	1.25

(e) The contracting officer shall select the Facility/Task Category after considering the following:

(1) Facility/Task Category A. The main focus of effort performed is related to:

(i) The manufacture, assembly, retrieval, disassembly, or disposal of nuclear weapons with explosive potential;

(ii) The physical cleanup, processing, handling, or storage of nuclear radioactive or toxic chemicals with consideration given to the degree the nature of the work advances state of the art technologies in cleanup, processing or storage operations and/or the inherent difficulty or risk of the work is significantly demanding when compared to similar industrial/DOE settings (*i.e.*, nuclear energy processing, industrial environmental cleanup);

(iii) Construction of facilities such as nuclear reactors, atomic particle accelerators, or complex laboratories or industrial units especially designed for handling radioactive materials;

(iv) Research and development directly supporting paragraphs (e)(1)(i), (ii), or (iii) of this subsection and not conducted in a laboratory, or

(v) As designated by the Procurement Executive, or designee. (Classification factor 3.0)

(2) Facility/Task Category B. The main focus of effort performed is related to:

(i) The safeguarding and maintenance of nuclear weapons or nuclear material;

(ii) The manufacture or assembly of nuclear components;

(iii) The physical cleanup, processing, handling, or storage of nuclear radioactive or toxic chemicals, or other substances which pose a significant threat to the environment or the health and safety of workers or the public, if the nature of the work uses state of the art technologies or applications in such operations and/or the inherent difficulty or risk of the work is more demanding than that found in similar industrial/DOE settings (*i.e.*, nuclear energy, chemical or petroleum processing, industrial environmental cleanup);

(iv) The detailed planning necessary for the assembly/disassembly of nuclear weapons/components;

(v) Construction of facilities involving operations requiring a high degree of design layout or process control;

(vi) Research and development directly supporting paragraphs (e)(2)(i), (ii), (iii), (iv) or (v) of this subsection and not conducted in a laboratory; or

(vii) As designated by the Procurement Executive, or designee. (Classification factor 2.5)

(3) Facility/Task Category C. The main focus of effort performed is related to:

(i) The physical cleanup, processing, or storage of nuclear radioactive or toxic chemicals if the nature of the work uses routine technologies in cleanup, processing or storage operations and/or the inherent difficulty or risk of the work is similar to that found in similar industrial/DOE settings (*i.e.*, nuclear energy, chemical processing, industrial environmental cleanup);

(ii) Plant and facility maintenance;

(iii) Plant and facility security (other than the safeguarding of nuclear weapons and material);

(iv) Construction of facilities involving operations requiring normal processes and operations; general or administrative service buildings; or routine infrastructure requirements;

(v) Research and development directly supporting paragraphs (e)(3)(i), (ii), (iii) or (iv) of this subsection and not conducted in a laboratory; or

(vi) As designated by the Procurement Executive, or designee. (Classification factor 2.0)

(4) Facility/Task Category D. The main focus of the effort performed is research and development conducted at a laboratory. (Classification factor 1.25)

(f) Where the Procurement Executive, or designee, has approved a base fee, the

Classification Factors shall be reduced, as approved by the Procurement Executive, or designee.

(g) Any risks which are indemnified by the Government (for example, by the Price-Anderson Act) will not be considered as risk to the contractor.

(h) All management and operating contracts awarded on a cost-plus-award-fee basis shall set forth in the contract, or the Performance Evaluation and Measurement Plan(s) required by the contract clause at 48 CFR 970.5215-1, Total Available Fee: Base Fee Amount and Performance Fee Amount, a site specific method of rating the contractor's performance of the contract requirements and a method of fee determination tied to the method of rating.

(i) Prior approval of the Procurement Executive, or designee, is required for an annual total available fee amount exceeding the guidelines in paragraph (c) of this subsection.

(j) DOE Operations/Field Office Managers must ensure that all important areas of contract performance are specified in the contract or Performance Evaluation and Measurement Plan(s), even if such areas are not assigned specific weights or percentages of available fee.

970.1504-1-10 Special considerations: Fee limitations.

In situations where the objective performance incentives are of unusual difficulty or where the successful completion of the performance incentives would provide extraordinary value to the Government, fees in excess of those allowed under 48 CFR 970.1504-1-5 and 48 CFR 970.1504-1-9 may be allowed with the approval of the Procurement Executive, or designee. Requests to allow fees in excess of those provided under other provisions of this fee policy must be accompanied by a written justification with detailed supporting rationale as to how the specific circumstances satisfy the two criteria listed in this subsection.

970.1504-1-11 Documentation.

The contracting officer shall tailor the documentation of the determination of fee prenegotiation objective based on 48 CFR 15.406-1, Prenegotiation objectives, and the determination of the negotiated fee in accordance with 48 CFR 15.406-3, Documenting the negotiation. The contracting officer shall include as part of the documentation: the rationale for the allocation of cost and the assignment of Facility/Task Categories; a discussion of the calculations described in 48 CFR 970.1504-1-5; and discussion of any

other relevant provision of this subsection.

970.1504-2 Price negotiation.

(a) Management and operating contract prices (fee) and DOE obligations to support contract performance shall be governed by:

(1) The level of activity authorized and the amount of funds appropriated for DOE approved programs by specific program legislation;

(2) Congressional budget and reporting limitations;

(3) The amount of funds apportioned to DOE;

(4) The amount of obligational authority allotted to program officials and Approved Funding Program limitations; and

(5) The amount of funds actually available to the DOE operating activity as determined in accordance with applicable financial regulations and directives.

(b) Funds shall be obligated and made available by contract provision or modification after the funds become available for obligation for payment to support performance of DOE approved projects, tasks, work authorizations, or services.

(c) Contractor expenditures shall be limited to the overall amount of funds available and obligated on the contract. As prescribed at 48 CFR 970.3270(b), the clause at 48 CFR 970.5232-4, Obligation of Funds, is used for this purpose.

970.1504-3 Documentation.

970.1504-3-1 Cost or pricing data.

(a) The certification requirements of 48 CFR 15.406-2 are not applied to DOE cost-reimbursement management and operating contracts.

(b) The contracting officer shall ensure that management and operating contractors and their subcontractors obtain cost or pricing data prior to the award of a negotiated subcontract or modification of a subcontract in accordance with 48 CFR 15.406-2, and incorporate appropriate contract provisions similar to those set forth at 48 CFR 52.215-10 and 48 CFR 52.215-11 that provide for the reduction of a negotiated subcontract price by any significant amount that the subcontract price was increased because of the submission of defective cost or pricing data by a subcontractor at any tier.

(c) The clauses at 48 CFR 52.215-12 and 48 CFR 52.215-13 shall be included in management and operating contracts.

970.1504-4 Special cost or pricing areas.

970.1504-4-1 Make-or-buy plans.

970.1504-4-2 Policy.

(a) Contracting officers shall require management and operating contractors to develop and implement make-or-buy plans that establish a preference for providing supplies or services (including construction and construction management) on a least-cost basis, subject to program specific make-or-buy criteria. The emphasis of this make-or-buy structure is to eliminate bias for in-house performance where an activity may be performed at less cost or otherwise more efficiently through subcontracting.

(b) A work activity, supply or service is provided at "least cost" when, after consideration of a variety of appropriate programmatic, business, and financial factors, it is concluded that performance by either "in-house" resources or by contracting out is likely to provide the property or service at the lowest overall cost. Programmatic factors include, but are not limited to, program specific make-or-buy criteria established by the Department of Energy, the impact of a "make" or a "buy" decision on mission accomplishment, and anticipated changes to the mission of the facility or site. Business factors pertain to such elements as market conditions, past experience in obtaining similar supplies or services, and overall operational efficiencies that might be available through either in-house performance or contracting out. Among the financial factors that may be considered to determine a least-cost alternative in a make-or-buy analysis are both recurring and one-time costs attributable to either retaining or contracting out a particular item, financial risk, and the anticipated contract price.

(c) In developing and implementing its make-or-buy plan, a contractor shall be required to assess subcontracting opportunities and implement subcontracting decisions in accordance with the following:

(1) The contractor shall conduct internal productivity improvement and cost-reduction programs so that in-house performance options can be made more efficient and cost-effective.

(2) The contractor shall consider subcontracting opportunities with the maximum practicable regard for open communications with potentially affected employees and their representatives. Similarly, a contractor will communicate its plans, activities, cost-benefit analyses, and decisions with those stakeholders likely to be affected by such decisions, including

representatives of the community and local businesses.

970.1504-4-3 Requirements.

(a) Development of program-specific make-or-buy criteria.

(1) Program specific make-or-buy criteria are those factors that reflect specific mission or program objectives (including operational efficiency, contractor diversity, environment, safety and health, work force displacement and restructuring, and collective bargaining agreements) and that, upon their application to a specific work effort, would override a decision based on a purely economic rationale. These criteria are to be used to assess each work effort identified in a facility's or site's make-or-buy plan to determine the appropriateness of a contractor's make-or-buy decisions.

(2) Heads of Contracting Activities shall ensure that program specific make-or-buy criteria are developed and provided to the contractor for use in its make-or-buy plan administration activities for the facility, site, or specific program, as appropriate. Although the Head of the Contracting Activity has the responsibility for ensuring that the program-specific make-or-buy criteria are developed and provided to the contractor, the actual development of the program specific make or buy criteria should be accomplished by the appropriate collaboration of headquarters and field office program, technical, and business specialists. Accordingly, these organizations and individuals should be relied on for the development of the program specific make or buy criteria so that they appropriately reflect program considerations applicable to the contractor's make-or-buy decisions.

(b) Make-or-buy plan property and services. Supplies or services estimated to cost less than one (1) percent of the estimated total operating cost for a year or \$1 million for the same year, whichever is less, need not be included in the contractor's make-or-buy plan. However, adjustments may be made to these thresholds where programmatic or cost considerations would indicate that a particular supply or service should be included in the make-or-buy plan.

(c) Competitive solicitation requirements.

(1) To the extent practicable, a competitive solicitation for the management and operation of a Department of Energy facility or site should:

(i) Identify those programs, projects, work areas, functions or services that the Department intends for the

successful offeror to include in any make-or-buy plan; and

(ii) Require the submission of a preliminary make-or-buy plan for the period of performance of the contract from each offeror as part of its proposal submitted in response to the competitive solicitation.

(2) If the requirement for each offeror to submit a preliminary make-or-buy plan as part of its proposal is impractical or otherwise incompatible with the acquisition strategy, consideration should be given to structuring the evaluation criteria for the competitive solicitation in such a manner as to permit the evaluation of an offeror's approach to conducting its make-or-buy program within the context of the contractual requirements.

(3) The successful offeror's preliminary make-or-buy plan shall be submitted for final approval within 180 days after contract award, consistent with the requirements of 48 CFR 970.5215-2(c), Make-or-Buy Plan.

(d) Evaluation of the contractor's make-or-buy plan. In evaluating the contractor's make-or-buy plan, the contracting officer shall consider the following factors:

(1) The program specific make-or-buy criteria (such as operational efficiency, contractor diversity, environment, safety and health, work force displacement and restructuring, and collective bargaining agreements) with particular attention to the effect of a "buy" decision on the contractor's ability to maintain core competencies needed to accomplish mission-related programs and projects;

(2) The impact of a "make" or "buy" decision on contract cost, schedule, and performance and financial risk;

(3) The potential impact of a "make" or "buy" decision on known future mission or program activities at the facility or site;

(4) Past experience at the facility or site regarding "make-or-buy" decisions for the same, or similar, supplies or services;

(5) Consistency with the contractor's approved subcontracting plan, as required by the clause entitled "Small, Small Disadvantaged and Women-Owned Small Business Subcontracting Plan" (48 CFR 52.219-9), and implementation of section 3021 of the Energy Policy Act of 1992.

(6) Local market conditions, including contractor work force displacement and the availability of firms that can meet the work requirements with regard to quality, quantity, cost, and timeliness;

(7) Where the construction of new or additional facilities is required, that the cost of such facilities is in the

Government's best interest when compared to subcontracting or privatization alternatives; and

(8) Whether all relevant requirements and costs of performing the work by the contractor and through subcontracting are considered and any different requirements for the same work are reconciled.

(e) Approval. The contracting officer shall approve all plans and revisions thereto. Once approved, a make-or-buy plan shall remain effective for the term of the contract (up to a period of five years), unless circumstances warrant a change.

(f) Administration. The contractor's performance against the approved make-or-buy plan shall be monitored to ensure that:

(1) The contractor is complying with the plan;

(2) Items identified for deferral decisions are addressed in a timely manner; and

(3) The contractor periodically updates the make-or-buy plan based on changed circumstances or significant new work.

970.1504-5 Solicitation provision contract clauses.

(a) The contracting officer shall insert the clause at 48 CFR 970.5215-1, Total Available Fee: Base Fee Amount and Performance Fee Amount, in management and operating contracts, and other contracts determined by the Procurement Executive, or designee, that include cost-plus-award-fee arrangements.

(1) The contracting officer shall include the clause with its Alternate I when the award fee cycle consists of two or more evaluation periods.

(2) The contracting officer shall include the clause with its Alternate II when the award fee cycle consists of one evaluation period.

(3) The contracting officer shall include the clause with its Alternate III when the DOE Operations/Field Office Manager, or designee, requires the contractor to submit a self-assessment.

(4) The contracting officer shall include the clause with its Alternate IV when the DOE Operations/Field Office Manager, or designee, permits the contractor to submit a self-assessment at the contractor's option.

(b) The contracting officer shall insert the clause at 48 CFR 970.5215-2, Make-or-Buy Plan, in management and operating contracts. The contracting officer may add a sentence at the end of paragraph (d) of the clause to identify where in the contract the make-or-buy plan is located.

(c) The contracting officer shall insert the clause at 48 CFR 970.5215-3,

Conditional Payment of Fee, Profit, or Incentives, in management and operating contracts, and other contracts determined by the Procurement Executive, or designee. The contracting officer shall include the clause with its Alternate I in contracts awarded on cost-plus-award-fee, multiple fee, or incentive fee basis which may include various types of fee and incentive arrangements.

(d) The contracting officer shall insert the clause at 48 CFR 970.5215-4, Cost Reduction, in management and operating contracts, and other contracts determined by the Procurement Executive, or designee, if cost savings programs are contemplated.

(e) The Contracting officer shall insert the provision at 48 CFR 970.5215-5, Limitation on Fee, in solicitations for management and operating contracts, and other contracts determined by the Procurement Executive, or designee.

Subpart 970.17—Special Contracting Methods

970.1706 Management and operating contracts.

970.1706-1 Award, renewal, and extension.

(a) *Contract term.* Effective work performance under a management and operating contract is facilitated by the use of a relatively long contract term of up to ten (10) years. Accordingly, management and operating contracts shall provide for a basic contract term not to exceed five (5) years and may include an option(s) to extend the term for additional periods; provided, that no one option period exceeds five (5) years in duration and the total term of the contract, including any options exercised, does not exceed ten (10) years. The specific term of the base period and of any options periods shall be determined at the time of the authorization to compete or extend the contract. The term "option" as used in this subpart means a unilateral right in the contract by which the Government can extend the term of the contract. Accordingly, except as may be provided for through the inclusion of an option(s) in the contract to extend the term, any extension to continue the contract with the incumbent contractor beyond its term shall only occur when such extension can be justified under one of the statutory authorities identified in 48 CFR 6.302 and when authorized by the Head of the Agency.

(b) *Exercise of option.* As part of the review required by 48 CFR 17.605(b), the contracting officer shall assess whether competing the contract will produce a more advantageous offer than

exercising the option. The incumbent contractor's past performance under the contract, the extent to which performance-based management contract provisions are present, or can be negotiated into, the contract, and the impact of a change in a contractor on the Department's discharge of its programs are considerations that shall be addressed in the contracting officer's decision that the exercise of the option is in the Government's best interest. The contracting officer's decision shall be approved by the Procurement Executive and the cognizant Assistant Secretary(s).

(c) *Conditional Authorization of Non-competitive Extension Made Pursuant to Authority Under CICA.* Authorization to extend a management and operating contract by the Head of the Agency shall be considered conditional upon the successful negotiation of the contract to be extended in accordance with the Department's negotiation objectives. The Head of the Contracting Activity shall advise the Procurement Executive no later than 6 months after receipt of the conditional authorization as to whether the Department's objectives will be met and, if not, the contracting activity's plans for competing the requirement.

970.1706-2 Contract clause.

The contracting officer shall insert the clause at 48 CFR 52.217-9, Option to Extend the Term of the Contract, in all management and operating contracts when the inclusion of an option is appropriate.

Subpart 970.19—Small, Small Disadvantaged and Women-Owned Small Business Concerns

970.1907 Subcontracting with Small Business, Small Disadvantaged Business and Woman-Owned Small Business Concerns.

970.1907-1 Subcontracting plan requirements.

Pursuant to the clause at 48 CFR 52.219-9, Small Business Subcontracting Plan, which is required for all management and operating contracts, each management and operating contract shall include a subcontracting plan which is effective for the term of the contract. Goals for the contract shall be negotiated annually when revised funding levels are determined. The plan should include provisions for revising the goals or any other sections of the plan. Such revisions shall be in writing, approved by the contracting officer, and shall be specifically made a material part of the contract.

Subpart 970.22—Application of Labor Policies

970.2200 Scope of subpart.

This subpart prescribes Department of Energy labor policies pertaining to the award and administration of management and operating contracts.

970.2201 Basic labor policies.

970.2201-1 Labor relations.

970.2201-1-1 General.

Contracting officers shall, in appropriate circumstances, follow the guidance in 48 CFR Subpart 22.1, as supplemented in this section, in the award and administration of management and operating contracts.

970.2201-1-2 Policies.

(a) The extent of Government ownership of the nation's energy plant and materials, and the overriding concerns of national defense and security, impose special conditions on personnel and labor relations in the energy program. Such special conditions include the need for continuity of vital operations at DOE installations; retention by DOE of absolute authority on all questions of security; and DOE review of labor expenses under management and operating contracts as a part of its responsibility for assuring judicious expenditure of public funds. It is the intent of DOE that personnel and labor policies throughout the energy program reflect the best experience of American industry in aiming to achieve the type of stable labor-management relations that are essential to the proper development of the energy program. The following enunciates the principles upon which the DOE policy is based:

(1) *Employment standards.* (i) Management and operating contractors are expected to bring experienced, proven personnel from their private operations to staff key positions on the contract work and to recruit other well-qualified personnel as needed. Such personnel should be employed and treated during employment without discrimination by reason of race, color, religion, sex, or national origin. Contractors shall be required to take affirmative action to achieve these objectives.

(ii) The job qualifications and suitability of prospective employees should be established by the contractor prior to employment by careful personnel investigations. Such personnel investigations should include, as appropriate: A credit check; verification of high school degree/diploma or degree/diploma granted by

an institution of higher learning within the last 5 years; contacts with listed personal references; contacts with listed employers for the past 3 years (excluding employment of less than 60 days duration, part-time employments, and craft/union employments); and local law enforcement checks when such checks are not prohibited by State or local law or regulation, and when the individual resides in the jurisdiction where the contractor is located. When a DOE access authorization (security clearance) will be required, the aforementioned preemployment checks must be conducted and the applicant's job qualifications and suitability must be established before a request is made to the DOE to process the applicant for access authorization. Evidence must be furnished to the DOE with the applicant's security forms that specify: The date each check was conducted, the entity contacted that provided information concerning the applicant, a synopsis of the information provided as a result of each contact, and a statement that all information available has been reviewed and favorably adjudicated in accordance with the contractor's personnel policies. When an applicant is being hired specifically for a position which requires a DOE access authorization, the applicant shall not be placed in that position prior to the access authorization being granted by the DOE unless an exception has been obtained from the Head of the Contracting Activity, or designee. If an applicant is placed in that position prior to access authorization being granted by the DOE, the applicant may not be afforded access to classified matter or special nuclear materials (in categories requiring access authorization) until the DOE notifies the employer that access authorization has been granted. Management and operating contractors and other contractors operating DOE facilities may include the requirements set forth in this subsection in subcontracts (appropriately modified to identify the parties) wherein subcontract employees will be required to hold DOE access authorization in order to perform on-site duties, such as protective force operations.

(iii) Consistent with the policies set forth in this subpart, the contractor is responsible for maintaining satisfactory standards for employee qualifications, performance, conduct, and business ethics under its own personnel policies.

(2) *Security.* On all matters of security at its facilities, DOE retains absolute authority and neither the regulations and policies pertaining to security, nor their administration, are matters for collective bargaining between the

contractor's management and labor. Insofar as DOE security regulations affect the collective bargaining process, the security policies and regulations will be made known to both parties. To the fullest extent feasible, DOE will consult with representatives of the contractor's management and labor when formulating security regulations and policies that may affect the collective bargaining process.

(3) *Wages, salaries, and employee benefits.* (i) Wages, salaries, and employee benefits shall be administered in a manner designated to adapt the normal practices and conditions of industry or institutions of higher education to the contract work, and to provide for appropriate review by DOE. Area practices, valid patterns, and well-established commercial or academic practices of the contractors, as appropriate, form the criteria for the establishment and adjustment of compensation schedules.

(ii) The aspects of wages, hours, and working conditions which are the substance of collective bargaining in normal organized industries will be left to the orderly processes of negotiation and agreement between DOE contractor management and employee representatives with maximum possible freedom from Government interference.

(4) *Employee relations.* The handling of employee relations on contract work, including such matters as the conduct and discipline of the work force and the handling of employee grievances, is part of the normal management responsibility of the contractor.

(5) *Collective bargaining.* (i) DOE review of collective bargaining practices will be premised on the view that management's trusteeship for the operation of the Government facilities includes the duty to adopt practices which are fundamental to the friendly adjustment of disputes, and which experience has shown, promote orderly collective bargaining relationships. Practices inconsistent with this view may be objected to if not found to be otherwise clearly warranted.

(ii) Consistent with the policy of assuring continuity of operation of vital facilities, all collective bargaining agreements at DOE-owned facilities should provide that grievances and disputes involving the interpretation or application of the agreement will be settled without resorting to strike, lockout, or other interruption of normal operations. For this purpose, each collective bargaining agreement entered into during the period of performance of this contract should provide an effective grievance procedure with arbitration as its final step, unless the parties

mutually agree upon some other method of assuring continuity of operation for the term of the collective bargaining agreement.

(iii) DOE expects its management and operating contractors and the unions representing the contractor's employees to cooperate fully with the Federal Mediation and Conciliation Service.

(6) *Personnel training.* DOE encourages and supports personnel training programs aimed at improving work efficiency or developing needed skills which are not otherwise obtainable.

(7) *Working conditions.* Accident, fire, health, and occupational hazards associated with DOE activities will be held to a practical minimum level and controlled in the interest of maintenance of health and prevention of accidents. Subject to DOE control, contractors shall be required to maintain comprehensive continuous preventive and protective programs appropriate to the particular activities throughout all operations. Appropriate financial protection in case of occupational disability must be provided to employees on DOE projects.

(b) Title to payroll and associated records under certain contracts for the management and operation of DOE facilities, and for necessary miscellaneous construction incidental to the function of these facilities, shall vest in the Government. Such records are to be disposed of in accordance with DOE directions. For such contracts, the Solicitor of Labor has granted a tolerance from the Department of Labor Regulations to omit from the prescribed labor clauses the requirement for the retention of payrolls and associated records for a period of three years after completion of the contract. Under this tolerance, the records retention requirements for all labor clauses in the contract and the Fair Labor Standards Act are satisfied by disposal of such records in accordance with applicable DOE directives.

970.2201-1-3 Contract clause.

In addition to the clause at 48 CFR 52.222-1, Notice to the Government of Labor Disputes, the contracting officer shall insert the clause at 970.5222-1, Collective Bargaining Agreements—Management and Operating Contracts, in all management and operating contracts.

970.2201-2 Overtime management.

970.2201-2-1 Policy.

Contracting officers shall ensure that management and operating contractors manage overtime cost effectively and

use overtime only when necessary to ensure performance of work under the contract.

970.2201-2-2 Contract clause.

The contracting officer shall insert the clause at 48 CFR 970.5222-2, Overtime Management, in management and operating contracts.

970.2204 Labor standards for contracts involving construction.

970.2204-1 Statutory and regulatory requirements.

970.2204-1-1 Administrative controls and criteria for application of the Davis-Bacon Act in operational or maintenance activities.

(a) Particular work items falling within one or more of the following criteria normally will be classified as noncovered by the Davis-Bacon Act, hereinafter referred to in this section as the "Act."

(1) Individual work items estimated to cost \$2,000 or less. The total dollar amount of the management and operating contract is not a factor to be considered and bears no relation to individual work items classified as construction, alteration and/or repair, including painting and decorating. However, no item of work, the cost of which is estimated to be in excess of \$2,000, shall be artificially divided into portions less than \$2,000 for the purpose of avoiding the application of the Act.

(2) Work and services that are a part of operational and maintenance activities or which, being very closely and directly involved therewith, are more in the nature of operational activities than construction, alteration, and/or repair work. This includes work and services which would involve a material risk to continuity of operations, to life or property, or to DOE operating requirements, if performed by persons other than the contractor's regular production and maintenance forces. However, any decision that contracts or work items are noncovered for these reasons must be made by the Head of the Contracting Activity without power of delegation.

(3) Assembly, modification, setup, installation, replacement, removal, rearrangement, connection, testing, adjustment, and calibration of machinery and equipment. However, it is noted that these activities are covered if they are part of, or would be a logical part of, the construction of a facility, or if construction-type work which is not "incidental" to the overall effort is involved.

(4) Experimental development of equipment, processes, or devices,

including assembly, fitting, installation, testing, reworking, and disassembly. This refers to equipment, processes, and devices which are assembled for the purpose of conducting a test or experiment. The design may be only conceptual in character, and professional personnel who are responsible for the experiment participate in the assembly. Specifically excluded from the category of experimental development are buildings and building utility services, as distinguished from temporary connections thereto. Also specifically excluded from this category is equipment to be used for continuous testing (e.g., a machine to be continuously used for testing the tensile strength of structural members).

(5) Experimental work in connection with peaceful uses of nuclear energy. This refers to equipment, processes and devices which are assembled and/or set in place and interconnected for the purpose of conducting a test or experiment. The nature of the test or experiment is such that professional personnel who are responsible for the test or experiment and/or data to be derived therefrom must, by necessity, participate in the assembly and interconnections. Specifically excluded from experimental work are buildings, building utility services, structural changes, drilling, tunneling, excavation, and back-filling work which can be performed according to customary drawings and specifications, and utility services of modifications to utility services, as distinguished from temporary connections thereto. Work in this category may be performed in mines or in other locations specifically constructed for tests or experiments.

(6) Emergency work to combat the effects of fire, flood, earthquake, equipment failure, accident, or other casualties, and to restart the operational activity following the casualty. Work which is not directly related to restarting the activity or which involves rebuilding or replacement of a structure, structural components, or equipment is excluded from this category.

(7) Decontamination, including washing, scrubbing, and scraping to remove contamination; removal of contaminated soil or other material; and painting or other resurfacing, provided that such painting or resurfacing is an integral part of the decontamination activity and performed by the employees of the contractors performing the decontamination.

(8) Burial of contaminated soil waste or contained liquid; however, initial preparatory work readying the burial ground for use (e.g., any grading or

excavating that is a part of initial site preparation, fencing, drilling wells for continued monitoring of contamination, construction of guard or other office space) is covered. Work performed subsequent to burial which involves the placement of concrete or other like activity is also covered.

(b) The classification of a contract as a contract for operational or maintenance activities does not necessarily mean that all work and activities at the contract location are classifiable as outside coverage of the Act since it may be necessary to separate work which should be classified as covered. Therefore, the Heads of Contracting Activities shall establish and maintain controls for the careful scrutiny of proposed work assignments under such contracts to assure that:

(1) Contractors whose contracts do not contemplate the performance of work covered by the Act with the contractor's own forces are neither asked nor authorized to perform work within the scope of the Act. If the actual work assignments do involve covered work, the contract should be modified to include applicable provisions of the Act.

(2) Where covered work is performed by a contractor whose contract contains provisions required by the Act, such work is performed as required by law and the contract. After the contractor has been informed, as provided in paragraph (b)(3) of this subsection, that certain work is covered, the responsibilities of the Head of the Contracting Activity to assure compliance is the same as it would be if the work were being performed under a separate construction contract.

(3) Controls provided for above include consideration by the Head of the Contracting Activity and the contractor, before work is begun or contracted out, of the relation of the Act to the annual programming of work; the contractor's work orders; and work contracted out in excess of \$2,000. The Head of the Contracting Activity may, if consistent with DOE's responsibilities as described in this subsection, prescribe from time to time classes of work as to which applicability or nonapplicability of the Act is clear, for which the Head of the Contracting Activity will require no further DOE determination on coverage in advance of the work. For all work, controls to be established by the Head of the Contracting Activity should provide for notification to the contractor before work is begun as to whether such work is covered. The Head of the Contracting Activity is responsible for submitting to

the Wage and Hours Division, Employment Standards Administration, Department of Labor, Washington, D.C. 20210, all DOE requests for project area or installation wage determinations, or individual determinations, or extensions or modification thereto. Requests for such determinations shall be made on Standard Form 308, at least 30 calendar days before they are required for use in advertising for bids or requests for proposals.

(c) *Experimental installations.* Within DOE programs, a variety of experiments are conducted involving materials, fuels, coolants, and processing equipment. Certain types of situations where tests and experiments have presented coverage questions are described as follows:

(1) *Set-ups of device and/or processes.* The proving out of investigative findings and theories of a scientific and technical nature may require the set-up of various devices and/or processes at an early, pre-prototype stage of development. These may range from laboratory bench size to much larger set-ups. As a rule, these set-ups are made within established facilities (normally laboratories), required utility connections are made to services provided as a part of the basic facilities, and the activity as a whole falls within the functional purpose of the facility. Such set-ups are generally not covered. However, the erection of structures which are public works is covered if construction type work, other than incidental work, is involved. Preparatory work for the set-up requiring structural changes or modifications of basic utility services, as distinguished from connections thereto, is covered. The following are illustrations of noncovered set-ups of devices and/or processes:

(i) Assembly of piping and equipment within existing "hot cell" facilities for proving out a conceptual design of a chemical processing unit;

(ii) Assembly of equipment, including adaptation and modification thereof, in existing "hot cell" facilities to prove out a conceptual design for remotely controlled machining equipment;

(iii) Assembly of the first graphite pile in a stadium at Stagg Field in Chicago;

(iv) Assembly of materials and equipment for particular aspects of the direct current thermonuclear experiments to explore feasibility and to study other ramifications of the concept of high energy injection and to collect data thereon.

(2) *Loops.* Many experiments are carried on in equipment assemblies, called loops, in which liquids or gases are circulated under monitored and

controlled conditions. For purposes of determining coverage under the Act, loops may be classed as loop facilities or as loop set-ups. Both of these classes of loops can include in-reactor loops and out-of-reactor loops. In differentiating between clearly identified loop set-ups and loop facilities, an area exists in which there have been some questions of coverage, such as certain loops at the Material Test Reactor and at Engineering Test Reactor and the Idaho National Engineering and Environmental Laboratory site. Upon clarification of this area, further illustrations will be added. In the meantime, the differentiation between loop set-ups and loop facilities must be made on a case-by-case basis, taking into account the total criteria set forth in this subpart.

(i) *Loop set-ups.* The assembly, erection, modification, and disassembly of a loop set-up is noncovered. A noncontroversial example of a loop set-up is one which is assembled in a laboratory, e.g., Oak Ridge National Laboratory, Argonne National Laboratory, or Lawrence Livermore National Laboratory, for a particular test and thereafter disassembled. However, preparatory work for a loop set-up requiring structural changes or modifications of basic utility services as distinguished from connections thereto is covered, as are material and equipment that are installed for a loop set-up which is a permanent part of the facility or which is used for a succession of experimental programs.

(ii) *Loop facilities.* A loop facility differs from a loop set-up in that it is of a more permanent character. It is usually, but not always, of greater size. It normally involves the building or modification of a structure. Sometimes it is installed as a part of construction of the facility. It may be designed for use in a succession of experimental programs over a longer period of time. Examples of loop facilities are the in-reactor "K" loops at Hanford and the large Aircraft Nuclear Propulsion loop at the Idaho National Engineering and Environmental Laboratory site. The on-site assembly and erection of such loop facilities are covered. However, once a loop facility is completed and becomes operational, the criteria set forth in this paragraph for operational and maintenance activities apply.

(3) *Reactor component experiments.* Other experiments are carried on by insertion of experimental components within reactor systems without the use of a loop assembly. An example of reactor facilities erected for such experimental purposes are the special power excursion test reactors (SPETRs)

at the National Reactor Test Site which are designed for studying reactor behavior and performance characteristics of certain reactor components. Such a facility may consist of a reactor vessel, pressurizing tank, coolant loops, pumps, heat exchangers, and other auxiliary equipment as needed. The facility also may include sufficient shielding to permit work on the reactor to proceed following a short period of power interruption, and buildings as needed to house the reactor and its auxiliary equipment. The erection and on-site assembly of such a reactor facility is covered, but the components whose characteristics are under study are excluded from coverage. To illustrate, one of the SPETRs planned for studies of nuclear reactor safety is designed to accommodate various internal fuel and control assemblies. The internal structure of the pressure vessel is designed so that cores of different shapes and sizes may be placed in the vessel for investigation, or the entire internal structure may be easily removed and replaced by a structure which will accept a different core design. Similarly, the control rod assembly is arranged to provide for flexibility in the removal of instrument leads and experimental assemblies from within the core.

(4) *Tests or experiments in peaceful uses of nuclear energy.* These tests or experiments are varied in nature and some are only in a planning stage. They consist of one or more nuclear or nonnuclear detonations for the purposes of acquiring data. The data can include seismic effects, radiation effects, amount of heat generated, amount of material moved and so forth. Some of these tests are conducted in existing mines, while others are conducted in facilities specifically constructed for the tests or experiments. In general, all work which can be performed in accordance with customary drawings and specifications, as well as other work in connection with preparation of facilities is treated as covered work. Such work includes tunneling, drilling, excavation and backfilling, erection of buildings or other structures, and installation of utilities. The installation of the nonnuclear material or nuclear device to be detonated, and the instrumentation and connection between such material or device and the instrumentation are treated as noncovered work.

(5) *Tests or experiments in military uses of nuclear energy.* As in 970.2204-1-1(c)(4), these tests or experiments can be varied in nature. However, under this category it is intended to include only detonation of nonnuclear material or

nuclear devices. The material or devices can be detonated either underground, at ground level, or above the ground.

These tests or experiments have been conducted in, on, or in connection with facilities specifically constructed for such tests or experiments. As in tests or experiments in peaceful uses of nuclear energy, all work which can be performed in accord with customary drawings and specifications, as well as other work in connection with preparation of facilities are treated as covered work. Such work includes building towers or similar structures, tunneling, drilling, excavation and backfilling, erection of buildings or other structures, and installation of utilities. The installation of the nonnuclear material or nuclear devices and instrumentation are treated as noncovered work.

(d) *Construction site contiguous to an established manufacturing facility.* As DOE-owned property sometimes encompasses several thousand acres of real estate, a number of separate facilities may be located in areas contiguous to each other on the same property. These facilities may be built over a period of years, and established manufacturing activities may be regularly carried on at one site at the same time that construction of another facility is underway at another site. On occasion, the regular manufacturing activities of the operating contractor at the first site may include the manufacture, assembly, and reconditioning of components and equipment which in other industries would normally be done in established commercial plants. While the manufacture of components and equipment in the manufacturing plant is noncovered, the installation of any such manufactured items on a construction job is covered.

970.2208 Equal employment opportunity.

The equal employment opportunity provisions of 48 CFR subpart 22.8 and subpart 922.8 of this chapter, including Executive Order 11246 and 41 CFR part 60, are applicable to DOE management and operating contracts.

970.2210 Service Contract Act.

The Service Contract Act of 1965 is not applicable to contracts for the management and operation of DOE facilities, but it is applicable to subcontracts under such contracts (see 48 CFR 970.5244-1).

970.2270 Unemployment compensation.

(a) Each state has its own unemployment compensation system to provide payments to workers who

become unemployed involuntarily and through no fault of their own. Funds are provided for unemployment compensation benefits through a payroll tax on employers. Most DOE contractors are subject to the unemployment compensation tax laws of the states in which they are located. It is the policy to assure, both in the negotiation and administration of cost-reimbursement type contracts, that economical and practical arrangements are made and practiced with respect to unemployment compensation.

(b) *Contract exempt from state laws.*

(1) Some contractors are exempt from state unemployment compensation laws, usually on grounds that they are nonprofit organizations or subdivisions of State governments. Most states, however, permit such employers to elect unemployment compensation coverage on a voluntary basis. Under such circumstances, all existing or prospective cost-reimbursement contractors shall be encouraged to provide unemployment compensation coverage or equivalent substitutes.

(2) It is also DOE policy that, prior to the award or extension of a management and operating contract, exempt contractors or prospective contractors shall be required to submit to the contracting officer a statement that they will either elect coverage or provide equivalent substitutes for unemployment compensation, or in the alternative, submit evidence that it is impractical to do so. If any exempt contractor or prospective contractor submits that it is impractical to elect coverage or to provide an equivalent substitute, appropriate Office of Contract and Resource Management, within the Headquarters procurement organization, staff shall review that position prior to recommending an award or extension of the contract. If there are substantial reasons for not electing coverage or for not providing equivalent substitutes, a contract may be awarded or extended. Headquarters' staff review and recommendation shall be based on such factors as:

(i) The specific provisions of the unemployment compensation law of the State;

(ii) The extent to which the establishment of special conditions on DOE work may have an adverse effect on the contractor's general policies and operating costs in its private operations;

(iii) The numerical relationship between the contractor's private work force and its employees performing only work for DOE;

(iv) The contractor's record with respect to work force stability and the

general outlook with respect to future work force stability;

(v) In a replacement contractor situation, whether or not the prior contractor had coverage or suitable substitutes; and

(vi) The particular labor relations implications involved.

Subpart 970.23—Environmental, Conservation, and Occupational Safety Programs

970.2303 Hazardous materials identification and material safety.

970.2303-1 General.

(a) The Department of Energy regulates the nuclear safety of its major facilities under its own statutory authority derived from the Atomic Energy Act and other legislation. The Department also regulates, under certain specific conditions, the use by its contractors of radioactive materials and ionizing radiation producing machines.

(b) The inclusion of environmental, safety and health clauses in DOE contracts shall be made by the contracting officer in accordance with this subpart and in consultation with appropriate environmental, safety and health program management personnel.

970.2303-2 Contract clauses.

(a) When work under management and operating contracts and subcontracts thereunder is to be performed at a facility where DOE will exercise its statutory authority to enforce occupational safety and health standards applicable to the working conditions of the contractor and subcontractor employees at such facility, the clause at 48 CFR 970.5223-1, Integration of Environment, Safety and Health into Work Planning and Execution, shall be used in such contract or subcontract and made applicable to the work if conditions in paragraphs (a)(1) through (3) of this section, are satisfied:

(1) DOE work is segregated from the contractor's or subcontractor's other work;

(2) The operation is of sufficient size to support its own safety and health services; and

(3) The facility is government-owned, or leased by or for the account of the government.

(b) The clause set forth in 952.223-72, Radiation Protection and Nuclear Criticality, shall be included in those contracts or subcontracts for, and be made applicable to, work to be performed at a facility where DOE does not elect to assert its statutory authority to enforce occupational safety and health standards applicable to the

working conditions of contractor and subcontractor employees, but does need to enforce radiological safety and health standards pursuant to provisions of the contract or subcontract rather than by reliance upon Nuclear Regulatory Commission licensing requirements (including agreements with States under section 274 of the Atomic Energy Act).

970.2304 Use of recovered/recycled materials.

970.2304-1 General.

The policy for the acquisition and use of environmentally preferable products and services is described at 48 CFR subpart 923.4.

970.2304-2 Contract clause.

The contracting officer shall insert the clause at 48 CFR 970.5223-2, Acquisition and Use of Environmentally Preferable Products and Services, in management and operating contracts.

970.2305 Workplace substance abuse programs—management and operating contracts.

970.2305-1 General.

(a) The Department of Energy (DOE), as part of its overall responsibilities to protect the environment, maintain public health and safety, and safeguard the national security, has established policies, criteria, and procedures for management and operating contractors to develop and implement programs that help maintain a workplace free from the use of illegal drugs.

(b) Regulations concerning DOE's management and operating contractor workplace substance abuse programs are promulgated at 10 CFR part 707, Workplace Substance Abuse Programs at DOE Sites.

970.2305-2 Applicability.

(a) All management and operating contracts awarded under the authority of the Atomic Energy Act of 1954, as amended, are required to implement the policies, criteria, and procedures of 10 CFR part 707, Workplace Substance Abuse Programs at DOE Sites.

(b) Except as otherwise provided for in this subpart, management and operating contracts subject to the requirements of 10 CFR part 707 and this subpart shall not be subject to 48 CFR 23.5, Drug Free Workplace.

970.2305-3 Definitions.

Terms and words relating to DOE's Workplace Substance Abuse Programs, as used in this section, have the same meanings assigned to such terms and words in 10 CFR part 707.

970.2305-4 Solicitation provision and contract clause.

(a) The contracting officer shall insert the provision at 48 CFR 970.5223-3, Agreement Regarding Workplace Substance Abuse Programs at DOE Sites, in solicitations for the management and operation of DOE-owned or -controlled sites operated under the authority of the Atomic Energy Act of 1954, as amended.

(b) The contracting officer shall insert the clause at 970.5223-4, Workplace Substance Abuse Programs at DOE Sites, in contracts for the management and operation of DOE-owned or -controlled sites operated under the authority of the Atomic Energy Act of 1954, as amended.

970.2306 Suspension of payments, termination of contract, and debarment and suspension actions.

(a) The contracting officer shall comply with the procedures of 48 CFR 23.506 regarding the suspension of contract payments, the termination of the contract for default, and the debarment and suspension of a contractor relative to failure to comply with the clause at 48 CFR 970.5223-4, Workplace Substance Abuse Programs at DOE Sites.

(b) For purposes of 10 CFR part 707, the specific causes for suspension of contract payments, termination of the contract for default, and debarment and suspension of the contractor are:

(1) The contractor fails to either comply with the requirements of 10 CFR part 707 or perform in a manner consistent with its approved program;

(2) The contractor has failed to comply with the terms of the provision at 48 CFR 970.5223-3, Agreement Regarding Workplace Substance Abuse Programs at DOE Sites;

(3) Such a number of contractor employees having been convicted of violations of criminal drug statutes for violations occurring on the DOE-owned or -controlled site, as to indicate that the contractor has failed to make a good faith effort to provide a drug free workplace; or,

(4) The offeror has submitted a false certification in response to the provision at 48 CFR 970.5223-3, Agreement Regarding Workplace Substance Abuse Programs at DOE Sites.

Subpart 970.26—Other Socioeconomic Programs**970.2670 Implementation of Section 3021 of the Energy Policy Act of 1992.****970.2670-1 Requirements.**

The goal requirements of section 3021 of the Energy Policy Act of 1992, and the attendant reporting requirements shall be included in the subcontracting

plan for the management and operating contract and shall apply to the annual dollar obligations specifically provided to the contractor for competitively awarded subcontracts that fulfill Energy Policy Act requirements.

970.2671 Diversity.**970.2671-1 Policy.**

Department of Energy policy recognizes that full utilization of the talents and capabilities of a diverse work force is critical to the achievement of its mission. The principal goals of this policy are to foster and enhance partnerships with small, small disadvantaged, women-owned small businesses, and educational institutions; to match capabilities with existing opportunities; to track small, small disadvantaged, women-owned small business, and educational activity; and to develop innovative strategies to increase opportunities.

970.2671-2 Contract clause.

The contracting officer shall insert the clause at 48 CFR 970.5226-1, Diversity Plan, in all management and operating contracts.

970.2672 Implementation of Section 3161 of the National Defense Authorization Act for Fiscal Year 1993.**970.2672-1 Policy.**

Consistent with the objectives of section 3161 of the National Defense Authorization Act for Fiscal Year 1993, 42 U.S.C. 7274h, in instances where the Department of Energy has determined that a change in work force at a DOE Defense Nuclear Facility is necessary, DOE contractors and subcontractors at DOE Defense Nuclear Facilities shall accomplish work force restructuring or displacement so as to mitigate social and economic impacts and in a manner consistent with any DOE work force restructuring plan in effect for the facility or site. In all cases, mitigation shall include the requirement for hiring preferences for employees whose positions have been terminated (except for termination for cause) as a result of changes to the work force at the facility due to restructuring accomplished under the requirements of section 3161. Where applicable, contractors may take additional actions to mitigate consistent with the Department's Workforce Restructuring Plan for the facility or site.

970.2672-2 Requirements.

The requirements set forth in 48 CFR 926.71, Implementation of Section 3161 of the National Defense Authorization Act for Fiscal Year 1993, for contractors

and subcontractors to provide a hiring preference for employees under Department of Energy contracts whose employment in positions at a Department of Energy Defense Nuclear Facility is terminated (except for a termination for cause) applies to management and operating contracts.

970.2672-3 Contract clause.

The contracting officer shall insert the clause at 48 CFR 970.5226-2, Workforce Restructuring Under Section 3161 of the National Defense Authorization Act for Fiscal Year 1993, in contracts for the management and operation of Department of Energy Defense Nuclear Facilities and, as appropriate, in other contracts that include site management responsibilities at a Department of Energy Defense Nuclear Facility.

970.2673 Regional partnerships.**970.2673-1 Policy.**

It is the policy of the DOE to be a constructive partner in the geographic region in which DOE conducts its business. The basic elements of this policy include:

(a) Recognizing the diverse interests of the region and its stakeholders,

(b) Engaging regional stakeholders in issues and concerns of mutual interest, and

(c) Recognizing that giving back to the community is a worthwhile business practice.

970.2673-2 Contract clause.

The contracting officer shall insert the clause at 48 CFR 970.5226-3, Community Commitment, in all management and operating contracts.

Subpart 970.27—Patents, Data, and Copyrights**970.2701 General.****970.2701-1 Applicability.**

This subpart applies to negotiation of patent rights, rights in technical data provisions and other related provisions for the Department of Energy contracts for the management and operation of DOE's major sites or facilities, including the conduct of research and development and nuclear weapons production, and contracts which involve major, long-term or continuing activities conducted at a DOE site.

970.2702 Patent related clauses.**970.2702-1 Authorization and consent.**

Contracting officers must use the clause at 970.5227-4, Authorization and Consent, instead of the clause at 48 CFR 52.227-1.

970.2702-2 Notice and assistance regarding patent and copyright infringement.

Contracting officers must use the clause at 970.5227-5, Notice and Assistance Regarding Patent and Copyright Infringement, instead of the clause at 48 CFR 52.227-2.

970.2702-3 Patent indemnity.

(a) Contracting officers must use the clause at 970.5227-6, Patent Indemnity—Subcontracts to assure that subcontracts appropriately address patent indemnity.

(b) Normally, the clause at 48 CFR 52.227-3 would not be appropriate for an M&O contract; however, if there is a question, such as when the mission of the contractor involves production, the contracting officer must consult with local patent counsel and use the clause where appropriate.

970.2702-4 Royalties.

Contracting officers must use the solicitation provision at 970.5227-7, Royalty Information, and the clause at 970.5227-8, Refund of Royalties instead of the provision at 48 CFR 52.227-8 and the clause at 48 CFR 52.227-9, respectively.

970.2702-5 Rights to proposal data.

Contracting officers must include the clause at 48 CFR 52.227-23, Rights to Proposal Data, in all solicitations and contracts for the management and operation of DOE sites and facilities.

970.2702-6 Notice of right to request patent waiver.

Contracting officers must include the provision at 970.5227-9 in all solicitations for contracts for the management and operation of DOE sites or facilities.

970.2703 Patent rights.**970.2703-1 Purposes of patent rights clauses.**

(a) DOE sites and facilities are managed and operated on behalf of the Department of Energy by a contractor, pursuant to management and operating contracts that are generally awarded for a five (5) year term, with the possibility for renewal. Special provisions relating to patent rights are appropriately incorporated into an M&O contract because of the unique circumstances and responsibilities of managing and operating a Government-owned facility, as compared to other federally funded research and development contracts.

(b)(1) *Technology transfer mission clause.* In accordance with Public Law 101-189, section 3133(d), DOE may grant technology transfer authority to

M&O contractors operating a DOE facility. Generally, M&O contractors have the right to elect to retain title to inventions made under the contract, whether a nonprofit or educational organizations, as a result of 35 U.S.C. 200 *et seq.* (Bayh-Dole Act), or a large business, as a result of a class patent waiver issued pursuant to 10 CFR part 784. Under such contracts, the M&O contractor assumes responsibilities for commercializing retained inventions, in accordance with the Technology Transfer Mission clause provided at 970.5227-3. That clause also governs such activities as the distribution of royalties earned from inventions made under the contract and the transfer of patent rights in inventions made under the contract to successor contractors.

(2) If the M&O contractor is a nonprofit organization or small business firm having technology transfer authority, the following clauses are inserted into the M&O contract: 970.5227-3 and 970.5227-10.

(3) If the M&O contract has technology transfer as a mission and is to be performed by a for-profit, large business firm that has been granted an advance class waiver, the following clauses are inserted into the M&O contract: 970.5227-3 and 970.5227-12. The terms of the clause at 970.5227-12 are subject to modification to conform to the terms of the class waiver.

(4) If the M&O contract does not have a technology transfer mission and is to be performed by a for-profit, large business firm and does not have advance class waiver under 10 CFR part 784, the patent rights clause at 970.5227-11 is inserted into the M&O contract, and the Technology Transfer Mission clause is inapplicable.

(5) If the contractor is an educational institution, a non-profit organization or a small business firm and is conducting privately funded technology transfer activities, involving the use of private funds to conduct licensing and marketing activities related to inventions made under the contract in accordance with the Bayh-Dole Act, DOE may modify the patent rights clause (970.5227-10) to address issues such as the disposition of royalties earned under the privately funded technology transfer program, the transfer of patent rights to a successor contractor, allowable cost restrictions concerning privately funded technology transfer activities, and the Government's freedom from any liability related to licensing under the contractor's privately funded technology transfer program.

(c) Contracting officers must consult with DOE patent counsel assisting the

contracting activity or the Assistant General Counsel for Technology Transfer and Intellectual Property for assistance in selecting for use in the solicitation, negotiating, or approving appropriate patent rights clauses for a M&O contract. It may be appropriate to include more than one patent rights clause in a solicitation if the successful contractor could, for instance, be either an educational or a large business. If a large business may be selected for performance of a contract that will include a technology transfer clause, the solicitation must include the clause at 970.5227-12 to reflect the waiver that will likely be granted. If the solicitation includes more than one patent clause, it must include an explanation of the circumstances under which the appropriate clause will be used. The final award must contain only one patent rights clause.

970.2703-2 Patent rights clause provisions for management and operating contractors.

(a) *Allocation of Principal Rights: Bayh-Dole provisions.* If the management and operating contractor is an educational institution or nonprofit organization, the patent rights clause provided at 970.5227-10 must be inserted into the M&O contract. Such entities are beneficiaries of Bayh-Dole Act, including the paramount right of the contractor to elect to retain title to inventions conceived or first actually reduced to practice in performance of work under the contract, except in DOE-exempted areas of technology or in operation of DOE facilities primarily dedicated to naval nuclear propulsion or weapons related programs.

(b) *Allocation of Principal Rights: Government title.* (1) The patent rights clause provided at 970.5227-11 must be incorporated into the M&O contract if the contractor is a for-profit, large business firm and the contract does not have a technology transfer mission or if, without regard to the type of contractor, the contract is for the operation of a DOE facility primarily dedicated to naval nuclear propulsion or weapons related programs. That clause provides for DOE's statutory obligation to take title to inventions conceived or first actually reduced to practice in the course of or under an M&O contract, and does not contemplate an advance class waiver of Government rights in inventions, or participation by the contractor in technology transfer activities.

(2) While only in rare circumstances does a for-profit large business contractor whose contract contains no technology transfer mission receive

rights in or title to inventions made under the contract, the contractor does have the right to request a license or foreign patent rights in inventions made under the contract, and may petition for a waiver of Government rights in identified inventions. The patent rights clause 970.5227-11 does not include many of the provisions of patent rights clauses 970.5227-10 and 970.5227-12, related to the filing of patent applications by the contractor, the granting of rights in inventions by the contractor to third parties (preference for United States industry), and conditions allowing the Government to grant licenses to third parties in inventions retained by the contractor (march-in rights). Any instrument granting rights in inventions made under a contract governed by patent rights clause 970.5227-11 must include these additional provisions within its terms and conditions.

(c) *Allocation of Principal Rights: Contractor right to elect title under an advance class waiver.* If the M&O contractor is a for-profit, large business firm and the Government has granted an advance class waiver of Government rights in inventions made in the course of or under the M&O contract, under the authority of the Atomic Energy Act of 1954 (42 U.S.C. 2182) and the Federal Nonnuclear Energy Act of 1974 (42 U.S.C. 5908(c)), the patent rights clause provided at 970.5227-12 must be inserted into the M&O contract, unless the terms and conditions of such an approved waiver alter or replace the patent rights clause provisions pursuant to 10 CFR part 784.

(d) *Extensions of time—DOE discretion.* The patent rights clauses for M&O contracts require the contractor to take certain actions within prescribed time periods to comply with the contract and preserve its rights in inventions. The M&O contractor may request extensions of time in which to take such actions by submitting written justification to DOE, and DOE may grant the contractor's requests, on a case-by-case basis. If the time period expired due to negligence by the contractor, DOE may grant a request for an extension of time upon a showing by the contractor that corrective procedures are in place to avoid such negligence in the future. If a contractor is requesting an extension of time in which to elect to retain title to an invention, DOE may grant the request if the extension allows the contractor to conduct further experimentation, market research, or other analysis helpful to determine contractor interest in electing title to the invention, among other considerations. Generally, the extensions of time are for

periods of between six (6) months to one (1) year.

(e) *Facilities license.* These include the rights to make, use, transfer, or otherwise dispose of all articles, materials, products, or processes embodying inventions or discoveries used or embodied in the facility regardless of whether or not conceived or first actually reduced to practice under or in the course of such a contract. The patent rights clauses, 970.5227-10, 970.5227-11, 970.5227-12, each contain a provision granting the Government this facilities license.

(f) *Deletion of classified inventions provision.* If DOE determines that the research, development, demonstration or production work to be performed during the course of a management and operating contract most probably will not involve classified subject matter or result in any inventions that require security classification, DOE patent counsel may advise the contracting officer to delete the patent rights clause provision entitled, "Classified Inventions" from the M&O contract.

(g) *Alternate 1—Weapons Related Research or Production.* If DOE grants technology transfer authority to a DOE facility, pursuant to Public Law 101-189, section 3133(d), and the DOE owned facility is involved in weapons related research and development, or production, then Alternate 1 of the patent rights clauses must be inserted into the M&O contract. Alternate 1 defines weapons related subject inventions and restricts the contractor's rights with respect to such inventions.

970.2704 Rights in data.

970.2704-1 General.

(a) Rights in data relating to the performance of the contract and to all facilities are significant in assuring continuity of the management and operation of DOE facilities. It is crucial in assuring DOE's continuing ability to perform its statutory missions that DOE obtain rights to all data produced or specifically used by its management and operating contractors and appropriate subcontractors. In order to obtain the necessary rights in technical data, DOE contracting officers shall assure that management and operating contracts contain either the Rights in Data clause at 48 CFR 970.5227-1, Rights in Data—Facilities, or the clause at 48 CFR 970.5227-2, Rights in Data—Technology Transfer. Selection of the appropriate clause is dependent upon whether technology transfer is a mission of the management and operating contract pursuant to the National Competitiveness Technology Transfer

Act of 1989, Public Law 101-189, (15 U.S.C. 3711 *et seq.*, as amended). If technology transfer is not a mission of the management and operating contract, the clause at 48 CFR 970.5227-1, Rights in Data—Facilities, shall be used. In those instances in which technology transfer is a mission of the contract, the clause at 48 CFR 970.5227-2, Rights in Data—Technology Transfer, shall be used.

(b) Employees of the management and operating contractor may not be used to assist in the preparation of a proposal or bid for services which are similar or related to those being performed under the contract, which are to be performed by the contractor or its parent or affiliate organization for commercial customers unless the employee has been separated from work under the DOE contract for such period as the Head of the Contracting Activity or designee shall have directed.

970.2704-2 Procedures.

(a) The clauses at 48 CFR 970.5227-1, Rights in Data—Facilities, and 48 CFR 970.5227-2, Rights in Data—Technology Transfer, both provide generally for Government ownership and for unlimited rights in the Government for all data first produced in the performance of the contract and unlimited rights in data specifically used in the performance of the contract. Both clauses provide that, subject to patent, security, and other provisions of the contract, the contractor may use contract data for its private purposes. The contractor, under either clause, must treat any data furnished by DOE or acquired from other Government agencies or private entities in the performance of their contracts in accordance with any restrictive legends contained therein.

(b) Since both clauses secure access to and, if requested, delivery of technical data used in the performance of the contract, there is generally no need to use the Additional Technical Data Requirements clause at 48 CFR 52.227-16 in the management and operating contract.

(c)(1) Paragraph (d) of the clause at 48 CFR 970.5227-1, Rights in Data—Facilities, and paragraph (f) of the clause at 48 CFR 970.5227-2, Rights in Data—Technology Transfer, provide for the inclusion in subcontracts of the Rights in Technical Data—General clause at 48 CFR 52.227-14, with Alternate V, and modified in accordance with DEAR 927.409. Those clauses also provide for the inclusion in appropriate subcontracts Alternates II, III, and IV to the clause at 48 CFR 52.227-14 with DOE's prior approval and the inclusion

of the Additional Technical Data Requirements clause at 48 CFR 52.227-16 in all subcontracts for research, development, or demonstration and all other subcontracts having special requirements for the production or delivery of data. In subcontracts, including subcontracts for related support services, involving the design or operation of any plants or facilities or specially designed equipment for such plants or facilities that are managed or operated by the contractor under its contract with DOE, the management and operating contractor shall use the Rights in Data—Facilities clause at 48 CFR 970.5227-1.

(2) Where, however, a subcontract is to be awarded by the management and operating contractor in connection with a program, as discussed at 927.404-70, which provides statutory authority to protect from public disclosure, data first produced under contracts awarded pursuant to the program, contracting officers shall ensure that the management and operating contractor includes in that subcontract the rights in data clause provided by DOE Patent Counsel, consistent with any accompanying guidance.

(3) Management and operating contractors and higher-tier subcontractors shall not use their power to award subcontracts as economic leverage to acquire rights in a subcontractor's limited rights data or restricted computer software for their private use, nor may they acquire rights in a subcontractor's limited rights data or restricted computer software except through the use of Alternate II or III to the clause at 48 CFR 52.227-14, respectively, without the prior approval of DOE Patent Counsel.

(d)(1) Paragraphs (e) and (f) of the clause at 48 CFR 970.5227-1, Rights in Data—Facilities, and paragraphs (g) and (h) of the clause at 48 CFR 970.5227-2, Rights in Data—Technology Transfer, provide for the contractor's granting a nonexclusive license in any limited rights data and restricted computer software specifically used in performance of the contract.

(2) In certain instances the objectives of DOE would be frustrated if the Government did not obtain, at the time of contracting, limited license rights on behalf of responsible third parties and the Government, and to limited rights data or restricted computer software or both necessary for the practice of subject inventions or data first produced or delivered in the performance of the contract. This situation may arise in the performance of management and operating contracts and contracts for the management or operation of a DOE

facility or site. Contracting officers should consult with program officials and Patent Counsel. No such rights should be obtained from a small business or non-profit organization, unless similar rights in background inventions of the small business or non-profit organization have been authorized in accordance with 35 U.S.C. 202(f). Where such a background license is in DOE's interest, a provision that provides substantially as Alternate VI at 48 CFR 952.227-14 should be added to the appropriate clause, 48 CFR 970.5227-1, Rights in Data—Facilities, or 48 CFR 970.5227-2, Rights in Data—Technology Transfer.

(e) The Rights in Data—Technology Transfer clause at 48 CFR 970.5227-2 differs from the clause at 48 CFR 970.5227-1, Rights in Data—Facilities, in the context of its more detailed treatment of copyright. In management and operating contracts that have technology transfer as a mission, the right to assert copyright in data first produced under the contract will be a valuable right, and commercialization of such data, including computer software, will assist the management and operating contractor in advancing the technology transfer mission of the contract. The clause at 48 CFR 970.5227-2, Rights in Data—Technology Transfer, provides for DOE approval of DOE's taking a limited copyright license for a period of five years, and, in certain rare cases, specified longer periods in order to contribute to commercialization of the data.

(f) Contracting officers should consult with Patent Counsel to assure that requirements regarding royalties and conflicts of interest associated with asserting copyright in data first produced under the contract are appropriately addressed in the Technology Transfer Mission clause (48 CFR 970.5227-3) of the management and operating contract. Where it is not otherwise clear which DOE program funded the development of a computer software package, such as where the development was funded out of a contractor's overhead account, the DOE program which was the primary source of funding for the entire contract is deemed to have administrative responsibility. This issue may arise, among others, in the decision whether to grant the contractor permission to assert copyright. See paragraph (e) of the Rights in Data—Technology Transfer clause at 970.5227-2.

(g) In management and operating contracts involving access to DOE-owned Category C-24 restricted data, as set forth in 10 CFR part 725, DOE has reserved the right to receive reasonable

compensation for the use of its inventions and discoveries, including its related restricted data and technology. Alternate I to each clause shall be used where access to Category C-24 restricted data is contemplated in the performance of a contract.

970.2704-3 Contract clauses.

(a) The contracting officer shall insert the clause at 48 CFR 970.5227-1, Rights in Data—Facilities, in management and operating contracts which do not contain the clause at 48 CFR 970.5227-2, Rights in Data—Technology Transfer. The contracting officer shall include the clause with its Alternate I in contracts where access to Category C-24 restricted data, as set forth in 10 CFR part 725, is to be provided to contractors.

(b) The contracting officer shall insert the clause at 970.5227-2, Rights in Data—Technology Transfer, in management and operating contracts which contain the clause at 970.5227-3, Technology Transfer Mission. The contracting officer shall include the clause with its Alternate I in contracts where access to Category C-24 restricted data, as set forth in 10 CFR part 725, is to be provided to contractors.

970.2770 Technology Transfer.

970.2770-1 General.

This subpart prescribes policies and procedures for implementing the National Competitiveness Technology Transfer Act of 1989, Public Law 101-189, (15 U.S.C. 3711 *et seq.*, as amended). The Act requires that technology transfer be established as a mission of each Government-owned laboratory operated under contract by a non-Federal entity. The National Defense Authorization Act for Fiscal Year 1994 expanded the definition of "laboratory" to include weapon production facilities that are operated for national security purposes and are engaged in the production, maintenance, testing, or dismantlement of a nuclear weapon or its components.

970.2770-2 Policy.

All new awards for or extensions of existing DOE laboratory or weapon production facility management and operating contracts shall have technology transfer, including authorization to award Cooperative Research and Development Agreements (CRADAs), as a laboratory or facility mission under Section 11(a)(1) of the Stevenson-Wydler Technology Innovation Act of 1980, Public Law 96-480 (15 U.S.C. 3701 *et seq.*, as amended). A management and operating contractor for a facility not deemed to be a laboratory or weapon production

facility may be authorized on a case-by-case basis to support the DOE technology transfer mission including, but not limited to, participating in CRADAs awarded by DOE laboratories and weapon production facilities.

970.2770-3 Technology transfer and patent rights.

The National Competitiveness Technology Transfer Act of 1989 (NCTTA) established technology transfer as a mission for Government-owned, contractor-operated laboratories, including weapons production facilities, and authorizes those laboratories to negotiate and award cooperative research and development agreements with public and private entities for purposes of conducting research and development and transferring technology to the private sector. In implementing the NCTTA, DOE has negotiated technology transfer clauses with the contractors managing and operating its laboratories. Those technology transfer clauses must be read in concert with the patent rights clause required by this subpart. Thus, each management and operating contractor holds title to subject inventions for the benefit of the laboratory or facility being managed and operated by that contractor.

970.2770-4 Contract clause.

(a) The contracting officer shall insert the clause at 970.5227-3, Technology Transfer Mission, in each solicitation for a new or an extension of an existing laboratory or weapon production facility management and operating contract.

(b) If the contractor is a nonprofit organization or small business eligible under 35 U.S.C. 200 *et seq.*, to receive title to any inventions under the contract and proposes to fund at private expense the maintaining, licensing, and marketing of the inventions, the contracting officer shall use the basic clause with its Alternate I.

(c) If the facility is operated for national security purposes and engaged in the production, maintenance, testing, or dismantlement of a nuclear weapon or its components, the contracting officer shall use the basic clause with its Alternate II.

Subpart 970.28—Bonds and Insurance

970.2803 Insurance.

970.2803-1 Workers' Compensation Insurance.

(a) *Policies and requirements.* (1) Workers' compensation insurance protects employers against liability imposed by workers' compensation laws for injury or death to employees arising

out of, or in the course of, their employment. This type of insurance is required by state laws unless employers have acceptable programs of self-insurance.

(2) *Special requirements.* Certain workers' compensation laws contain provisions which result in limiting the protection afforded persons subject to such laws. The policy with respect to these limitations as they affect persons employed by management and operating contractors is set forth as follows:

(i) *Elective provisions.* Some worker's compensation laws permit an employer to elect not to be subject to its provisions. It is DOE policy to require these contractors to be subject to workers' compensation laws in jurisdictions permitting election.

(ii) *Statutory immunity.* Under the provisions of some workers' compensation laws, certain types of employers; e.g., nonprofit educational institutions, are relieved from liability. If a contractor has a statutory option to accept liability, it is DOE policy to require the contractor to do so.

(iii) *Limited medical benefits.* Some workers' compensation laws limit the liability of the employer for medical care to a maximum dollar amount or to a specified period of time. In such cases, a contractor's workers' compensation insurance policy should contain a standard extrastatutory medical coverage endorsement.

(iv) *Limits on occupational disease coverage and employers' liability.* Some workers' compensation laws do not provide coverage for all occupational diseases. In such situations, a contractor's workers' compensation insurance policy should contain voluntary coverage for all occupational diseases.

(3) *Contractor "employees' benefit plan"—self-insurers.* The policies and requirements set forth in paragraph (a)(2) of this section apply where management and operating contractors purchase workers' compensation insurance. With respect to self-insured contractors, the objectives specified in paragraph (a)(2) also shall be met through primary or excess workers' compensation and employers' liability insurance policy(ies) or an approved combination thereof. "Employees' benefit plans" which were established in prior years may be continued to contrast termination at existing benefit levels.

(b) *Assignment of responsibilities.* (1) Office of Contract and Resource Management, within the Headquarters procurement organization, other officials, and the Heads of Contracting Activities, consistent with their

delegations of responsibility, shall assure management and operating contracts are consistent with the policies and requirements of paragraph (a) of this section.

(2) In discharging assigned responsibility, the Heads of Contracting Activities shall:

(i) Periodically review workers' compensation insurance programs of management and operating contractors in the light of applicable workers' compensation statutes to assure conformance with the requirements of paragraph (a) of this section.

(ii) Evaluate the adequacy of coverage of "self-insured" workers' compensation programs;

(iii) Provide arrangements for the administration of any existing "employees' benefit plans until such plans" are terminated; and

(iv) Submit to the Office of Contract and Resource Management, within the Headquarters procurement organization, all proposals for the modification of existing "employees' benefit plans."

(3) The Office of Contract and Resource Management, within the Headquarters procurement organization, is responsible for approving management and operating contractor "employees' benefit plans."

970.2803-2 Contract clause.

The contracting officer shall insert the clause at 48 CFR 970.5228-1, Insurance—Litigation and Claims, in all management and operating contracts. Paragraphs (h)(3) and (j)(2) of that clause apply to a nonprofit contractor only to the extent specifically provided in the individual contract.

Subpart 970.29—Taxes

970.2902 Federal excise taxes.

970.2902-1 Exemptions from Federal excise taxes.

(a) The exemption respecting taxes on communication services or facilities has been held to extend to such services when furnished to DOE management and operating contractors who pay for such services or facilities from advances made to them by DOE under their contracts.

(b) Where it is considered that a request for an additional exemption in the performance of a management and operating contract would be justified, a recommendation that such a request be made should be forwarded to the Chief Financial Officer, Headquarters.

(c) Where tax exemption certificates are required in connection with the taxes cited in this section, the Head of the Contracting Activity will supply standard Government forms (SF 1094,

U.S. Tax Exemption Certificate) on request.

970.2903 State and local taxes.

970.2903-1 Applicability of state and local taxes to the government.

It is DOE policy to secure those immunities or exemptions from state and local taxes to which it is entitled under the Federal Constitution or state laws. In carrying out this policy, the Heads of Contracting Activities shall:

(a) Take all necessary steps to preclude payment of any taxes for which any of the immunities or exemptions cited in this subpart are available. Advice of Counsel should be sought as to the availability of such immunities or exemptions;

(b) Acquire directly and furnish to contractors as Government furnished property, equipment, material, or services when, in the opinion of the Head of the Contracting Activity:

(1) Such direct acquisition will result in substantial savings to the Government, taking into consideration any additional administrative costs;

(2) Such direct acquisition will not have a substantial adverse effect on the relationship between DOE and its contractor; and

(3) Such direct acquisition will not have a substantial adverse effect on the DOE program or schedules.

970.2904 Contract clauses.

970.2904-1 Management and operating contracts.

(a) Pursuant to 48 CFR 29.401-6(b), the clause at 48 CFR 52.229-10, State of New Mexico Gross Receipts and Compensating Tax, is applicable to management and operating contracts that meet the three conditions stated. The contracting officer shall modify paragraph (b) of the clause to replace the phrase "Allowable Cost and Payment clause" with the phrase "Payments and advances."

(b) Contracting officers shall include the clause at 48 CFR 970.5229-1, State and Local Taxes, in management and operating contracts.

Subpart 970.30—Cost Accounting Standards

970.3002 CAS program requirements.

970.3002-1 Applicability.

The provisions of 48 CFR part 30 and 48 CFR chapter 99 (FAR Appendix) shall be followed for management and operating contracts.

Subpart 970.31—Contract Cost Principles and Procedures

970.3101-00-70 Scope of subpart.

(a) The Procurement Executive is responsible for developing and revising the policy and procedures for the determination of allowable costs reimbursable under a management and operating contract, and for coordination with other Headquarters' offices having joint interests.

(b) The Head of the Contracting Activity is responsible for following the policy, principles and standards set forth in this subpart in establishing the compensation and reimbursement provisions of contracts and subcontracts and for submission of deviations for Headquarters consideration and approval.

970.3101-9 Advance agreements (DOE coverage-paragraph (i)).

(i) At any time, in accordance with the contract terms and conditions, the contracting officer may pursue an advance agreement in connection with any cost item under a contract.

970.3101-10 Cost certification.

(a) Certain contracts require certification of the costs proposed for final payment purposes. Section 48 CFR 970.4207-03-02 states the administrative procedures for the certification provisions and the related contract clause prescription.

(b) If unallowable costs are included in final cost settlement proposals, penalties may be assessed. Section 48 CFR 970.4207-03-02 states the administrative procedures for penalty assessment provisions and the related clause prescription.

970.3102-3-70 Home office expenses.

(a) For on-site work, DOE's fee for management and operating contracts, determined under the policy of and calculated per the procedures in 48 CFR 970.1504-1-3, generally provides adequate compensation for home or corporate office general and administrative expenses incurred in the general management of the contractor's business as a whole.

(1) DOE recognizes that some Home Office Expenses are incurred for the benefit of a management and operating contract. DOE has elected to recognize that benefit through fee due to the difficulty of determining the dollar value applicable to any management and operating contract. The difficulty arises because:

(i) The general construct of a management and operating contract results in minimal Home Office involvement in the contract work, and

(ii) Conventional Home Office Expense allocation techniques that use bases such as total operating costs, labor dollars, hours etc., are not appropriate because they inherently assume significant contractor investment (in terms of its own resources, such as, labor, material, overhead, etc.). Contractor investments are minimal under DOE's operating and management contracts. The contracts are totally financed by DOE advance payments, and DOE provides government-owned facilities, property, and other needed resources.

(2) From time to time, the fee for a management and operating contract may not be adequate compensation for Home Office Expenses incurred for the benefit of the contract. An indication that such a case exists is the need for significant home office support to deal with issues at the site that occur without the fault or negligence of the contractor, for example, the need for home office legal support to deal with third party, environmental, safety, or health issues.

(3) In such a case, the contracting officer, after obtaining the HCA's approval, may consider a contractor request for additional compensation. The contractor may request:

(i) Fee in addition to its normal fee (but see 48 CFR 970.1504-1-3(b)(1) if the contract is for the management and operation of a laboratory); or

(ii) Compensation on the basis of actual cost.

(4) Because the contract's fee provides some compensation for Home Office Expenses, the contractor's request for additional compensation must always be for an amount less than the Home Office Expenses that are incurred for the benefit of the management and operating contract.

(b) For off-site work, the DOE allows Home Office Expenses under architect-engineer, supply and research contracts with commercial contractors performing the work in their own facilities. Home Office Expenses may, however, be included for reimbursement under such DOE off-site architect-engineer, supply and research contracts, only to the extent that they are determined, after careful examination, to be allowable, reasonable, and properly allocable to the work. Work performed in a contractor's own facilities under a management and operating or construction contract may likewise be allowed to bear the properly allocable portion of allowable Home Office Expenses.

970.3102-05 Application of cost principles.**970.3102-05-4 Bonding costs. (DOE coverage-paragraph (d))**

(d) The allowability of bonding costs shall be determined pursuant to 48 CFR 970.5228-1, Insurance-litigation and claims.

970.3102-05-6 Compensation for personal services. (DOE coverage-paragraphs (a) and (p))

(a)(6) In determining the reasonableness of compensation, the compensation of each individual contractor employee normally need not be subjected to review and approval. Generally, the compensation paid individual employees should be left to the judgment of contractors subject to the limitations of DOE-approved compensation policies, programs, classification systems, and schedules, and amounts of money authorized for wage and salary increases for groups of employees. However, the contracting officer shall designate a compensation threshold appropriate for the particular situation. The contract shall specifically provide that contracting officer approval is required for compensating an individual contractor employee above the threshold if a total of 50 percent or more of such compensation is reimbursed under DOE cost-type contracts. For purposes of designating the threshold, total compensation includes only the employee's salary and cash bonus or incentive compensation.

(7)(i) Reimbursable costs for compensation for personal services are to be set forth in a personnel appendix which is a part of the contract. This personnel appendix shall be negotiated using the principles and policies of 48 CFR 31.205-6, Compensation, as supplemented by this section, 970.3102-05-6, and other pertinent parts of the DEAR. Costs that are unallowable under other contract terms shall not be allowable as compensation for personnel services.

(ii) The personnel appendix sets forth in detail personnel costs and related expenses allowable under the contract and documents personnel policies, practices and plans which have been found acceptable by the contracting officer. The contractor will advise DOE of any proposed changes in any matters covered by these policies, practices or plans which relate to personnel costs. The personnel appendix may be modified from time to time in writing by mutual agreement of the contractor and DOE without execution of an amendment to the contract. Such modifications shall be evidenced by execution of written numbered approval

letters from the contracting officer or his representative. Types of personnel costs and related expenses addressed in the personnel appendix, or amendments thereto, are as follows: Salaries and wages; bonuses and incentive compensation; overtime, shift differential, holiday, and other premium pay for time worked; welfare benefits and retirement programs; paid time off, and salaries and wages to employees in their capacity as union stewards and committeemen for time spent in handling grievances, or serving on labor management (contractor) committees provided, however, that the contracting officer's approval is required in each instance of total compensation to an individual employee above an annual rate as specified in the personnel appendix.

(p)(1) Notwithstanding the costs cited in this subsection, incurred for compensation of a senior executive in excess of the benchmark compensation amount determined applicable for the contractor fiscal year by the Administrator, Office of Federal Procurement Policy, are unallowable. Allowable costs of executive compensation shall be determined pursuant to Federal Acquisition Regulation 31.205-6(p).

970.3102-05-18 Independent research and development and bid and proposal costs. (DOE coverage-paragraphs (c)).

(c) Independent Research and Development and Bid and Proposal costs are unallowable. However, contracting officer approved Laboratory Directed Research and Development costs and those costs incurred in support of the Department's various reimbursable programs are allowable.

970.3102-05-19 Insurance and indemnification.

The supplemental material on the costs of insurance and indemnification is found in 48 CFR 970.5228-1, Insurance-Litigation and Claims.

970.3102-05-22 Lobbying and political activity costs. (DOE coverage-paragraph(b)).

(b) Costs of the following activities are excepted from 48 CFR 31.205-22, Lobbying and political activity costs, coverage, provided that the resultant costs are reasonable and otherwise fall into the following exceptions:

(1) Providing Members of Congress, their staff members or staff of cognizant legislative committees, in response to a request (written or oral, prior or contemporaneous) from Members of Congress, their staff members or staff of cognizant legislative committees, or as otherwise directed by the Contracting

Officer, information or expert advice of a factual, technical, or scientific nature, with respect to topics directly related to the performance of the contract or proposed legislation. In providing this information or expert advice, the contractor shall indicate to the recipient that it is not presenting the views of DOE. Reasonable costs for transportation, lodging or meals incurred by contractor employees for the purpose of providing such information or expert advice shall also be reimbursable, provided the request for such information or expert advice is a prior written request signed by a Member of Congress.

(2) Providing State legislatures or subdivisions thereof, their staff members, or staff of cognizant legislative committees, in response to a prior written request from a State legislator, or as otherwise directed by the Contracting Officer, information or expert advice of a factual, technical, or scientific nature, with respect to topics directly related to the performance of the contract or proposed legislation. In providing this information or expert advice, the contractor shall indicate to the recipient that it is not presenting the views of DOE. Reasonable costs for transportation, lodging, or meals incurred by contractor employees shall be reimbursable.

970.3102-05-28 Other business expenses. (DOE coverage-paragraph (i)).

(i) Reasonable costs associated with the establishment and maintenance of financial institution accounts in connection with the work hereunder are allowable, including, but not limited to, service charges, the cost of disbursing cash, necessary guards, cashiers, and paymasters. If payments to employees are made by check, facilities and arrangements for cashing checks may be provided without expense to the employees, subject to the approval of the contracting officer.

970.3102-05-30 Patent costs and technology transfer costs.

(a) For management and operating contracts that do not include the clause at 970.5227-3, Technology Transfer Mission, the cost principle at 48 CFR 31.205-30 applies.

(b) For management and operating contracts that do include the clause at 970.5227-3, Technology Transfer Mission, the following patent and technology transfer costs are allowable:

(1) Costs of preparing invention disclosures, reports, and other patent related documents required by the contract;

(2) Costs of searching the art relating to invention disclosures;

(3) Costs incurred in connection with the filing and prosecution of patent applications for subject inventions, except where those costs are incurred as part of a privately funded technology transfer program recognized under the contract; and

(4) Other costs incurred in accordance with the patent rights clause and the Technology Transfer Mission clause included in the contract.

970.3102-05-46 Travel costs.

(a) Costs for transportation, lodging, meals, and incidental expenses.

(1) Costs incurred by contractor personnel on official company business are allowable, subject to the limitations contained in this subsection. Costs for transportation may be based on mileage rates, actual costs incurred, or on a combination thereof, provided the method used results in a reasonable charge. Costs for lodging, meals, and incidental expenses may be based on per diem, actual expenses, or a combination thereof, provided the method used results in a reasonable charge.

(2) Except as provided in paragraph (a)(3) of this subsection, costs incurred for lodging, meals, and incidental expenses (as defined in the regulations cited in paragraphs (a)(2)(i) through (iii) of this subsection) shall be considered to be reasonable and allowable only to the extent that they do not exceed on a daily basis the maximum per diem rates in effect at the time of travel as set forth in the—

(i) Federal Travel Regulation, prescribed by the General Services Administration (41 CFR chapters 300 through 304), for travel in the conterminous 48 United States, available on a subscription basis from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402, Stock No. 922-002-00000-2;

(ii) Joint Travel Regulations, DoD Civilian Personnel, Appendix A, prescribed by the Department of Defense, for travel in Alaska, Hawaii, The Commonwealth of Puerto Rico, and territories and possessions of the United States, available on a subscription basis from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402, Stock No. 908-010-00000-1; or

(iii) Standardized Regulations (Government Civilians, Foreign Areas), section 925, "Maximum Travel Per Diem Allowances for Foreign Areas," prescribed by the Department of State, for travel in areas not covered in

paragraphs (a)(2)(i) and (ii) of this subsection, available on a subscription basis from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402, Stock No. 744-008-00000-0.

(3) In special or unusual situations, actual costs in excess of the maximum per diem rates are allowable provided that such amounts do not exceed the higher amounts authorized for Federal civilian employees as permitted in the regulations referenced in paragraphs (a)(2)(i), (ii), or (iii) of this subsection. For such higher amounts to be allowable, all of the following conditions must be met:

(i) One of the conditions warranting approval of the actual expense method, as set forth in the regulations referred to in paragraphs (a)(2)(i), (ii), or (iii) of this subsection, must exist.

(ii) A written justification for use of the higher amounts must be approved by an officer of the contractor's organization or designee to ensure that the authority is properly administered and controlled to prevent abuse.

(iii) If it becomes necessary to exercise the authority to use the higher actual expense method repetitively or on a continuing basis in a particular area, the contractor must obtain advance approval from the contracting officer.

(iv) Documentation to support actual costs incurred shall be in accordance with the contractor's established practices, subject to paragraph (a)(7) of this subsection, and provided that a receipt is required for each expenditure of \$75.00 or more. The approved justification required by paragraph (a)(3)(ii) and, if applicable, paragraph (a)(3)(iii) of this subsection must be retained.

(4) Paragraphs (a)(2) and (a)(3) of this subsection do not incorporate the regulations cited in paragraphs (a)(2)(i), (ii), and (iii) of this subsection in their entirety. Only the maximum per diem rates, the definitions of lodging, meals, and incidental expenses, and the regulatory coverage dealing with special or unusual situations are incorporated in this subsection.

(5) An advance agreement (see 48 CFR 31.109 and 48 CFR 970.3101-9) with respect to compliance with paragraphs (a)(2) and (a)(3) of this subsection may be useful and desirable.

(6)(i) The maximum per diem rates referenced in paragraph (a)(2) of this subsection generally would not constitute a reasonable daily charge—

(A) When no lodging costs are incurred; and/or

(B) On partial travel days (e.g., day of departure and return).

(ii) Appropriate downward adjustments from the maximum per diem rates would normally be required under these circumstances. While these adjustments need not be calculated in accordance with the Federal Travel Regulation or Joint Travel Regulations, they must result in a reasonable charge.

(7) Costs shall be allowable only if the following information is documented:

(i) Date and place (city, town, or other similar designation) of the expenses;

(ii) Purpose of the trip; and

(iii) Name of person on trip and that person's title or relationship to the contractor.

(b) Travel costs incurred in the normal course of overall administration of the business are allowable and shall be treated as indirect costs.

(c) Travel costs directly attributable to specific contract performance are allowable and may be charged to the contract under 48 CFR 31.202.

(d) Airfare costs in excess of the lowest customary standard, coach, or equivalent airfare offered during normal business hours are unallowable except when such accommodations require circuitous routing, require travel during unreasonable hours, excessively prolong travel, result in increased cost that would offset transportation savings, are not reasonably adequate for the physical or medical needs of the traveler, or are not reasonably available to meet mission requirements. However, in order for airfare costs in excess of the standard airfare to be allowable, the applicable condition(s) must be documented and justified.

(e)(1) "Cost of travel by contractor-owned, -leased, or -chartered aircraft," as used in this paragraph, includes the cost of lease, charter, operation (including personnel), maintenance, depreciation, insurance, and other related costs.

(2) The costs of travel by contractor-owned, -leased, or -chartered aircraft are limited to the standard airfare described in paragraph (d) of this subsection for the flight destination unless travel by such aircraft is specifically required by contract specification, term, or condition, or a higher amount is approved by the contracting officer. A higher amount may be agreed to when one or more of the circumstances for justifying higher than standard airfare listed in paragraph (d) of this subsection are applicable, or when an advance agreement under paragraph (e)(3) of this subsection has been executed. In all cases, travel by contractor-owned, -leased, or -chartered aircraft must be fully documented and justified. For each contractor-owned, -leased, or -chartered aircraft used for any business

purpose which is charged or allocated, directly or indirectly, to a Government contract, the contractor must maintain and make available manifest/logs for all flights on such company aircraft. As a minimum, the manifest/log shall indicate—

- (i) Date, time, and points of departure;
- (ii) Destination, date, and time of arrival;
- (iii) Name of each passenger and relationship to the contractor;
- (iv) Authorization for trip; and
- (v) Purpose of trip.

(3) Where an advance agreement is proposed (see 31.109), consideration may be given to the following:

- (i) Whether scheduled commercial airlines or other suitable, less costly, travel facilities are available at reasonable times, with reasonable frequency, and serve the required destinations conveniently;
- (ii) Whether increased flexibility in scheduling results in time savings and more effective use of personnel that would outweigh additional travel costs.

(f) Costs of contractor-owned or -leased automobiles, as used in this paragraph, include the costs of lease, operation (including personnel), maintenance, depreciation, insurance, etc. These costs are allowable, if reasonable, to the extent that the automobiles are used for company business. That portion of the cost of company-furnished automobiles that relates to personal use by employees (including transportation to and from work) is compensation for personal services and is unallowable as stated in 48 CFR 31.205–6(m)(2).

970.3102–05–47 Costs related to legal and other proceedings. (DOE coverage-paragraph (h)).

(h) Costs Associated with Whistleblower Actions.

Section 931.205–47(h) of this chapter is applicable to management and operating contracts under this part and must be included in the contract's cost reimbursement subcontracts.

970.3102–05–53 Preexisting conditions.

Clause 48 CFR 970.5231–4, Preexisting conditions, provides guidance on situations where this category of costs may be allowable.

970.3170 Contract clause.

The contracting officer shall insert the clause at 48 CFR 970.5231–4, Preexisting Conditions, in all management and operating contracts.

(a) The contracting officer shall include the clause with its Alternate I in contracts with incumbent management and operating contractors.

(b) The contracting officer shall include the clause with its Alternate II in contracts with management and operating contractors not previously working at that particular site or facility.

Subpart 970.32—Contract Financing

970.3200 Policy.

It is the policy of the DOE to finance management and operating contracts through advance payments and the use of special financial institution accounts.

970.3200–1 Reduction or suspension of advance, partial, or progress payments.

(a) The procedures prescribed at 48 CFR 32.006 shall be followed regarding the reduction or suspension of payments under management and operating contracts.

(b) Agency head responsibilities under 48 CFR 32.006 have been delegated to the Senior Procurement Executive.

(c) The remedy coordination official is responsible for receiving, assessing, and making recommendations to the Senior Procurement Executive.

970.3200–1–1 Contract clause.

The contracting officer shall insert the clause at 48 CFR 970.5232–1, Reduction or suspension of contract payments, in management and operating contracts.

970.3204 Advance payments.

970.3204–1 Applicability.

(a) The Head of the Contracting Activity shall authorize advance payments without interest, and approve the findings, determinations and the contract terms and conditions concerning advance payments in accordance with the procedures set forth in 48 CFR subpart 32.4, Advance Payments, as supplemented by 48 CFR subpart 932.4.

(b) Advance payments shall be made under a payments cleared financing arrangement for deposit in a special financial institution account or, at the option of the Government, by direct payment or other payment mechanism to the contractor.

(c) Prior to providing any advance payments, the contracting officer shall enter into an agreement with the contractor and a financial institution regarding a special financial institution account where the advanced funds will be deposited by the Government. Such agreement shall:

(1) Provide that DOE shall retain title to the unexpended balance of funds in the special financial institution account including collections, if any, deposited by the contractor;

(2) Provide that the title in paragraph (c)(1) of this subsection shall be superior

to any claim or lien of the financial institution of deposit or others; and

(3) Incorporate all applicable requirements, as determined by the Office of Chief Financial Officer.

(d) Deviations from the requirements cited in paragraph (c) of this subsection shall be considered a deviation requiring approval of the Head of the Contracting Activity.

(e) Letter-of-credit arrangements shall be prepared in accordance with 48 CFR 32.406, Letters of Credit, and shall be coordinated between the procurement and finance organizations.

970.3270 Standard financial management clauses.

(a) The following DEAR and FAR clauses are standard financial management clauses. The contracting officer shall insert them in all management and operating contracts:

(1) 48 CFR 970.5232–2, Payments and Advances.

(i) The contracting officer shall insert the basic clause with its Alternate I if a separate fixed-fee is provided for a separate item of work.

(ii) The contracting officer shall insert the basic clause with its Alternate II when total available fee provisions in the basic clause are used.

(iii) The contracting officer shall insert the basic clause with its Alternate III in management and operating contracts with integrated accounting systems.

(iv) The contracting officer shall insert the basic clause with its Alternate IV in management and operating contracts without integrated accounting systems.

(2) 48 CFR 970.5232–3, Accounts, records, and inspection.

(i) If the contract includes the clause at 48 CFR 52.215–11, Price Reduction for Defective Cost or Pricing Data, the contracting officer shall use the clause with its Alternate I.

(ii) If the contract is a cost-reimbursement contract involving an estimated cost exceeding \$5 million and expected to run for more than 2 years, or any other cost-reimbursement contract determined by the Head of the Contracting Activity in which the contractor has an established internal audit organization, the contracting officer shall insert the clause with its Alternate II.

(3) 48 CFR 970.5232–4, Obligation of funds. The contracting officer may use the clause with its Alternate I in contracts which, expressly or otherwise, provide a contractual basis for equivalent controls in a separate clause.

(4) 48 CFR 970.5203–1, Management controls.

(5) 48 CFR 970.5232–5, Liability with respect to Cost Accounting Standards.

(6) 48 CFR 970.5232–6, Work for others funding authorization.
 (7) 48 CFR 52.230–2, Cost Accounting Standards.

(8) 48 CFR 52.230–6, Administration of Cost Accounting Standards.

(b) The following DEAR clauses are standard financial management clauses. The contracting officer shall insert them in all management and operating contracts with integrated accounting systems:

(1) 48 CFR 970.5232–7, Financial management system.

(2) 48 CFR 970.5232–8, Integrated accounting.

(c) Any deviations from the standard financial management clauses specified in paragraphs (a) and (b) of this section require the approval of the Head of the Contracting Activity and the written concurrence of the Department's Chief Financial Officer.

Subpart 970.34—Major System Acquisition

970.3400 General requirements.

970.3400–1 Mission-oriented solicitation.

Contractors shall be required to promptly advise the DOE contracting officer of any advance notices of, or solicitations for, requirements which would logically involve DOE facilities or resources operated or managed by the contractor, which are received from another agency pursuant to 48 CFR 34.005. Management and operating contracts shall provide that the contractor shall not respond or otherwise propose to participate in response to the requirements of such solicitations unless the contractor has obtained the prior written approval of the DOE manager of the field activity having cognizance over the contract. Such approval shall not be given except in compliance with applicable DOE directives, and with the concurrence of the cognizant Senior Program Official.

970.35 Research and development contracting.

970.3500 Scope of subpart.

This subpart implements 48 CFR 35.017 regarding the establishment, use, review, and termination of Federally Funded Research and Development Centers (FFRDCs) sponsored by the Department of Energy.

970.3501 Federally funded research and development centers.

970.3501–1 Sponsoring agreements.

(a) The contract award document constitutes the sponsoring agreement between the Department of Energy and the contractor operating an FFRDC.

(b) The contract statement of work shall define the purpose and mission of the FFRDC.

(c) Other elements of the sponsoring agreement which shall be incorporated into the contract include:

(1) The appropriate termination clause of the contract (as prescribed in 48 CFR subpart 49.5).

(2) The plan for the identification, use, and disposition of retained earnings developed pursuant to 48 CFR 970.1504–1–3(c)(6), if applicable;

(3) The clause entitled “Federally Funded Research and Development Center Sponsoring Agreement,” which, in part, prescribes limitations on the FFRDC competing with the private sector, and requirements for the FFRDC's acceptance of work from a nonsponsor; and

(4) Other terms and conditions considered necessary for the particular circumstances of the FFRDC (e.g., advance understandings on particular cost items).

970.3501–2 Using an FFRDC.

The contractor may only accept work from a nonsponsor (as defined in 48 CFR 35.017) in accordance with the requirements of DOE Order 481.1, Work for Others (Non-Department of Energy Funded Work).

970.3501–3 Reviewing FFRDC's.

(a) All Department of Energy sponsored FFRDC's are operated by management and operating contractors.

(b) Coincident with the review required by 48 CFR 17.605(b) and 48 CFR 970.1702–1(b) regarding the decision to extend or compete a management and operating contract, the contracting officer shall, in accordance with internal Departmental procedures:

(1) Conduct the review required by 48 CFR 35.017–4 concerning the use and need for the FFRDC; and

(2) Recommend for Secretarial approval, the continuation or termination of the Department's sponsorship of an FFRDC at the time authorization is required to extend or compete a management and operating contract.

970.3501–4 Contract clause.

The contracting officer shall insert the clause at 48 CFR 970.5235–1, Federally Funded Research and Development Center Sponsoring Agreement, in all solicitations and contracts for the management and operation of an FFRDC sponsored by the Department of Energy.

Subpart 970.36—Construction and Architect-Engineer Contracts

970.3605 Contract clauses.

970.3605–1 Other contracts.

The clause in 48 CFR 52.236–8, Other Contracts, shall be used in all management and operating contracts.

970.3605–2 Special construction clause for operating contracts.

The clause in 48 CFR 970.5236–1, Government Facility Subcontract Approval, shall be used in management and operating contracts when the contractor will not perform covered work with its own forces but may procure construction by subcontract.

Subpart 970.37—Facilities Management Contracting

970.3770 Facilities management.

970.3770–1 Policy.

Contractors managing DOE facilities shall be required to comply with the DOE Directives applicable to facilities management.

970.3770–2 Contract clause.

The contracting officer shall insert the clause at 48 CFR 970.5237–2, Facilities Management, in all management and operating contracts.

Subpart 970.41—Acquisition of Utility Services

970.4102 Acquiring utility services.

970.4102–1 Policy.

(a) Utility services defined at 48 CFR 41.101 for the furnishing of electricity, gas (natural or manufactured), steam, water, and/or sewerage to facilities owned or leased by DOE shall be acquired directly by DOE and not by a contractor using a subcontractor arrangement, except as provided in paragraph (b) of this subsection.

(b) Where it is determined to be in the best interest of the Government, a DOE contracting activity may authorize a management and operating contractor for a facility to acquire such utility service for the facility, after requesting and receiving concurrence to make such an authorization from the Director, Public Utilities Branch, Headquarters. Any request for such concurrence should be included in the Utility Service Requirements and Options Studies required by DOE directives in subseries 4540 (Public Services). Alternatively, it may be made in a separate document submitted to the Director of that office early in the acquisition cycle. Any request shall set forth why it is in the best interest of the

DOE to acquire utility service(s) by subcontract, *i.e.*, what the benefits are, such as economic advantage.

(c) The requirements of 48 CFR part 41, this section, and DOE directives in subseries 4540 shall be applied to a subcontract level acquisition for furnishing utility services to a facility owned or leased by DOE.

Subpart 970.42—Contract Administration

970.4207–03–02 Certificate of costs.

(a) The contracting officer shall require that management and operating contractors provide a submission, pursuant to 48 CFR 970.5232–2–(j), for settlement of costs incurred during the period stipulated on the submission and a certification that the costs included in the submission are allowable. The contracting officer shall assess a penalty pursuant to 48 CFR 970.5242–1 if unallowable costs are included in the submission. Unallowable costs are either expressly unallowable or determined unallowable.

(1) An expressly unallowable cost is a particular item or type of cost which, under the express provisions of an applicable law, regulation, or this contract, is specifically named and stated to be unallowable.

(2) A cost determined unallowable is one which, for that contractor,

(i) Was subject to a contracting officer's final decision and not appealed;

(ii) The Department's Board of Contract Appeals or a court has previously ruled as unallowable; or

(iii) Was mutually agreed to be unallowable.

(b) If, during the review of the submission, the contracting officer determines that the submission contains an expressly unallowable cost or a cost determined to be unallowable prior to the submission, the contracting officer shall assess a penalty.

(c) If the contracting officer determines that a cost submitted by the contractor in its submission for settlement is:

(1) Expressly unallowable, then the contracting officer shall assess a penalty in an amount equal to the disallowed cost allocated to the contract plus interest on the paid portion of the disallowed cost. Interest shall be computed from the date of overpayment to the date of repayment using the interest rate specified by the Secretary of the Treasury pursuant to Public Law 92–41 (85 Stat. 97).

(2) Determined unallowable, then the contracting officer shall assess a penalty in an amount equal to two times the

amount of the disallowed cost allocated to the contract.

(d) The contracting officer may waive the penalty provisions when:

(1) The contractor withdraws the submission before the formal initiation of an audit of the submission and submits a revised submission;

(2) The amount of the unallowable costs allocated to covered contracts is \$10,000 or less; or

(3) The contractor demonstrates to the contracting officer's satisfaction that:

(i) It has established appropriate policies, personnel training, and an internal control and review system that provides assurances that unallowable costs subject to penalties are precluded from the contractor's submission for settlement of costs; and

(ii) The unallowable costs subject to the penalty were inadvertently incorporated into the submission.

(e) The Head of the Contracting Activity may waive the certification when—

(1) It determines that it would be in the best interest of the United States to waive such certification; and

(2) It states in writing the reasons for that determination and makes such determination available to the public.

970.4207–03–70 Contract clause.

The contracting officer shall insert the clause at 48 CFR 970.5242–1, Penalties for unallowable costs, in all management and operating solicitations and contracts.

970.4207–05–01 Contracting officer determination procedure. (DOE coverage-paragraph (b))

(b)(4) A contracting officer shall not resolve any questioned costs until the contracting officer has obtained:

(i) Adequate documentation with respect to such costs; and

(ii) The opinion of the Department of Energy's auditor on the allowability of such costs.

(5) The contracting officer shall ensure that the documentation supporting the final settlement addresses the amount of the questioned costs and the subsequent disposition of such questioned costs.

(6) The contracting officer shall ensure, to the maximum extent practicable, that the Department of Energy's auditor is afforded an opportunity to attend any negotiation or meeting with the contractor regarding a determination of allowability.

Subpart 970.43—Contract Modifications

970.4302 Changes.

970.4302–1 Contract clause.

The contracting officer shall insert the clause at 48 CFR 970.5243–1, Changes, in all management and operating contracts.

Subpart 970.44—Management and Operating Contractor Purchasing

970.4400 Scope.

This subpart prescribes policies and procedures concerning the purchasing systems and activities of management and operating contractors.

970.4401 Responsibilities.

970.4401–1 General.

(a) In the Department of Energy, overall responsibility for the oversight of the performance of management and operating contractors, including their purchasing activities, rests with the cognizant DOE contracting activity and, in particular, the Head of the Contracting Activity (HCA). Contracting officers are responsible for the management and operating contractors' conformance with this subpart and the applicable terms and conditions of their contracts, and for determining whether those purchasing activities provide timely and effective support to DOE programs.

(b) In carrying out their overall responsibilities, HCAs shall:

(1) Require management and operating contractors to maintain written descriptions of their individual purchasing systems and methods and further require that, upon award or extension of the contract, the entire written description be submitted to the contracting officer for review and acceptance;

(2) Require that any changes to the management and operating contractor's written description having any substantive impact upon the contractor's purchasing system and methods be submitted to the contracting officer for review and acceptance prior to issuance;

(3) Ensure the review of individual purchasing actions of certain types, or above stated dollar levels, by the contracting officer pursuant to 48 CFR subpart 44.2 or as set forth in the contractor's approved system and methods; and

(4) Ensure that periodic appraisals of the contractor's management of all facets of the purchasing function, including compliance with the contractor's approved system and

methods, are performed by the contracting officer. Such appraisals shall be performed through either of the following methodologies:

(i) Contractor Purchasing System Reviews, conducted in accordance with 48 CFR subpart 44.3; or

(ii) When approved by the contracting officer, contractor participation in the conduct of the Balanced Scorecard performance measurement and performance management system.

(c) In performing the reviews required by paragraphs (b)(1) and (2), and the appraisals required by paragraph (b)(4) of this subsection, HCAs shall assure that contracting officers determine that the contractors' written systems and methods are consistent with this subpart and the applicable terms and conditions of their contracts.

970.4401-2 Review and approval.

(a) The Heads of the Contracting Activities shall establish thresholds, by subcontract type and dollar level, for the review and approval of proposed subcontracting actions by each management and operating contractor under their cognizance. Such thresholds may not exceed the authority delegated to the Head of the Contracting Activity by the Senior Procurement Executive. In establishing these thresholds, the Heads of the Contracting Activities should consider such factors as the following:

(1) The nature of work to be performed under the management and operating contract;

(2) The size, experience, ability, reliability, and organization of the management and operating contractor's purchasing function;

(3) The internal controls, procedures, and organizational stature of the management and operating contractor's purchasing function; and

(4) Policies with respect to such reviews and approvals established by the Senior Procurement Executive.

(b) Prior approval shall be required for the subcontracting of any work a contractor is obligated to perform under a contract entered into under section 41, entitled Production of Special Nuclear Material, of the Atomic Energy Act of 1954, as amended.

(c) The Heads of the Contracting Activities shall take such action as may be required to insure compliance with the procedure for purchasing from contractor-affiliated sources or the purchase of specific items, or classes of items, which by the terms of the contract may require DOE approval.

(d) The Heads of the Contracting Activities may raise or lower the review and approval thresholds established pursuant to paragraph (a) of this

subsection at any time. Such action may be considered upon the periodic review of the contractor's purchasing system, but in any case those adjusted thresholds may not exceed the approval authority delegated to the Head of the Contracting Activity by the Senior Procurement Executive.

(e) DOE approvals of specific proposed purchases pursuant to this subpart shall communicate that such approval does not relieve the management and operating contractor of any obligation under its prime contract with DOE; is given without prejudice to any rights or claims of the Government thereunder; creates no obligation on the part of the Government to the subcontractor, and is not a predetermination of the allowability of costs to be incurred under the subcontract.

(f) Contracting officers shall assure that management and operating contractors establish and maintain subcontract files which contain those documents essential to present an accurate and adequate record of all purchasing transactions.

(g) Contracting officers shall assure that management and operating contractors document purchases in writing, setting forth the information and data used in determining that the purchases are in the best interest of the Government. The scope and detail of this documentation shall be consistent with the nature, dollar value, and complexity of the purchase.

(h) The Heads of the Contracting Activities shall assure that the contracting activity establishes and maintains files of the documents associated with the review and approval of subcontract actions subject to DOE review and approval. Those files shall include, among other necessary documentation, an appraisal of the proposed action by the contracting activity and a copy of the approving or disapproving document forwarded to the management and operating contractor, including a listing of any deficiencies, a listing of any required corrective actions, any suggestions, or other relevant comments.

970.4401-3 Advance notification.

(a) Contracting officers shall assure that the written description of the management and operating contractor's purchasing system and methods provides for advance notice to the DOE contracting officer of the proposed award of the following specified types of subcontracts, except as stated in paragraph (b) of this subsection:

(1) Pursuant to section 304(b) of the Federal Property and Administrative

Service Act of 1949, as amended (41 U.S.C. 254(b)):

(i) Cost reimbursement-type subcontracts of any award value; and

(ii) Fixed price-type subcontracts which exceed the simplified acquisition threshold, or 5 percent of the total estimated cost of the prime contract.

(2) Purchases from contractor-affiliated sources over a value established by the HCA.

(b) Pursuant to section 602(d)(13) of the Act (40 U.S.C. 474(13)) referred to in paragraph (a) of this section, the advance notification requirement for the types of purchases listed in paragraphs (a) (1) and (2) of this subsection shall not apply to subcontracts relating to functions derived from the Atomic Energy Commission.

(c) The advance notice shall contain, at a minimum, a description of work, estimated cost, type of contract or reimbursement provisions, and extent of competition, or justification for a noncompetitive purchase procurement. The contracting officer may at any time request additional information that must be furnished promptly and prior to award of the subcontract.

970.4402 Contractor purchasing system.

970.4402-1 Policy.

(a) DOE contracts for the management and operation of its facilities, the design and production of nuclear weapons, energy research and development, and the performance of other services. These management and operating (M&O) contractors have been selected for their technical and managerial expertise and are expected to bring to bear these technical and managerial skills to accomplish the significant Federal mission(s) described in their contracts with, and work plans approved by, DOE.

(b) Purchasing done by management and operating contractors is one area in which the particular skills of the contractors will be brought to bear in order to more readily accomplish the contractors' assigned missions. The contracting procedures of the contractor's organization, therefore, form the basis for the development of a purchasing system and methods that will comply with its contract with DOE and this subpart.

970.4402-2 General requirements.

The following shall apply to the purchasing systems of management and operating contractors:

(a) The objective of a management and operating contractor's purchasing system is to deliver to its customers on a timely basis those best value products

and services necessary to accomplish the purposes of the Government's contract. To achieve this objective, contractors are expected to use their experience, expertise and initiative consistent with this subpart.

(b) The purchasing systems and methods used by management and operating contractors shall be well-defined, consistently applied, and shall follow purchasing practices appropriate for the requirement and dollar value of the purchase. It is anticipated that purchasing practices and procedures will vary among contractors and according to the type and kinds of purchases to be made.

(c) Contractor purchases are not Federal procurements, and are not directly subject to the Federal Acquisition Regulations in 48 CFR. Nonetheless, certain Federal laws, Executive Orders, and regulations may affect contractor purchasing, as required by statute, regulation, or contract terms and conditions.

(d) Contractor purchasing systems shall identify and apply the best in commercial purchasing practices and procedures (although nothing precludes the adoption of Federal procurement practices and procedures) to achieve system objectives. Where specific requirements do not otherwise apply, the contractor purchasing system shall provide for appropriate measures to ensure the:

(1) Acquisition of quality products and services at fair and reasonable prices;

(2) Use of capable and reliable subcontractors who either:

(i) Have track records of successful past performance, or

(ii) Can demonstrate a current superior ability to perform;

(3) Minimization of acquisition lead-time and administrative costs of purchasing;

(4) Use of effective competitive techniques;

(5) Reduction of performance risks associated with subcontractors, and facilitation of quality relationships which can include techniques such as partnering agreements, ombudsmen, and alternative disputes procedures;

(6) Use of self-assessment and benchmarking techniques to support continuous improvement in purchasing;

(7) Maintenance of the highest professional and ethical standards;

(8) Maintenance of file documentation appropriate to the value of the purchase and which is adequate to establish the propriety of the transaction and the price paid; and

(9) Maximization of opportunities for small business, HUBZone small

business, small disadvantaged business, and woman-owned small business concerns to participate in contract performance.

970.4402-3 Purchasing from contractor-affiliated sources.

(a) A management and operating contractor may purchase from sources affiliated with the contractor (any division, subsidiary, or affiliate of the contractor or its parent company) in the same manner as from other sources, provided:

(1) The management and operating contractor's purchasing function is independent of the proposed contractor-affiliated source;

(2) The same terms and conditions would apply if the purchase were from a third party;

(3) Award is made in accordance with policies and procedures designed to permit effective competition which have been approved by the contracting officer. (This requirement for competition shall not preclude acquisition of technical services from contractor-affiliated entities where those entities have a special expertise, and the basis therefor is documented.); and

(4) The award is legally enforceable where the entities are separately incorporated.

(b) Subcontracts for performance of contract work itself (as distinguished from the purchase of supplies and services needed in connection with the performance of work) require DOE authorization and may involve an adjustment of the contractor's fee, if any. If the management and operating contractor seeks authorization to have some part of the contract work performed by a contractor-affiliated source, and that contractor's performance of that work was a factor in the negotiated fee, DOE approval would normally require:

(1) That the contractor-affiliated source perform such work without fee or profit, or

(2) An equitable downward adjustment to the management and operating contractor's fee, if any.

(c) Determination on cost of money allowance as prescribed at 48 CFR 31.205-10 shall be treated as follows:

(1) When a purchase from a contractor-affiliated source results from competition and is in accord with provisions and conditions of paragraphs (a)(1) through (a)(4) of this subsection, the contractor-affiliated source may include cost of money as an allowable element of the costs of its goods or services supplied to the contractor; provided:

(i) The purchase is based on cost as set forth in 48 CFR 970.3102-3-21 and

(ii) The cost of money amount is computed in accordance with 48 CFR 31.205-10 and related procedures (see 48 CFR 970.30).

(2) When a purchase from a contractor-affiliated source is made non-competitively, cost of money shall not be considered an allowable element of the cost of the contractor-affiliated source purchase.

970.4402-4 Nuclear material transfers.

(a) Management and operating contractors, in preparing subcontracts or other agreements in which monetary payments or credits depend on the quantity and quality of nuclear material, shall be required to assure that each such subcontract or agreement contains a:

(1) Description of the material to be transferred;

(2) Provision specifying the method by which the quantities are to be measured and reported;

(3) Provision specifying the procedures to be used in resolving any differences arising as a result of such measurements;

(4) Provision for the use of an independent third party as an umpire to settle unresolved differences in the analytical samples; and

(5) Provision specifying in detail which party shall bear the costs of resolving a difference and what constitutes such costs.

(b) The provisions providing for resolution of measurement differences must be such that resolution is always accomplished, while at the same time minimizing any advantage one party may have over the other.

970.4403 Contract clause.

The contracting officer shall insert the clause at 970.5244-1, Contractor Purchasing System, in all management and operating contracts.

Subpart 970.45—Government Property

970.4501 General.

970.4501-1 Contract clause.

(a) The contracting officer shall insert the clause at 970.5245-1, Property, in management and operating contracts. Paragraph (f)(1)(i)(c) of the clause applies to a non-profit contractor only to the extent specifically provided in the individual contract. Specific managerial personnel may be listed in paragraph (j), provided their listing is consistent with the clause and the DEAR.

(b) The contracting officer shall insert the basic clause with its Alternate I in contracts with nonprofit contractors.

Subpart 970.49—Termination of Contracts**970.4905 Contract termination clause.****970.4905-1 Termination for convenience of the government and default.**

(a) The contracting officer shall include the clause at 48 CFR 52.249-6, Termination (Cost Reimbursement), as modified pursuant to paragraph (b) of this subsection, in all cost-reimbursement management and operating contracts, regardless of whether the contract is for production, or research and development with an educational or nonprofit institution.

(b) The contracting officer shall modify paragraph (i) of the clause to insert "as supplemented in subpart 970.31 of the Department of Energy Acquisition Regulation," after the phrase, "part 31 of the Federal Acquisition Regulation."

Subpart 970.50—Extraordinary Contractual Actions**970.5004 Residual powers.****970.5004-1 Contract clause.**

When use of the clause at 48 CFR 52.250-1, Indemnification Under Public Law 85-804, is appropriate, the contracting officer may substitute the words "Obligation of funds" for the words "Limitation of Cost or Limitation of Funds."

970.5070 Indemnification.**970.5070-1 Scope and applicability.**

(a) Section 170d. of the Atomic Energy Act of 1954, as amended, requires DOE to enter into agreements of indemnity with contractors whose work involves the risk of public liability for the occurrence of a nuclear incident or precautionary evacuation.

(b) Details of such indemnification are discussed at 48 CFR 950.70.

970.5070-2 General.

DOE contractors with whom statutory nuclear hazards indemnity agreements under the authority of section 170d. of the Atomic Energy Act of 1954, as amended, are executed will not normally be required or permitted to furnish financial protection by purchase of insurance to cover public liability for nuclear incidents. However, if authorized by the DOE Headquarters office having responsibility for contractor casualty insurance programs, DOE contractors may be

(a) Permitted to furnish financial protection to themselves, or

(b) Permitted to continue to carry such insurance at cost to the

Government if they currently maintain insurance for such liability.

970.5070-3 Contract clauses.

(a) The clause at 48 CFR 952.250-70, Nuclear Hazards Indemnity Agreement, shall be included in all management and operating contracts involving the risk of public liability for the occurrence of a nuclear incident or precautionary evacuation arising out of or in connection with the contract work, including such events caused by a product delivered to a DOE-owned, facility for use by DOE or its contractors. The clause at 48 CFR 952.250-70 also shall be included in any management and operating contract for the design of a DOE facility, the construction or operation of which may involve the risk of public liability for a nuclear incident or a precautionary evacuation.

(b) The clause at 48 CFR 952.250-70 shall not be included in contracts in which the contractor is subject to Nuclear Regulatory Commission (NRC) financial protection requirements under section 170b. of the Act or NRC agreements of indemnification under section 170 c. or k. of the Act for activities to be performed under the contract.

Subpart 970.52—Solicitation Provisions and Contract Clauses for Management and Operating Contracts**970.5200 Scope of subpart.**

This subpart prescribes some of the solicitation provisions and contract clauses for use in management and operating contracts. The provisions and clauses contained in this subpart supplement the provisions and clauses prescribed in the FAR and in other parts of the DEAR (48 CFR 901 through 48 CFR 952), and, pursuant to the individual provision or clause prescription, are to be used in addition to or in place of such clauses. Management and operating contracts are hybrid contracts, in some cases including aspects of several FAR contract types, for example, supplies and construction. For some FAR solicitation provisions and contract clauses, this subpart prescribes their use despite the hybrid nature of the work required. To assist Departmental contracting personnel in determining the applicability of FAR and DEAR clauses to management and operating contracts, additional guidance is published and made available by the Office of Procurement and Assistance Policy, within the Headquarters procurement organization.

970.5201 Text of provisions and clauses.**970.5203-1 Management controls.**

As prescribed in 48 CFR 970.0370-2(a) and 48 CFR 970.3270(a)(4), insert the following clause:

Management Controls (DEC 2000)

(a)(1) The contractor shall be responsible for maintaining, as an integral part of its organization, effective systems of management controls for both administrative and programmatic functions. Management controls comprise the plan of organization, methods, and procedures adopted by management to reasonably ensure that: the mission and functions assigned to the contractor are properly executed; efficient and effective operations are promoted; resources are safeguarded against waste, loss, mismanagement, unauthorized use, or misappropriation; all encumbrances and costs that are incurred under the contract and fees that are earned are in compliance with applicable clauses and other current terms, conditions, and intended purposes; all collections accruing to the contractor in connection with the work under this contract, expenditures, and all other transactions and assets are properly recorded, managed, and reported; and financial, statistical, and other reports necessary to maintain accountability and managerial control are accurate, reliable, and timely.

(2) The systems of controls employed by the contractor shall be documented and satisfactory to DOE.

(3) Such systems shall be an integral part of the contractor's management functions, including defining specific roles and responsibilities for each level of management, and holding employees accountable for the adequacy of the management systems and controls in their areas of assigned responsibility.

(4) The contractor shall, as part of the internal audit program required elsewhere in this contract, periodically review the management systems and controls employed in programs and administrative areas to ensure that they are adequate to provide reasonable assurance that the objectives of the systems are being accomplished and that these systems and controls are working effectively.

(b) The contractor shall be responsible for maintaining, as a part of its operational responsibilities, a baseline quality assurance program that implements documented performance, quality standards, and control and assessment techniques.

(End of Clause)

970.5203-2 Performance improvement and collaboration.

As prescribed in 48 CFR 970.0370-2(b), insert the following clause:

Performance Improvement and Collaboration (DEC 2000)

(a) The contractor agrees that it shall affirmatively identify, evaluate, and institute practices, where appropriate, that will improve performance in the areas of environmental and health, safety, scientific and technical, security, business and

administrative, and any other areas of performance in the management and operation of the contract. This may entail the alteration of existing practices or the institution of new procedures to more effectively or efficiently perform any aspect of contract performance or reduce overall cost of operation under the contract. Such improvements may result from changes in organization, simplification of systems while retaining necessary controls, or any other approaches consistent with the statement of work and performance measures of this contract.

(b) The contractor agrees to work collaboratively with the Department, all other management and operating, DOE major facilities management contractors and affiliated contractors which manage or operate DOE sites or facilities for the following purposes: (i) to exchange information generally, (ii) to evaluate concepts that may be of benefit in resolving common issues, in confronting common problems, or in reducing costs of operations, and (iii) to otherwise identify and implement DOE-complex-wide management improvements discussed in paragraph (a). In doing so, it shall also affirmatively provide information relating to its management improvements to such contractors, including lessons learned, subject to security considerations and the protection of data proprietary to third parties.

(c) The contractor may consult with the contracting officer in those instances in which improvements being considered pursuant to paragraph (a) involve the cooperation of the DOE. The contractor may request the assistance of the contracting officer in the communication of the success of improvements to other management and operating contractors in accordance with paragraph (b) of this clause.

(d) The contractor shall notify the contracting officer and seek approval where necessary to fulfill its obligations under the contract. Compliance with this clause in no way alters the obligations of the Contractor under any other provision of this contract.

(End of Clause)

970.5203-3 Contractor's organization.

As prescribed in 48 CFR 970.0371-9, insert the following clause:

Contractor's Organization (DEC 2000)

(a) Organization chart. As promptly as possible after the execution of this contract, the contractor shall furnish to the contracting officer a chart showing the names, duties, and organization of key personnel (see 48 CFR 952.215-70) to be employed in connection with the work, and shall furnish supplemental information to reflect any changes as they occur.

(b) Supervisory representative of contractor. Unless otherwise directed by the contracting officer, a competent full-time resident supervisory representative of the contractor satisfactory to the contracting officer shall be in charge of the work at the site, and any work off-site, at all times.

(c) Control of employees. The contractor shall be responsible for maintaining satisfactory standards of employee

competency, conduct, and integrity and shall be responsible for taking such disciplinary action with respect to its employees as may be necessary. In the event the contractor fails to remove any employee from the contract work whom DOE deems incompetent, careless, or insubordinate, or whose continued employment on the work is deemed by DOE to be inimical to the Department's mission, the contracting officer may require, with the approval of the Secretary of Energy, the contractor to remove the employee from work under the contract. This includes the right to direct the contractor to remove its most senior key person from work under the contract for serious contract performance deficiencies.

(d) Standards and procedures. The contractor shall establish such standards and procedures as are necessary to implement the requirements set forth in 48 CFR 970.0371. Such standards and procedures shall be subject to the approval of the contracting officer.

(End of Clause)

970.5204-1 Counterintelligence.

(a) As prescribed in 48 CFR 970.0404-4(a), insert the following clause in contracts containing the clauses at 48 CFR 952.204-2, Security, and 48 CFR 952.204-70, Classification/Declassification:

Counterintelligence (DEC 2000)

(a) The contractor shall take all reasonable precautions in the work under this contract to protect DOE programs, facilities, technology, personnel, unclassified sensitive information and classified matter from foreign intelligence threats and activities conducted for governmental or industrial purposes, in accordance with DOE Order 5670.3, Counterintelligence Program; Executive Order 12333, U.S. Intelligence Activities; and other pertinent national and Departmental Counterintelligence requirements.

(b) The contractor shall appoint a qualified employee(s) to function as the Contractor Counterintelligence Officer. The Contractor Counterintelligence Officer will be responsible for conducting defensive Counterintelligence briefings and debriefings of employees traveling to foreign countries or interacting with foreign nationals; providing thoroughly documented written reports relative to targeting, suspicious activity and other matters of Counterintelligence interest; immediately reporting targeting, suspicious activity and other Counterintelligence concerns to the DOE Headquarters Counterintelligence Division; and providing assistance to other elements of the U.S. Intelligence Community as stated in the aforementioned Executive Order, the DOE Counterintelligence Order, and other pertinent national and Departmental Counterintelligence requirements.

(End of Clause)

970.5204-2 Laws, regulations, and DOE directives.

As prescribed in 48 CFR 970.0470-2, insert the following clause:

Laws, Regulations, and DOE Directives (DEC 2000)

(a) In performing work under this contract, the contractor shall comply with the requirements of applicable Federal, State, and local laws and regulations (including DOE regulations), unless relief has been granted in writing by the appropriate regulatory agency. A List of Applicable Laws and regulations (List A) may be appended to this contract for information purposes. Omission of any applicable law or regulation from List A does not affect the obligation of the contractor to comply with such law or regulation pursuant to this paragraph.

(b) In performing work under this contract, the contractor shall comply with the requirements of those Department of Energy directives, or parts thereof, identified in the List of Applicable Directives (List B) appended to this contract. Except as otherwise provided for in paragraph (d) of this clause, the contracting officer may, from time to time and at any time, revise List B by unilateral modification to the contract to add, modify, or delete specific requirements. Prior to revising List B, the contracting officer shall notify the contractor in writing of the Department's intent to revise List B and provide the contractor with the opportunity to assess the effect of the contractor's compliance with the revised list on contract cost and funding, technical performance, and schedule; and identify any potential inconsistencies between the revised list and the other terms and conditions of the contract. Within 30 days after receipt of the contracting officer's notice, the contractor shall advise the contracting officer in writing of the potential impact of the contractor's compliance with the revised list. Based on the information provided by the contractor and any other information available, the contracting officer shall decide whether to revise List B and so advise the contractor not later than 30 days prior to the effective date of the revision of List B. The contractor and the contracting officer shall identify and, if appropriate, agree to any changes to other contract terms and conditions, including cost and schedule, associated with the revision of List B pursuant to the clause of this contract entitled, "Changes."

(c) Environmental, safety, and health (ES&H) requirements appropriate for work conducted under this contract may be determined by a DOE approved process to evaluate the work and the associated hazards and identify an appropriately tailored set of standards, practices, and controls, such as a tailoring process included in a DOE approved Safety Management System implemented under the clause entitled "Integration of Environment, Safety, and Health into Work Planning and Execution." When such a process is used, the set of tailored (ES&H) requirements, as approved by DOE pursuant to the process, shall be incorporated into List B as contract requirements with full force and effect. These requirements shall supersede, in whole or in part, the contractual environmental, safety, and health requirements previously made applicable to the contract by List B. If the tailored set of requirements identifies an alternative requirement varying from an ES&H

requirement of an applicable law or regulation, the contractor shall request an exemption or other appropriate regulatory relief specified in the regulation.

(d) Except as otherwise directed by the contracting officer, the contractor shall procure all necessary permits or licenses required for the performance of work under this contract.

(e) Regardless of the performer of the work, the contractor is responsible for compliance with the requirements of this clause. The contractor is responsible for flowing down the requirements of this clause to subcontracts at any tier to the extent necessary to ensure the contractor's compliance with the requirements.

(End of Clause)

970.5204-3 Access to and ownership of records.

As prescribed in 48 CFR 970.0407-1-3, insert the following clause:

Access to and Ownership of Records (DEC 2000)

(a) Government-owned records. Except as provided in paragraph (b) of this clause, all records acquired or generated by the contractor in its performance of this contract shall be the property of the Government and shall be delivered to the Government or otherwise disposed of by the contractor either as the contracting officer may from time to time direct during the progress of the work or, in any event, as the contracting officer shall direct upon completion or termination of the contract.

(b) Contractor-owned records. The following records are considered the property of the contractor and are not within the scope of paragraph (a) of this clause. [The contracting officer shall identify which of the following categories of records will be included in the clause.]

(1) Employment-related records (such as workers' compensation files; employee relations records, records on salary and employee benefits; drug testing records, labor negotiation records; records on ethics, employee concerns, and other employee related investigations conducted under an expectation of confidentiality; employee assistance program records; and personnel and medical/ health-related records and similar files), and non-employee patient medical/health related records, except for those records described by the contract as being maintained in Privacy Act systems of records.

(2) Confidential contractor financial information, and correspondence between the contractor and other segments of the contractor located away from the DOE facility (*i.e.*, the contractor's corporate headquarters);

(3) Records relating to any procurement action by the contractor, except for records that under 48 CFR 970.5232-3, Accounts, Records, and Inspection, are described as the property of the Government; and

(4) Legal records, including legal opinions, litigation files, and documents covered by the attorney-client and attorney work product privileges; and

(5) The following categories of records maintained pursuant to the technology transfer clause of this contract:

(i) Executed license agreements, including exhibits or appendices containing information on royalties, royalty rates, other financial information, or commercialization plans, and all related documents, notes and correspondence.

(ii) The contractor's protected Cooperative Research and Development Agreement (CRADA) information and appendices to a CRADA that contain licensing terms and conditions, or royalty or royalty rate information.

(iii) Patent, copyright, mask work, and trademark application files and related contractor invention disclosures, documents and correspondence, where the contractor has elected rights or has permission to assert rights and has not relinquished such rights or turned such rights over to the Government.

(c) *Contract completion or termination.* In the event of completion or termination of this contract, copies of any of the contractor-owned records identified in paragraph (b) of this clause, upon the request of the Government, shall be delivered to DOE or its designees, including successor contractors. Upon delivery, title to such records shall vest in DOE or its designees, and such records shall be protected in accordance with applicable federal laws (including the Privacy Act), as appropriate.

(d) *Inspection, copying, and audit of records.* All records acquired or generated by the contractor under this contract in the possession of the contractor, including those described at paragraph (b) of this clause, shall be subject to inspection, copying, and audit by the Government or its designees at all reasonable times, and the contractor shall afford the Government or its designees reasonable facilities for such inspection, copying, and audit; provided, however, that upon request by the contracting officer, the contractor shall deliver such records to a location specified by the contracting officer for inspection, copying, and audit. The Government or its designees shall use such records in accordance with applicable federal laws (including the Privacy Act), as appropriate.

(e) *Applicability.* Paragraphs (b), (c), and (d) of this clause apply to all records without regard to the date or origination of such records.

(f) *Records retention standards.* Special records retention standards, described at DOE Order 200.1, Information Management Program (version in effect on effective date of contract), are applicable for the classes of records described therein, whether or not the records are owned by the Government or the contractor. In addition, the contractor shall retain individual radiation exposure records generated in the performance of work under this contract until DOE authorizes disposal. The Government may waive application of these record retention schedules, if, upon termination or completion of the contract, the Government exercises its right under paragraph (c) of this clause to obtain copies and delivery of records described in paragraphs (a) and (b) of this clause.

(g) *Subcontracts.* The contractor shall include the requirements of this clause in all subcontracts that are of a cost-reimbursement type if any of the following factors is present:

(1) The value of the subcontract is greater than \$2 million (unless specifically waived by the contracting officer);

(2) The contracting officer determines that the subcontract is, or involves, a critical task related to the contract; or

(3) The subcontract includes 48 CFR 970.5223-1, Integration of Environment, Safety, and Health into Work Planning and Execution, or similar clause.

(End of Clause)

970.5208-1 Printing.

As prescribed in 48 CFR 970.0808-3, insert the following clause:

Printing (DEC 2000)

(a) To the extent that duplicating or printing services may be required in the performance of this contract, the Contractor shall provide or secure such services in accordance with the Government Printing and Binding Regulations, Title 44 of the U.S. Code, and DOE Directives relative thereto.

(b) The term "Printing" includes the following processes: Composition, platemaking, presswork, binding, microform publishing, or the end items produced by such processes. Provided, however, that performance of a requirement under this contract involving the duplication of less than 5,000 copies of a single page, or no more than 25,000 units in the aggregate of multiple pages, will not be deemed to be printing.

(c) Printing services not obtained in compliance with this guidance shall result in the cost of such printing being disallowed.

(d) The Contractor shall include the substance of this clause in all subcontracts hereunder which require printing (as that term is defined in Title I of the U.S. Government Printing and Binding Regulations).

(End of Clause)

970.5209-1 Requirement for guarantee of performance.

As prescribed in 48 CFR 970.0970-2, the contracting officer shall insert the following provision in solicitations for management and operating contracts:

Requirement for Guarantee of Performance (DEC 2000)

The successful offeror is required by other provisions of this solicitation to organize a dedicated corporate entity to carry out the work under the contract to be awarded as a result of this solicitation. The successful offeror will be required, as part of the determination of responsibility of the newly organized, dedicated corporate entity and as a condition of the award of the contract to that entity, to furnish a guarantee of that entity's performance. That guarantee of performance must be satisfactory in all respects to the Department of Energy.

(End of Clause)

970.5215-1 Total available fee: Base fee amount and performance fee amount.

As prescribed in 48 CFR 970.1504-5(a), insert the following clause. The clause should be tailored to reflect the

contract's actual inclusion of base fee amount and performance fee amount.

Total Available Fee: Base Fee Amount and Performance Fee Amount (DEC 2000)

(a) *Total available fee.* Total available fee, consisting of a base fee amount (which may be zero) and a performance fee amount (consisting of an incentive fee component for objective performance requirements, an award fee component for subjective performance requirements, or both) determined in accordance with the provisions of this clause, is available for payment in accordance with the clause of this contract entitled, "Payments and advances."

(b) *Fee Negotiations.* Prior to the beginning of each fiscal year under this contract, or other appropriate period as mutually agreed upon and, if exceeding one year, approved by the Senior Procurement Executive, or designee, the contracting officer and Contractor shall enter into negotiation of the requirements for the year or appropriate period, including the evaluation areas and individual requirements subject to incentives, the total available fee, and the allocation of fee. The contracting officer shall modify this contract at the conclusion of each negotiation to reflect the negotiated requirements, evaluation areas and individual requirements subject to incentives, the total available fee, and the allocation of fee. In the event the parties fail to agree on the requirements, the evaluation areas and individual requirements subject to incentives, the total available fee, or the allocation of fee, a unilateral determination will be made by the contracting officer. The total available fee amount shall be allocated to a twelve month cycle composed of one or more evaluation periods, or such longer period as may be mutually agreed to between the parties and approved by the Senior Procurement Executive, or designee.

(c) *Determination of Total Available Fee Amount Earned.* (1) The Government shall, at the conclusion of each specified evaluation period, evaluate the contractor's performance of all requirements, including performance based incentives completed during the period, and determine the total available fee amount earned. At the contracting officer's discretion, evaluation of incentivized performance may occur at the scheduled completion of specific incentivized requirements.

(2) The DOE Operations/Field Office Manager, or designee, will be (insert title of DOE Operations/Field Office Manager, or designee). The contractor agrees that the determination as to the total available fee earned is a unilateral determination made by the DOE Operations/Field Office Manager, or designee.

(3) The evaluation of contractor performance shall be in accordance with the Performance Evaluation and Measurement Plan(s) described in subparagraph (d) of this clause unless otherwise set forth in the contract. The Contractor shall be promptly advised in writing of the fee determination, and the basis of the fee determination. In the event that the contractor's performance is

considered to be less than the level of performance set forth in the Statement of Work, as amended to include the current Work Authorization Directive or similar document, for any contract requirement, it will be considered by the DOE Operations/Field Office Manager, or designee, who may at his/her discretion adjust the fee determination to reflect such performance. Any such adjustment shall be in accordance with the clause entitled, "Conditional Payment of Fee, Profit, or Incentives" if contained in the contract.

(d) *Performance Evaluation and Measurement Plan(s).* To the extent not set forth elsewhere in the contract:

(1) The Government shall establish a Performance Evaluation and Measurement Plan(s) upon which the determination of the total available fee amount earned shall be based. The Performance Evaluation and Measurement Plan(s) will address all of the requirements of contract performance specified in the contract directly or by reference. A copy of the Performance Evaluation and Measurement Plan(s) shall be provided to the Contractor:

(i) prior to the start of an evaluation period if the requirements, evaluation areas, specific incentives, amount of fee, and allocation of fee to such evaluation areas and specific incentives have been mutually agreed to by the parties; or

(ii) not later than thirty days prior to the scheduled start date of the evaluation period, if the requirements, evaluation areas, specific incentives, amount of fee, and allocation of fee to such evaluation areas and specific incentives have been unilaterally established by the contracting officer.

(2) The Performance Evaluation and Measurement Plan(s) will set forth the criteria upon which the Contractor will be evaluated relating to any technical, schedule, management, and/or cost objectives selected for evaluation. Such criteria should be objective, but may also include subjective criteria. The Plan(s) shall also set forth the method by which the total available fee amount will be allocated and the amount earned determined.

(3) The Performance Evaluation and Measurement Plan(s) may, consistent with the contract statement of work, be revised during the period of performance. The contracting officer shall notify the contractor:

(i) of such unilateral changes at least ninety calendar days prior to the end of the affected evaluation period and at least thirty calendar days prior to the effective date of the change;

(ii) of such bilateral changes at least sixty calendar days prior to the end of the affected evaluation period; or

(iii) if such change, whether unilateral or bilateral, is urgent and high priority, at least thirty calendar days prior to the end of the evaluation period.

(e) *Schedule for total available fee amount earned determinations.* The DOE Operations/Field Office Manager, or designee, shall issue the final total available fee amount earned determination in accordance with: the schedule set forth in the Performance Evaluation and Measurement Plan(s); or as otherwise set forth in this contract. However,

a determination must be made within sixty calendar days after the receipt by the contracting officer of the Contractor's self-assessment, if one is required or permitted by paragraph (f) of this clause, or seventy calendar days after the end of the evaluation period, whichever is later, or a longer period if the Contractor and contracting officer agree. If the contracting officer evaluates the Contractor's performance of specific requirements on their completion, the payment of any earned fee amount must be made within seventy calendar days (or such other time period as mutually agreed to between the contracting officer and the Contractor) after such completion. If the determination is delayed beyond that date, the Contractor shall be entitled to interest on the determined total available fee amount earned at the rate established by the Secretary of the Treasury under section 12 of the Contract Disputes Act of 1978 (41 U.S.C. 611) that is in effect on the payment date. This rate is referred to as the "Renegotiation Board Interest Rate," and is published in the **Federal Register** semiannually on or about January 1 and July 1. The interest on any late total available fee amount earned determination will accrue daily and be compounded in 30-day increments inclusive from the first day after the schedule determination date through the actual date the determination is issued. That is, interest accrued at the end of any 30-day period will be added to the determined amount of fee earned and be subject to interest if not paid in the succeeding 30-day period.

(End of Clause)

Alternate I (DEC 2000). As prescribed in 48 CFR 970.1504-5(a)(1), when the award fee cycle consists of two or more evaluation periods, add the following to paragraph (c):

(4) At the sole discretion of the Government, unearned total available fee amounts may be carried over from one evaluation period to the next, so long as the periods are within the same award fee cycle.

Alternate II (DEC 2000). As prescribed in 48 CFR 970.1504-5(a)(2), when the award fee cycle consists of one evaluation period, add the following to paragraph (c):

(4) Award fee not earned during the evaluation period shall not be allocated to future evaluation periods.

Alternate III (DEC 2000). As prescribed in 48 CFR 970.1504-5(a)(3), when the DOE Operations/Field Office Manager, or designee, requires the contractor to submit a self-assessment, add the following as paragraph (f):

(f) *Contractor self-assessment.* Following each evaluation period, the Contractor shall submit a self-assessment within (Insert Number) calendar days after the end of the period. This self-assessment shall address both the strengths and weaknesses of the Contractor's performance during the evaluation period. Where deficiencies in performance are noted, the Contractor

shall describe the actions planned or taken to correct such deficiencies and avoid their recurrence. The DOE Operations/Field Office Manager, or designee, will review the Contractor's self-assessment, if submitted, as part of its independent evaluation of the contractor's management during the period. A self-assessment, in and of itself may not be the only basis for the award fee determination.

Alternate IV (DEC 2000). As prescribed in 48 CFR 970.1504-5(a)(4), when the DOE Operations/Field Office Manager, or designee, permits the contractor to submit a self-assessment at the contractor's option, add the following text as paragraph (f):

(f) *Contractor self-assessment.* Following each evaluation period, the Contractor may submit a self-assessment, provided such assessment is submitted within *(Insert Number)* calendar days after the end of the period. This self-assessment shall address both the strengths and weaknesses of the Contractor's performance during the evaluation period. Where deficiencies in performance are noted, the Contractor shall describe the actions planned or taken to correct such deficiencies and avoid their recurrence. The DOE Operations/Field Office Manager, or designee, will review the Contractor's self-assessment, if submitted, as part of its independent evaluation of the Contractor's management during the period. A self-assessment, in and of itself may not be the only basis for the award fee determination.

970.5215-2 Make-or-buy plan.

As prescribed in 48 CFR 970.1504-5(b), insert the following clause:

Make-or-Buy Plan (DEC 2000)

(a) Definitions.

Buy item means a work activity, supply, or service to be produced or performed by an outside source, including a subcontractor or an affiliate, subsidiary, or division of the contractor.

Make item means a work activity, supply, or service to be produced or performed by the contractor using its personnel and other resources at the Department of Energy facility or site.

Make-or-buy plan means a contractor's written program for the contract that identifies work efforts or requirements that either are "make items" or "buy items."

(b) *Make-or-buy plan.* The contractor shall develop and implement a make-or-buy plan that establishes a preference for providing supplies and services on a least-cost basis, subject to any specific make or buy criteria identified in the contract or otherwise provided by the contracting officer. In developing and implementing its make-or-buy plan, the contractor agrees to assess subcontracting opportunities and implement subcontracting decisions in accordance with the following:

(1) The contractor shall conduct internal productivity improvement and cost-reduction programs so that in-house performance options can be made more efficient and cost-effective.

(2) The contractor shall consider subcontracting opportunities with the maximum practicable regard for open communications with potentially affected employees and their representatives. Similarly, a contractor shall communicate its plans, activities, cost-benefit analyses, and decisions to those stakeholders, including representatives of the community and local businesses, likely to be affected by such actions.

(c) *Submission and approval.* For new contract awards, the contractor shall submit an initial make-or-buy plan, for approval, within 180 days after contract award. If the existing contract is to be extended, the contractor shall submit a make-or-buy plan for review and approval at least 90 days prior to the commencement of the negotiations for the extension. The following documentation shall be prepared and submitted:

(1) A description of the each work item, and if appropriate, the identification of the associated Work Authorization or Work Breakdown Structure element;

(2) The categorization of each work item as "must make," "must buy," or "can make or buy," with the reasons for such categorization in consideration of the program specific make or buy criteria (including least cost considerations). For non-core capabilities categorized as "must make," a cost/benefit analysis must be performed for each item if:

(i) The contractor is not the least-cost performer, and

(ii) A program specific make-or-buy criterion does not otherwise justify a "must make" categorization;

(3) A decision to either "make" or "buy" in consideration of the program specific make or buy criteria (including least cost considerations) for work effort categorized as "can make or buy";

(4) Identification of potential suppliers and subcontractors, if known, and their location and size status;

(5) A recommendation to defer a make or buy decision where categorization of an identifiable work effort is impracticable at the time of initial development of the plan and a schedule for future re-evaluation;

(6) A description of the impact of a change in current practice of making or buying on the existing work force; and

(7) Any additional information appropriate to support and explain the plan.

(d) *Conduct of operations.* Once a make-or-buy plan is approved, the contractor shall perform in accordance with the plan.

(e) *Changes to the make-or-buy plan.* The make-or-buy plan established in accordance with paragraph (b) of this clause shall remain in effect for the term of the contract, unless:

(1) A lesser period is provided either for the total plan or for individual items or work effort;

(2) The circumstances supporting the make-or-buy decisions change, or

(3) New work is identified.

At least annually, the contractor shall review its approved make-or-buy plan to ensure that it reflects current conditions. Changes to the approved make-or-buy plan shall be submitted in advance of the effective

date of the proposed change in sufficient time to permit evaluation and review. Changes shall be submitted in accordance with the instructions provided by the contracting officer. Modification of the make-or-buy plan to incorporate proposed changes or additions shall be effective upon the contractor's receipt of the contracting officer's written approval.

(End of Clause)

970.5215-3 Conditional payment of fee, profit, or incentives.

As prescribed in 48 CFR 970.1504-5(c), insert the following clause:

Conditional Payment of Fee, Profit, or Incentives (DEC 2000)

In order for the Contractor to receive all otherwise earned fee, fixed fee, profit, or share of cost savings under the contract in an evaluation period, the Contractor must meet the minimum requirements in paragraphs (a) and (b) of this clause, and if Alternate I is applicable, (a) through (d) of this clause. If the Contractor does not meet the minimum requirements, the DOE Operations/Field Office Manager or designee may make a unilateral determination to reduce the evaluation period's otherwise earned fee, fixed fee, profit or share of cost savings as described in the following paragraphs of this clause.

(a) *Minimum requirements for Environment, Safety & Health (ES&H) Program.* The Contractor shall develop, obtain DOE approval of, and implement a Safety Management System in accordance with the provisions of the clause entitled, "Integration of Environment, Safety and Health into Work Planning and Execution," if included in the contract, or as otherwise agreed to with the contracting officer. The minimum performance requirements of the system will be set forth in the approved Safety Management System, or similar document. If the Contractor fails to obtain approval of the Safety Management System or fails to achieve the minimum performance requirements of the system during the evaluation period, the DOE Operations/Field Office Manager or designee, at his/her sole discretion, may reduce any otherwise earned fees, fixed fee, profit or share of cost savings for the evaluation period by an amount up to the amount earned.

(b) *Minimum requirements for catastrophic event.* If, in the performance of this contract, there is a catastrophic event (such as a fatality, or a serious workplace-related injury or illness to one or more Federal, contractor, or subcontractor employees or the general public, loss of control over classified or special nuclear material, or significant damage to the environment), the DOE Operations/Field Office Manager or designee may reduce any otherwise earned fee for the evaluation period by an amount up to the amount earned. In determining any diminution of fee, fixed fee, profit, or share

of cost savings resulting from a catastrophic event, the DOE Operations/Field Office Manager or designee will consider whether willful misconduct and/or negligence contributed to the occurrence and will take into consideration any mitigating circumstances presented by the contractor or other sources.

(End of Clause)

Alternate 1 (DEC 2000). As prescribed in 48 CFR 970.1504-5(c), for contracts awarded on a cost-plus-award-fee, incentive fee or multiple fee basis, add the following paragraphs (c) and (d):

(c) *Minimum requirements for specified level of performance.* (1) At a minimum the Contractor must perform the following:

(i) the requirements with specific incentives at the level of performance set forth in the Statement of Work, Work Authorization Directive, or similar document unless an otherwise minimal level of performance has been established in the specific incentive;

(ii) all of the performance requirements directly related to requirements specifically incentivized at a level of performance such that the overall performance of these related requirements is at an acceptable level; and

(iii) all other requirements at a level of performance such that the total performance of the contract is not jeopardized.

(2) The evaluation of the Contractor's achievement of the level of performance shall be unilaterally determined by the contracting officer. To the extent that the Contractor fails to achieve the minimum performance levels specified in the Statement of Work, Work Authorization Directive, or similar document, during the evaluation period, the DOE Operations/Field Office Manager, or designee, may reduce any otherwise earned fee, fixed fee, profit, or shared net savings for the evaluation period. Such reduction shall not result in the total of earned fee, fixed fee, profit, or shared net savings being less than 25% of the total available fee amount. Such 25% shall include base fee, if any.

(d) *Minimum requirements for cost performance.* (1) Requirements incentivized by other than cost incentives must be performed within their specified cost constraint and must not adversely impact the costs of performing unrelated activities.

(2) The performance of requirements with a specific cost incentive must not adversely impact the costs of performing unrelated requirements.

(3) The Contractor's performance within the stipulated cost performance levels for the evaluation period shall be determined by the contracting officer. To the extent the Contractor fails to achieve the stipulated cost performance levels, the DOE Operations/Field Office Manager, or designee, at his/her sole discretion, may reduce in whole or in part any otherwise earned fee, fixed fee, profit, or shared net savings for the evaluation period. Such reduction shall not result in the total of earned fee, fixed fee,

profit or shared net savings being less than 25% of the total available fee amount. Such 25% shall include base fee, if any.

970.5215-4 Cost reduction.

As prescribed in 48 CFR 970.1504-5(d), insert the following clause:

Cost Reduction (DEC 2000)

(a) *General.* It is the Department of Energy's (DOE's) intent to have its facilities and laboratories operated in an efficient and effective manner. To this end, the Contractor shall assess its operations and identify areas where cost reductions would bring cost efficiency to operations without adversely affecting the level of performance required by the contract. The Contractor, to the maximum extent practical, shall identify areas where cost reductions may be effected, and develop and submit Cost Reduction Proposals (CRPs) to the contracting officer. If accepted, the Contractor may share in any shared net savings from accepted CRPs in accordance with paragraph (g) of this clause.

(b) *Definitions.* *Administrative cost* is the contractor cost of developing and administering the CRP.

Design, process, or method change is a change to a design, process, or method which has established cost, technical and schedule baseline, is defined, and is subject to a formal control procedure. Such a change must be innovative, initiated by the contractor, and applied to a specific project or program.

Development cost is the Contractor cost of up-front planning, engineering, prototyping, and testing of a design, process, or method.

DOE cost is the Government cost incurred implementing and validating the CRP.

Implementation cost is the Contractor cost of tooling, facilities, documentation, etc., required to effect a design, process, or method change once it has been tested and approved.

Net Savings means a reduction in the total amount (to include all related costs and fee) of performing the effort where the savings revert to DOE control and may be available for deobligation. Such savings may result from a specific cost reduction effort which is negotiated on a cost-plus-incentive-fee, fixed-price incentive, or firm-fixed-price basis, or may result directly from a design, process, or method change. They may also be savings resulting from formal or informal direction given by DOE or from changes in the mission, work scope, or routine reorganization of the Contractor due to changes in the budget.

Shared Net Savings are those net savings which result from:

(1) a specific cost reduction effort which is negotiated on a cost-plus-incentive-fee or fixed-price incentive basis, and is the difference between the negotiated target cost of performing an effort as negotiated and the actual allowable cost of performing that effort; or

(2) a design, process, or method change, which occurs in the fiscal year in which the change is accepted and the subsequent fiscal

year, and is the difference between the estimated cost of performing an effort as originally planned and the actual allowable cost of performing that same effort utilizing a revised plan intended to reduce costs along with any Contractor development costs, implementation costs, administrative costs, and DOE costs associated with the revised plan. Administrative costs and DOE costs are only included at the discretion of the contracting officer. Savings resulting from formal or informal direction given by the DOE or changes in the mission, work scope, or routine reorganization of the Contractor due to changes in the budget are not to be considered as shared net savings for purposes of this clause and do not qualify for incentive sharing.

(c) *Procedure for submission of CRPs.* (1) CRPs for the establishment of cost-plus-incentive-fee, fixed-price incentive, or firm-fixed-price efforts or for design, process, or methods changes submitted by the Contractor shall contain, at a minimum, the following:

(i) *Current Method (Baseline)*—A verifiable description of the current scope of work, cost, and schedule to be impacted by the initiative, and supporting documentation.

(ii) *New Method (New Proposed Baseline)*—A verifiable description of the new scope of work, cost, and schedule, how the initiative will be accomplished, and supporting documentation.

(iii) *Feasibility Assessment*—A description and evaluation of the proposed initiative and benefits, risks, and impacts of implementation. This evaluation shall include an assessment of the difference between the current method (baseline) and proposed new method including all related costs.

(2) In addition, CRPs for the establishment of cost-plus-incentive-fee, fixed-price incentive, or firm-fixed-price efforts shall contain, at a minimum, the following:

(i) The proposed contractual arrangement and the justification for its use; and

(ii) A detailed cost/price estimate and supporting rationale. If the approach is proposed on an incentive basis, minimum and maximum cost estimates should be included along with any proposed sharing arrangements.

(d) *Evaluation and Decision.* All CRPs must be submitted to and approved by the contracting officer. Included in the information provided by the CRP must be a discussion of the extent the proposed cost reduction effort may:

(1) Pose a risk to the health and safety of workers, the community, or to the environment;

(2) Result in a waiver or deviation from DOE requirements, such as DOE Orders and joint oversight agreements;

(3) Require a change in other contractual agreements;

(4) Result in significant organizational and personnel impacts;

(5) Create a negative impact on the cost, schedule, or scope of work in another area;

(6) Pose a potential negative impact on the credibility of the Contractor or the DOE; and

(7) Impact successful and timely completion of any of the work in the cost, technical, and schedule baseline.

(e) *Acceptance or Rejection of CRPs.*

Acceptance or rejection of a CRP is a unilateral determination made by the contracting officer. The contracting officer will notify the Contractor that a CRP has been accepted, rejected, or deferred within (*Insert Number*) days of receipt. The only CRPs that will be considered for acceptance are those which the Contractor can demonstrate, at a minimum, will:

- (1) Result in net savings (in the sharing period if a design, process, or method change);
- (2) Not reappear as costs in subsequent periods; and
- (3) Not result in any impairment of essential functions.

(f) The failure of the contracting officer to notify the Contractor of the acceptance, rejection, or deferral of a CRP within the specified time shall not be construed as approval.

(g) *Adjustment to Original Estimated Cost and Fee.* If a CRP is established on a cost-plus-incentive-fee, fixed-price incentive or firm-fixed-price basis, the originally estimated cost and fee for the total effort shall be adjusted to remove the estimated cost and fee amount associated with the CRP effort.

(h) *Sharing Arrangement.* If a CRP is accepted, the Contractor may share in the shared net savings. For a CRP negotiated on a cost-plus-incentive-fee or fixed-price incentive basis, with the specific incentive arrangement (negotiated target costs, target fees, share lines, ceilings, profit, etc.) set forth in the contractual document authorizing the effort, the Contractor's share shall be the actual fee or profit resulting from such an arrangement. For a CRP negotiated as a cost savings incentive resulting from a design, process, or method change, the Contractor's share shall be a percentage, not to exceed 25% of the shared net savings. The specific percentage and sharing period shall be set forth in the contractual document.

(i) *Validation of Shared Net Savings.* The contracting officer shall validate actual shared net savings. If actual shared net savings cannot be validated, the contractor will not be entitled to a share of the net shared savings.

(j) *Relationship to Other Incentives.* Only those benefits of an accepted CRP not rewardable under other clauses of this contract shall be rewarded under this clause.

(k) *Subcontracts.* The Contractor may include a clause similar to this clause in any subcontract. In calculating any estimated shared net savings in a CRP under this contract, the Contractor's administration, development, and implementation costs shall include any subcontractor's allowable costs, and any CRP incentive payments to a subcontractor resulting from the acceptance of such CRP. The Contractor may choose any arrangement for subcontractor CRP incentive payments, provided that the payments not reduce the DOE's share of shared net savings.

(End of Clause)

970.5215-5 Limitation on fee.

As prescribed in 48 CFR 970.1504-5(e), the contracting officer shall insert the following provision:

Limitation on Fee (DEC 2000)

(a) For the purpose of this solicitation, fee amounts shall not exceed the total available fee allowed by the fee policy at 48 CFR 970.1504-1-1, or as specifically stated elsewhere in the solicitation.

(b) The Government reserves the unilateral right, in the event an offeror's proposal is selected for award, to limit: fixed fee to not exceed an amount established pursuant to 48 CFR 970.1504-1-5; and total available fee to not exceed an amount established pursuant to 48 CFR 970.1504-1-9; or fixed fee or total available fee to an amount as specifically stated elsewhere in the solicitation.

(End of Clause)

970.5222-1 Collective Bargaining Agreements Management and Operating Contracts.

As prescribed in 48 CFR 970.2201-1-3, insert the following clause:

Collective Bargaining Agreements—Management and Operating Contracts (DEC 2000)

When negotiating collective bargaining agreements applicable to the work force under this contract, the Contractor shall use its best efforts to ensure such agreements contain provisions designed to assure continuity of services. All such agreements entered into during the contract period of performance should provide that grievances and disputes involving the interpretation or application of the agreement will be settled without resorting to strike, lockout, or other interruption of normal operations. For this purpose, each collective bargaining agreement should provide an effective grievance procedure with arbitration as its final step, unless the parties mutually agree upon some other method of assuring continuity of operations. As part of such agreements, management and labor should agree to cooperate fully with the Federal Mediation and Conciliation Service. The contractor shall include the substance of this clause in any subcontracts for protective services or other services performed on the DOE-owned site which will affect the continuity of operation of the facility.

(End of Clause)

970.5222-2 Overtime management.

As prescribed in 48 CFR 970.2201-2-2, insert the following clause:

Overtime Management (DEC 2000)

(a) The contractor shall maintain adequate internal controls to ensure that employee overtime is authorized only if cost effective and necessary to ensure performance of work under this contract.

(b) The contractor shall notify the contracting officer when in any given year it is likely that overtime usage as a percentage of payroll may exceed 4%.

(c) The contracting officer may require the submission, for approval, of a formal annual

overtime control plan whenever contractor overtime usage as a percentage of payroll has exceeded, or is likely to exceed, 4%, or if the contracting officer otherwise deems overtime expenditures excessive. The plan shall include, at a minimum:

- (1) An overtime premium fund (maximum dollar amount);
- (2) Specific controls for casual overtime for non-exempt employees;
- (3) Specific parameters for allowability of exempt overtime;
- (4) An evaluation of alternatives to the use of overtime; and
- (5) Submission of a semi-annual report that includes for exempt and non-exempt employees:
 - (i) Total cost of overtime;
 - (ii) Total cost of straight time;
 - (iii) Overtime cost as a percentage of straight-time cost;
 - (iv) Total overtime hours;
 - (v) Total straight-time hours; and
 - (vi) Overtime hours as a percentage of straight-time hours.

(End of Clause)

970.5223-1 Integration of environment, safety, and health into work planning and execution.

As prescribed in 48 CFR 970.2303-2(a), insert the following clause:

Integration of Environment, Safety, and Health Into Work Planning and Execution (DEC 2000)

- (a) For the purposes of this clause,
- (1) Safety encompasses environment, safety and health, including pollution prevention and waste minimization; and
 - (2) Employees include subcontractor employees.

(b) In performing work under this contract, the contractor shall perform work safely, in a manner that ensures adequate protection for employees, the public, and the environment, and shall be accountable for the safe performance of work. The contractor shall exercise a degree of care commensurate with the work and the associated hazards. The contractor shall ensure that management of environment, safety and health (ES&H) functions and activities becomes an integral but visible part of the contractor's work planning and execution processes. The contractor shall, in the performance of work, ensure that:

- (1) Line management is responsible for the protection of employees, the public, and the environment. Line management includes those contractor and subcontractor employees managing or supervising employees performing work.
- (2) Clear and unambiguous lines of authority and responsibility for ensuring (ES&H) are established and maintained at all organizational levels.
- (3) Personnel possess the experience, knowledge, skills, and abilities that are necessary to discharge their responsibilities.
- (4) Resources are effectively allocated to address ES&H, programmatic, and operational considerations. Protecting employees, the public, and the environment is a priority whenever activities are planned and performed.

(5) Before work is performed, the associated hazards are evaluated and an agreed-upon set of ES&H standards and requirements are established which, if properly implemented, provide adequate assurance that employees, the public, and the environment are protected from adverse consequences.

(6) Administrative and engineering controls to prevent and mitigate hazards are tailored to the work being performed and associated hazards. Emphasis should be on designing the work and/or controls to reduce or eliminate the hazards and to prevent accidents and unplanned releases and exposures.

(7) The conditions and requirements to be satisfied for operations to be initiated and conducted are established and agreed-upon by DOE and the contractor. These agreed-upon conditions and requirements are requirements of the contract and binding upon the contractor. The extent of documentation and level of authority for agreement shall be tailored to the complexity and hazards associated with the work and shall be established in a Safety Management System.

(c) The contractor shall manage and perform work in accordance with a documented Safety Management System (System) that fulfills all conditions in paragraph (b) of this clause at a minimum. Documentation of the System shall describe how the contractor will:

- (1) Define the scope of work;
- (2) Identify and analyze hazards associated with the work;
- (3) Develop and implement hazard controls;
- (4) Perform work within controls; and
- (5) Provide feedback on adequacy of controls and continue to improve safety management.

(d) The System shall describe how the contractor will establish, document, and implement safety performance objectives, performance measures, and commitments in response to DOE program and budget execution guidance while maintaining the integrity of the System. The System shall also describe how the contractor will measure system effectiveness.

(e) The contractor shall submit to the contracting officer documentation of its System for review and approval. Dates for submittal, discussions, and revisions to the System will be established by the contracting officer. Guidance on the preparation, content, review, and approval of the System will be provided by the contracting officer. On an annual basis, the contractor shall review and update, for DOE approval, its safety performance objectives, performance measures, and commitments consistent with and in response to DOE's program and budget execution guidance and direction. Resources shall be identified and allocated to meet the safety objectives and performance commitments as well as maintain the integrity of the entire System. Accordingly, the System shall be integrated with the contractor's business processes for work planning, budgeting, authorization, execution, and change control.

(f) The contractor shall comply with, and assist the Department of Energy in complying with, ES&H requirements of all applicable

laws and regulations, and applicable directives identified in the clause of this contract entitled "Laws, Regulations, and DOE Directives." The contractor shall cooperate with Federal and non-Federal agencies having jurisdiction over ES&H matters under this contract.

(g) The contractor shall promptly evaluate and resolve any noncompliance with applicable ES&H requirements and the System. If the contractor fails to provide resolution or if, at any time, the contractor's acts or failure to act causes substantial harm or an imminent danger to the environment or health and safety of employees or the public, the contracting officer may issue an order stopping work in whole or in part. Any stop work order issued by a contracting officer under this clause (or issued by the contractor to a subcontractor in accordance with paragraph (i) of this clause) shall be without prejudice to any other legal or contractual rights of the Government. In the event that the contracting officer issues a stop work order, an order authorizing the resumption of the work may be issued at the discretion of the contracting officer. The contractor shall not be entitled to an extension of time or additional fee or damages by reason of, or in connection with, any work stoppage ordered in accordance with this clause.

(h) Regardless of the performer of the work, the contractor is responsible for compliance with the ES&H requirements applicable to this contract. The contractor is responsible for flowing down the ES&H requirements applicable to this contract to subcontracts at any tier to the extent necessary to ensure the contractor's compliance with the requirements.

(i) The contractor shall include a clause substantially the same as this clause in subcontracts involving complex or hazardous work on site at a DOE-owned or -leased facility. Such subcontracts shall provide for the right to stop work under the conditions described in paragraph (g) of this clause. Depending on the complexity and hazards associated with the work, the contractor may choose not to require the subcontractor to submit a Safety Management System for the contractor's review and approval.

(End of Clause)

970.5223-2 Acquisition and use of environmentally preferable products and services.

As prescribed in 48 CFR 970.2304-2, insert the following clause:

Acquisition and Use of Environmentally Preferable Products and Services (DEC 2000)

(a) In the performance of this contract, the Contractor shall comply with the requirements of the following issuances:

(1) Executive Order 13101 of September 14, 1998, entitled "Greening the Government Through Waste Prevention, Recycling and Federal Acquisition."

(2) Section 6002 of the Resource Conservation and Recovery Act (RCRA) of 1976, as amended (42 U.S.C. 6962, Pub. L. 94-580, 90 Stat. 2822).

(3) Title 40 of the Code of Federal Regulations, Subchapter I, Part 247 (Comprehensive Guidelines for the Procurement of Products Containing Recovered Materials) and such other

Subchapter I Parts or Comprehensive Procurement Guidelines as the Environmental Protection Agency may issue from time to time as guidelines for the procurement of products that contain recovered/recycled materials.

(4) "U.S. Department of Energy Affirmative Procurement Program for Products Containing Recovered Materials" and related guidance document(s), as they are identified in writing by the Department.

(b) The Contractor shall prepare and submit reports on matters related to the use of environmentally preferable products and services from time to time in accordance with written direction (e.g., in a specified format) from the contracting officer.

(c) In complying with the requirements of paragraph (a) of this clause, the Contractor shall coordinate its concerns and seek implementing guidance on Federal and Departmental policy, plans, and program guidance with the DOE recycling point of contact, who shall be identified by the contracting officer. Reports required pursuant to paragraph (b) of this clause, shall be submitted through the DOE recycling point of contact.

(End of Clause)

970.5223-3 Agreement regarding Workplace Substance Abuse Programs at DOE facilities.

As prescribed in 970.2305-4(a), the contracting officer shall insert the following provision:

Agreement Regarding Workplace Substance Abuse Programs at DOE Sites (DEC 2000)

(a) Any contract awarded as a result of this solicitation will be subject to the policies, criteria, and procedures of 10 CFR part 707, Workplace Substance Abuse Programs at DOE Sites.

(b) By submission of its offer, the officer agrees to provide to the contracting officer, within 30 days after notification of selection for award, or award of a contract, whichever occurs first, pursuant to this solicitation, its written workplace substance abuse program consistent with the requirements of 10 CFR part 707.

(c) Failure of the offeror to agree to the condition of responsibility set forth in paragraph (b) of this provision, renders the offeror unqualified and ineligible for award. (End of Provision)

970.5223-4 Workplace Substance Abuse Programs at DOE Sites.

As prescribed in 48 CFR 970.2305-4(b), insert the following clause:

Workplace Substance Abuse Programs at DOE Sites (DEC 2000)

(a) *Program Implementation.* The contractor shall, consistent with 10 CFR part 707, Workplace Substance Abuse Programs at DOE Sites, incorporated herein by reference with full force and effect, develop, implement, and maintain a workplace substance abuse program.

(b) *Remedies.* In addition to any other remedies available to the Government, the

contractor's failure to comply with the requirements of 10 CFR part 707 or to perform in a manner consistent with its approved program may render the contractor subject to: the suspension of contract payments, or, where applicable, a reduction in award fee; termination for default; and suspension or debarment.

(c) *Subcontracts.* (1) The contractor agrees to notify the contracting officer reasonably in advance of, but not later than 30 days prior to, the award of any subcontract the contractor believes may be subject to the requirements of 10 CFR part 707.

(2) The DOE prime contractor shall require all subcontracts subject to the provisions of 10 CFR part 707 to agree to develop and implement a workplace substance abuse program that complies with the requirements of 10 CFR part 707, Workplace Substance Abuse Programs at DOE Sites, as a condition for award of the subcontract. The DOE prime contractor shall review and approve each subcontractor's program, and shall periodically monitor each subcontractor's implementation of the program for effectiveness and compliance with 10 CFR part 707.

(3) The contractor agrees to include, and require the inclusion of, the requirements of this clause in all subcontracts, at any tier, that are subject to the provisions of 10 CFR part 707.

(End of clause)

970.5226-1 Diversity plan.

As prescribed in 48 CFR 970.2671-2, insert the following clause:

Diversity Plan (DEC 2000)

The Contractor shall submit a Diversity Plan to the contracting officer for approval within 90 days after the effective date of this contract (or contract modification, if appropriate). The contractor shall submit an update to its Plan annually or with its annual fee proposal. Guidance for preparation of a Diversity Plan is provided in Appendix _____. The Plan shall include innovative strategies for increasing opportunities to fully use the talents and capabilities of a diverse work force. The Plan shall address, at a minimum, the Contractor's approach for promoting diversity through (1) the Contractor's work force, (2) educational outreach, (3) community involvement and outreach, (4) subcontracting, (5) economic development (including technology transfer), and (6) the prevention of profiling based on race or national origin.

(End of Clause)

970.5226-2 Workforce restructuring under section 3161 of the National Defense Authorization Act for fiscal year 1993.

As prescribed in 48 CFR 970.2672-3, insert the following clause:

Workforce Restructuring under Section 3161 of the National Defense Authorization Act for Fiscal Year 1993 (DEC 2000)

(a) Consistent with the objectives of Section 3161 of the National Defense Authorization Act for Fiscal Year 1993, 42

U.S.C. 7274h, in instances where the Department of Energy has determined that a change in workforce at a Department of Energy Defense Nuclear Facility is necessary, the contractor agrees to (1) comply with the Department of Energy Workforce Restructuring Plan for the facility, if applicable, and (2) use its best efforts to accomplish workforce restructuring or displacement so as to mitigate social and economic impacts.

(b) The requirements of this clause shall be included in subcontracts at any tier (except subcontracts for commercial items pursuant to 41 U.S.C. 403) expected to exceed \$500,000.

(End of Clause)

970.5226-3 Community commitment.

As prescribed in 48 CFR 970.2673-2, insert the following clause:

Community Commitment (DEC 2000)

It is the policy of the DOE to be a constructive partner in the geographic region in which DOE conducts its business. The basic elements of this policy include: (1) Recognizing the diverse interests of the region and its stakeholders, (2) engaging regional stakeholders in issues and concerns of mutual interest, and (3) recognizing that giving back to the community is a worthwhile business practice. Accordingly, the Contractor agrees that its business operations and performance under the Contract will be consistent with the intent of the policy and elements set forth above.

(End of Clause)

970.5227-1 Rights in data-facilities.

As prescribed in 48 CFR 970.2704-3(a), insert the following clause:

Rights in Data—Facilities (DEC 2000)

(a) *Definitions.* (1) *Computer data bases*, as used in this clause, means a collection of data in a form capable of, and for the purpose of, being stored in, processed, and operated on by a computer. The term does not include computer software.

(2) *Computer software*, as used in this clause, means (i) computer programs which are data comprising a series of instructions, rules, routines, or statements, regardless of the media in which recorded, that allow or cause a computer to perform a specific operation or series of operations and (ii) data comprising source code listings, design details, algorithms, processes, flow charts, formulae, and related material that would enable the computer program to be produced, created, or compiled. The term does not include computer data bases.

(3) *Data*, as used in this clause, means recorded information, regardless of form or the media on which it may be recorded. The term includes technical data and computer software. The term "data" does not include data incidental to the administration of this contract, such as financial, administrative, cost and pricing, or management information.

(4) *Limited rights data*, as used in this clause, means data, other than computer software, developed at private expense that

embody trade secrets or are commercial or financial and confidential or privileged. The Government's rights to use, duplicate, or disclose limited rights data are as set forth in the Limited Rights Notice of subparagraph (e) of this clause.

(5) *Restricted computer software*, as used in this clause, means computer software developed at private expense and that is a trade secret; is commercial or financial and is confidential or privileged; or is published copyrighted computer software, including minor modifications of any such computer software. The Government's rights to use, duplicate, or disclose restricted computer software are as set forth in the Restricted Rights Notice of paragraph (f) of this clause.

(6) *Technical data*, as used in this clause, means recorded data, regardless of form or characteristic, that are of a scientific or technical nature. Technical data does not include computer software, but does include manuals and instructional materials and technical data formatted as a computer data base.

(7) *Unlimited rights*, as used in this clause, means the right of the Government to use, disclose, reproduce, prepare derivative works, distribute copies to the public, including by electronic means, and perform publicly and display publicly, in any manner, including by electronic means, and for any purpose whatsoever, and to have or permit others to do so.

(b) *Allocation of Rights.* (1) The Government shall have:

(i) Ownership of all technical data and computer software first produced in the performance of this Contract;

(ii) Unlimited rights in technical data and computer software specifically used in the performance of this Contract, except as provided herein regarding copyright, limited rights data, or restricted computer software, or except for other data specifically protected by statute for a period of time or, where, approved by DOE, appropriate instances of the DOE Work for Others Program;

(iii) The right to inspect technical data and computer software first produced or specifically used in the performance of this Contract at all reasonable times. The Contractor shall make available all necessary facilities to allow DOE personnel to perform such inspection;

(iv) The right to have all technical data and computer software first produced or specifically used in the performance of this Contract delivered to the Government or otherwise disposed of by the Contractor, either as the contracting officer may from time to time direct during the progress of the work or in any event as the contracting officer shall direct upon completion or termination of this Contract. The Contractor agrees to leave a copy of such data at the facility or plant to which such data relate, and to make available for access or to deliver to the Government such data upon request by the contracting officer. If such data are limited rights data or restricted computer

software, the rights of the Government in such data shall be governed solely by the provisions of paragraph (e) of this clause ("Rights in Limited Rights Data") or paragraph (f) of this clause ("Rights in Restricted Computer Software"); and

(v) The right to remove, cancel, correct, or ignore any markings not authorized by the terms of this Contract on any data furnished hereunder if, in response to a written inquiry by DOE concerning the propriety of the markings, the Contractor fails to respond thereto within 60 days or fails to substantiate the propriety of the markings. In either case DOE will notify the Contractor of the action taken.

(2) The Contractor shall have:

(i) The right to withhold limited rights data and restricted computer software unless otherwise provided in accordance with the provisions of this clause; and

(ii) The right to use for its private purposes, subject to patent, security or other provisions of this Contract, data it first produces in the performance of this Contract, except for data in DOE's Uranium Enrichment Technology, including diffusion, centrifuge, and atomic vapor laser isotope separation, provided the data requirements of this Contract have been met as of the date of the private use of such data.

(3) The Contractor agrees that for limited rights data or restricted computer software or other technical, business or financial data in the form of recorded information which it receives from, or is given access to by, DOE or a third party, including a DOE Contractor or subcontractor, and for technical data or computer software it first produces under this Contract which is authorized to be marked by DOE, the Contractor shall treat such data in accordance with any restrictive legend contained thereon.

(c) *Copyrighted Material.* (1) The Contractor shall not, without prior written authorization of the Patent Counsel, assert copyright in any technical data or computer software first produced in the performance of this contract. To the extent such authorization is granted, the Government reserves for itself and others acting on its behalf, a nonexclusive, paid-up, irrevocable, world-wide license for Governmental purposes to publish, distribute, translate, duplicate, exhibit, and perform any such data copyrighted by the Contractor.

(2) The Contractor agrees not to include in the technical data or computer software delivered under the contract any material copyrighted by the Contractor and not to knowingly include any material copyrighted by others without first granting or obtaining at no cost a license therein for the benefit of the Government of the same scope as set forth in paragraph (c)(1) of this clause. If the Contractor believes that such copyrighted material for which the license cannot be obtained must be included in the technical data or computer software to be delivered, rather than merely incorporated therein by reference, the Contractor shall obtain the written authorization of the contracting officer to include such material in the technical data or computer software prior to its delivery.

(d) *Subcontracting.* (1) Unless otherwise directed by the contracting officer, the

Contractor agrees to use in subcontracts in which technical data or computer software is expected to be produced or in subcontracts for supplies that contain a requirement for production or delivery of data in accordance with the policy and procedures of 48 CFR Subpart 27.4 as supplemented by 48 CFR 927.401 through 927.409, the clause entitled, "Rights in Data-General" at 48 CFR 52.227-14 modified in accordance with 927.409(a) and including Alternate V. Alternates II through IV of that clause may be included as appropriate with the prior approval of DOE Patent Counsel, and the Contractor shall not acquire rights in a subcontractor's limited rights data or restricted computer software, except through the use of Alternates II or III, respectively, without the prior approval of DOE Patent Counsel. The clause at 48 CFR 52.227-16, Additional Data Requirements, shall be included in subcontracts in accordance with DEAR 927.409(h). The contractor shall use instead the Rights in Data-Facilities clause at 48 CFR 970.5227-1 in subcontracts, including subcontracts for related support services, involving the design or operation of any plants or facilities or specially designed equipment for such plants or facilities that are managed or operated under its contract with DOE.

(2) It is the responsibility of the Contractor to obtain from its subcontractors technical data and computer software and rights therein, on behalf of the Government, necessary to fulfill the Contractor's obligations to the Government with respect to such data. In the event of refusal by a subcontractor to accept a clause affording the Government such rights, the Contractor shall:

(i) Promptly submit written notice to the contracting officer setting forth reasons or the subcontractor's refusal and other pertinent information which may expedite disposition of the matter, and

(ii) Not proceed with the subcontract without the written authorization of the contracting officer.

(3) Neither the Contractor nor higher-tier subcontractors shall use their power to award subcontracts as economic leverage to acquire rights in a subcontractor's limited rights data or restricted computer software for their private use.

(e) *Rights in Limited Rights Data.* Except as may be otherwise specified in this Contract as data which are not subject to this paragraph, the Contractor agrees to and does hereby grant to the Government an irrevocable, nonexclusive, paid-up license by or for the Government, in any limited rights data of the Contractor specifically used in the performance of this Contract, provided, however, that to the extent that any limited rights data when furnished or delivered is specifically identified by the Contractor at the time of initial delivery to the Government or a representative of the Government, such data shall not be used within or outside the Government except as provided in the "Limited Rights Notice" set forth. All such limited rights data shall be marked with the following "Limited Rights Notice":

Limited Rights Notice

These data contain "limited rights data," furnished under Contract No.

_____ with the United States

Department of Energy which may be duplicated and used by the Government with the express limitations that the "limited rights data" may not be disclosed outside the Government or be used for purposes of manufacture without prior permission of the Contractor, except that further disclosure or use may be made solely for the following purposes:

(a) Use (except for manufacture) by support services contractors within the scope of their contracts;

(b) This "limited rights data" may be disclosed for evaluation purposes under the restriction that the "limited rights data" be retained in confidence and not be further disclosed;

(c) This "limited rights data" may be disclosed to other contractors participating in the Government's program of which this Contract is a part for information or use (except for manufacture) in connection with the work performed under their contracts and under the restriction that the "limited rights data" be retained in confidence and not be further disclosed;

(d) This "limited rights data" may be used by the Government or others on its behalf for emergency repair or overhaul work under the restriction that the "limited rights data" be retained in confidence and not be further disclosed; and

(e) Release to a foreign government, or instrumentality thereof, as the interests of the United States Government may require, for information or evaluation, or for emergency repair or overhaul work by such government. This Notice shall be marked on any reproduction of this data in whole or in part. (End of Notice)

(f) *Rights in Restricted Computer Software.*

(1) Except as may be otherwise specified in this Contract as data which are not subject to this paragraph, the Contractor agrees to and does hereby grant to the Government an irrevocable, nonexclusive, paid-up, license by or for the Government, in any restricted computer software of the Contractor specifically used in the performance of this Contract, provided, however, that to the extent that any restricted computer software when furnished or delivered is specifically identified by the Contractor at the time of initial delivery to the Government or a representative of the Government, such data shall not be used within or outside the Government except as provided in the "Restricted Rights Notice" set forth below. All such restricted computer software shall be marked with the following "Restricted Rights Notice":

Restricted Rights Notice-Long Form

(a) This computer software is submitted with restricted rights under Department of Energy Contract No. _____. It may not be used, reproduced, or disclosed by the Government except as provided in paragraph (b) of this notice.

(b) This computer software may be:

(1) Used or copied for use in or with the computer or computers for which it was acquired, including use at any Government installation to which such computer or computers may be transferred;

(2) Used, copied for use, in a backup or replacement computer if any computer for

which it was acquired is inoperative or is replaced;

(3) Reproduced for safekeeping (archives) or backup purposes;

(4) Modified, adapted, or combined with other computer software, provided that only the portions of the derivative software consisting of the restricted computer software are to be made subject to the same restricted rights; and

(5) Disclosed to and reproduced for use by contractors under a service contract (of the type defined in 48 CFR 37.101) in accordance with subparagraphs (b)(1) through (4) of this Notice, provided the Government makes such disclosure or reproduction subject to these restricted rights.

(c) Notwithstanding the foregoing, if this computer software has been published under copyright, it is licensed to the Government, without disclosure prohibitions, with the rights set forth in the restricted rights notice above.

(d) This Notice shall be marked on any reproduction of this computer software, in whole or in part.

(End of Notice)

(2) Where it is impractical to include the Restricted Rights Notice on restricted computer software, the following short-form Notice may be used.

Restricted Rights Notice—Short Form

Use, reproduction, or disclosure is subject to restrictions set forth in the Long Form Notice of DOE Contract No. _____ with (name of Contractor).

(End of Notice)

(3) If the software is embedded, or if it is commercially impractical to mark it with human readable text, then the symbol R and the clause date (mo/yr), in brackets or a box, a [R-mo/yr], may be used. This will be read to mean restricted computer software, subject to the rights of the Government as described in the Long Form Notice, in effect as of the date indicated next to the symbol. The symbol shall not be used to mark human readable material. In the event this Contract contains any variation to the rights in the Long Form Notice, then the contract number must also be cited.

(4) If restricted computer software is delivered with the copyright notice of 17 U.S.C. 401, the software will be presumed to be published copyrighted computer software licensed to the Government without disclosure prohibitions and with unlimited rights, unless the Contractor includes the following statement with such copyright notice "Unpublished-rights reserved under the Copyright Laws of the United States."

(g) *Relationship to patents.* Nothing contained in this clause creates or is intended to imply a license to the Government in any patent or is intended to be construed as affecting the scope of any licenses or other rights otherwise granted to the Government under any patent.

(End of Clause)

Alternate I (DEC 2000). As prescribed in 48 CFR 970.2704-3(a), where access to Category C-24 restricted data is contemplated in the performance of a contract the contracting officer shall insert the phrase "and except

Restricted Data in category C-24, 10 CFR part 725, in which DOE has reserved the right to receive reasonable compensation for the use of its inventions and discoveries, including related data and technology" after "laser isotope separation" and before the comma in paragraph (b)(2)(ii) of the clause at 48 CFR 970.5227-1, Rights in Data—Facilities, as appropriate.

(End of Clause)

970.5227-2 Rights in data-technology transfer.

As prescribed in 48 CFR 970.2704-3(b), insert the following clause:

Rights in Data—Technology Transfer (DEC 2000)

(a) *Definitions.* (1) *Computer data bases*, as used in this clause, means a collection of data in a form capable of, and for the purpose of, being stored in, processed, and operated on by a computer. The term does not include computer software.

(2) *Computer software*, as used in this clause, means (i) computer programs which are data comprising a series of instructions, rules, routines, or statements, regardless of the media in which recorded, that allow or cause a computer to perform a specific operation or series of operations and (ii) data comprising source code listings, design details, algorithms, processes, flow charts, formulae, and related material that would enable the computer program to be produced, created, or compiled. The term does not include computer data bases.

(3) *Data*, as used in this clause, means recorded information, regardless of form or the media on which it may be recorded. The term includes technical data and computer software. The term "data" does not include data incidental to the administration of this contract, such as financial, administrative, cost and pricing, or management information.

(4) *Limited rights data*, as used in this clause, means data, other than computer software, developed at private expense that embody trade secrets or are commercial or financial and confidential or privileged. The Government's rights to use, duplicate, or disclose limited rights data are as set forth in the Limited Rights Notice of paragraph (g) of this clause.

(5) *Restricted computer software*, as used in this clause, means computer software developed at private expense and that is a trade secret; is commercial or financial and is confidential or privileged; or is published copyrighted computer software, including minor modifications of any such computer software. The Government's rights to use, duplicate, or disclose restricted computer software are as set forth in the Restricted Rights Notice of subparagraph (h) of this clause.

(6) *Technical data*, as used in this clause, means recorded data, regardless of form or characteristic, that are of a scientific or technical nature. Technical data does not include computer software, but does include manuals and instructional materials and technical data formatted as a computer data base.

(7) *Unlimited rights*, as used in this clause, means the rights of the Government to use,

disclose, reproduce, prepare derivative works, distribute copies to the public, including by electronic means, and perform publicly and display publicly, in any manner, including by electronic means, and for any purpose whatsoever, and to have or permit others to do so.

(b) *Allocation of Rights.* (1) The Government shall have:

(i) Ownership of all technical data and computer software first produced in the performance of this Contract;

(ii) Unlimited rights in technical data and computer software specifically used in the performance of this Contract, except as provided herein regarding copyright, limited rights data, or restricted computer software, and except for data subject to the withholding provisions for protected Cooperative Research and Development Agreement (CRADA) information in accordance with Technology Transfer actions under this Contract, or other data specifically protected by statute for a period of time or, where, approved by DOE, appropriate instances of the DOE Work for Others Program;

(iii) The right to inspect technical data and computer software first produced or specifically used in the performance of this Contract at all reasonable times. The Contractor shall make available all necessary facilities to allow DOE personnel to perform such inspection;

(iv) The right to have all technical data and computer software first produced or specifically used in the performance of this Contract delivered to the Government or otherwise disposed of by the Contractor, either as the contracting officer may from time to time direct during the progress of the work or in any event as the contracting officer shall direct upon completion or termination of this Contract. The Contractor agrees to leave a copy of such data at the facility or plant to which such data relate, and to make available for access or to deliver to the Government such data upon request by the contracting officer. If such data are limited rights data or restricted computer software, the rights of the Government in such data shall be governed solely by the provisions of paragraph (g) of this clause ("Rights in Limited Rights Data") or paragraph (h) of this clause ("Rights in Restricted Computer Software"); and (v) The right to remove, cancel, correct, or ignore any markings not authorized by the terms of this Contract on any data furnished hereunder if, in response to a written inquiry by DOE concerning the propriety of the markings, the Contractor fails to respond thereto within 60 days or fails to substantiate the propriety of the markings. In either case DOE will notify the Contractor of the action taken.

(2) The Contractor shall have:

(i) The right to withhold limited rights data and restricted computer software unless otherwise provided in provisions of this clause;

(ii) The right to use for its private purposes, subject to patent, security or other provisions of this Contract, data it first produces in the performance of this Contract, except for data in DOE's Uranium Enrichment Technology, including diffusion, centrifuge, and atomic

vapor laser isotope separation, provided the data requirements of this Contract have been met as of the date of the private use of such data; and

(iii) The right to assert copyright subsisting in scientific and technical articles as provided in paragraph (d) of this clause and the right to request permission to assert copyright subsisting in works other than scientific and technical articles as provided in paragraph (e) of this clause.

(3) The Contractor agrees that for limited rights data or restricted computer software or other technical business or financial data in the form of recorded information which it receives from, or is given access to by DOE or a third party, including a DOE contractor or subcontractor, and for technical data or computer software it first produces under this Contract which is authorized to be marked by DOE, the Contractor shall treat such data in accordance with any restrictive legend contained thereon.

(c) *Copyright (General)*. (1) The Contractor agrees not to mark, register, or otherwise assert copyright in any data in a published or unpublished work, other than as set forth in paragraphs (d) and (e) of this clause.

(2) Except for material to which the Contractor has obtained the right to assert copyright in accordance with either paragraph (d) or (e) of this clause, the Contractor agrees not to include in the data delivered under this Contract any material copyrighted by the Contractor and not to knowingly include any material copyrighted by others without first granting or obtaining at no cost a license therein for the benefit of the Government of the same scope as set forth in paragraph (d) of this clause. If the Contractor believes that such copyrighted material for which the license cannot be obtained must be included in the data to be delivered, rather than merely incorporated therein by reference, the Contractor shall obtain the written authorization of the contracting officer to include such material in the data prior to its delivery.

(d) *Copyrighted works (scientific and technical articles)*. (1) The Contractor shall have the right to assert, without prior approval of the contracting officer, copyright subsisting in scientific and technical articles composed under this contract or based on or containing data first produced in the performance of this Contract, and published in academic, technical or professional journals, symposia, proceedings, or similar works. When assertion of copyright is made, the Contractor shall affix the applicable copyright notice of 17 U.S.C. 401 or 402 and acknowledgment of Government sponsorship (including contract number) on the data when such data are delivered to the Government as well as when the data are published or deposited for registration as a published work in the U.S. Copyright Office. The Contractor grants to the Government, and others acting on its behalf, a nonexclusive, paid-up, irrevocable, world-wide license in such copyrighted data to reproduce, prepare derivative works, distribute copies to the public, and perform publicly and display publicly, by or on behalf of the Government.

(2) The contractor shall mark each scientific or technical article first produced

or composed under this Contract and submitted for journal publication or similar means of dissemination with a notice, similar in all material respects to the following, on the front reflecting the Government's non-exclusive, paid-up, irrevocable, world-wide license in the copyright.

Notice: This manuscript has been authored by [insert the name of the Contractor] under Contract No. [insert the contract number] with the U.S. Department of Energy. The United States Government retains and the publisher, by accepting the article for publication, acknowledges that the United States Government retains a non-exclusive, paid-up, irrevocable, world-wide license to publish or reproduce the published form of this manuscript, or allow others to do so, for United States Government purposes.

(End of Notice)

(3) The title to the copyright of the original of unclassified graduate theses and the original of related unclassified scientific papers shall vest in the author thereof, subject to the right of DOE to retain duplicates of such documents and to use such documents for any purpose whatsoever without any claim on the part of the author or the contractor for additional compensation.

(e) *Copyrighted works (other than scientific and technical articles and data produced under a CRADA)*. The Contractor may obtain permission to assert copyright subsisting in technical data and computer software first produced by the Contractor in performance of this Contract, where the Contractor can show that commercialization would be enhanced by such copyright protection, subject to the following:

(1) Contractor Request to Assert Copyright.

(i) For data other than scientific and technical articles and data produced under a CRADA, the Contractor shall submit in writing to Patent Counsel its request to assert copyright in data first produced in the performance of this Contract pursuant to this clause. The right of the Contractor to copyright data first produced under a CRADA is as described in the individual CRADA. Each request by the Contractor must include:

(A) The identity of the data (including any computer program) for which the Contractor requests permission to assert copyright, as well as an abstract which is descriptive of the data and is suitable for dissemination purposes, (B) The program under which it was funded, (C) Whether, to the best knowledge of the Contractor, the data is subject to an international treaty or agreement, (D) Whether the data is subject to export control, (E) A statement that the Contractor plans to commercialize the data in compliance with the clause of this contract entitled, "Technology Transfer Mission," within five (5) years after obtaining permission to assert copyright or, on a case-by-case basis, a specified longer period where the Contractor can demonstrate that the ability to commercialize effectively is dependent upon such longer period, and (F) For data other than computer software, a statement explaining why the assertion of copyright is necessary to enhance

commercialization and is consistent with DOE's dissemination responsibilities.

(ii) For data that is developed using other funding sources in addition to DOE funding, the permission to assert copyright in accordance with this clause must also be obtained by the Contractor from all other funding sources prior to the Contractor's request to Patent Counsel. The request shall include the Contractor's certification or other documentation acceptable to Patent Counsel demonstrating such permission has been obtained.

(iii) Permission for the Contractor to assert copyright in excepted categories of data as determined by DOE will be expressly withheld. Such excepted categories include data whose release (A) would be detrimental to national security, i.e., involve classified information or data or sensitive information under Section 148 of the Atomic Energy Act of 1954, as amended, or are subject to export control for nonproliferation and other nuclear-related national security purposes, (B) would not enhance the appropriate transfer or dissemination and commercialization of such data, (C) would have a negative impact on U.S. industrial competitiveness, (D) would prevent DOE from meeting its obligations under treaties and international agreements, or (E) would be detrimental to one or more of DOE's programs. Additional excepted categories may be added by the Assistant General Counsel for Technology Transfer and Intellectual Property. Where data are determined to be under export control restriction, the Contractor may obtain permission to assert copyright subject to the provisions of this clause for purposes of limited commercialization in a manner that complies with export control statutes and applicable regulations. In addition, notwithstanding any other provision of this Contract, all data developed with Naval Reactors' funding and those data that are classified fall within excepted categories. The rights of the Contractor in data are subject to the disposition of data rights in the treaties and international agreements identified under this Contract as well as those additional treaties and international agreements which DOE may from time to time identify by unilateral amendment to the Contract; such amendment listing added treaties and international agreements is effective only for data which is developed after the date such treaty or international agreement is added to this Contract. Also, the Contractor will not be permitted to assert copyright in data in the form of various technical reports generated by the Contractor under the Contract without first obtaining the advanced written permission of the contracting officer.

(2) DOE Review and Response to Contractor's Request. The Patent Counsel shall use its best efforts to respond in writing within 90 days of receipt of a complete request by the Contractor to assert copyright in technical data and computer software pursuant to this clause. Such response shall either give or withhold DOE's permission for the Contractor to assert copyright or advise the Contractor that DOE needs additional time to respond, and the reasons therefor.

(3) Permission for Contractor to Assert Copyright.

(i) For computer software, the Contractor shall furnish to the DOE designated, centralized software distribution and control point, the Energy Science and Technology Software Center, at the time permission to assert copyright is given under paragraph (e)(2) of this clause: (A) An abstract describing the software suitable for publication, (B) the source code for each software program, and (C) the object code and at least the minimum support documentation needed by a technically competent user to understand and use the software. The Patent Counsel, for good cause shown by the Contractor, may allow the minimum support documentation to be delivered within 60 days after permission to assert copyright is given or at such time the minimum support documentation becomes available. The Contractor acknowledges that the DOE designated software distribution and control point may provide a technical description of the software in an announcement identifying its availability from the copyright holder.

(ii) Unless otherwise directed by the contracting officer, for data other than computer software to which the Contractor has received permission to assert copyright under paragraph (e)(2) of this clause above, the Contractor shall within sixty (60) days of obtaining such permission furnish to DOE's Office of Scientific and Technical Information (OSTI) a copy of such data as well as an abstract of the data suitable for dissemination purposes. The Contractor acknowledges that OSTI may provide an abstract of the data in an announcement to DOE, its contractors and to the public identifying its availability from the copyright holder.

(iii) For a five year period or such other specified period as specifically approved by Patent Counsel beginning on the date the Contractor is given permission to assert copyright in data, the Contractor grants to the Government, and others acting on its behalf, a paid-up, nonexclusive, irrevocable worldwide license in such copyrighted data to reproduce, prepare derivative works and perform publicly and display publicly, by or on behalf of the Government. Upon request, the initial period may be extended after DOE approval. The DOE approval will be based on the standard that the work is still commercially available and the market demand is being met.

(iv) After the period approved by Patent Counsel for application of the limited Government license described in paragraph (e)(3)(iii) of this clause, or if, prior to the end of such period(s), the Contractor abandons commercialization activities pertaining to the data to which the Contractor has been given permission to assert copyright, the Contractor grants to the Government, and others acting on its behalf, a paid-up, nonexclusive, irrevocable worldwide license in such copyrighted data to reproduce, distribute copies to the public, prepare derivative works, perform publicly and display publicly, and to permit others to do so.

(v) Whenever the Contractor asserts copyright in data pursuant to this paragraph

(e), the Contractor shall affix the applicable copyright notice of 17 U.S.C. 401 or 402 on the copyrighted data and also an acknowledgment of the Government sponsorship and license rights of paragraphs (e)(3) (iii) and (iv) of this clause. Such action shall be taken when the data are delivered to the Government, published, licensed or deposited for registration as a published work in the U.S. Copyright Office. The acknowledgment of Government sponsorship and license rights shall be as follows: Notice: These data were produced by (insert name of Contractor) under Contract No.

_____ with the Department of Energy. For (period approved by DOE Patent Counsel) from (date permission to assert copyright was obtained), the Government is granted for itself and others acting on its behalf a nonexclusive, paid-up, irrevocable worldwide license in this data to reproduce, prepare derivative works, and perform publicly and display publicly, by or on behalf of the Government. There is provision for the possible extension of the term of this license. Subsequent to that period or any extension granted, the Government is granted for itself and others acting on its behalf a nonexclusive, paid-up, irrevocable worldwide license in this data to reproduce, prepare derivative works, distribute copies to the public, perform publicly and display publicly, and to permit others to do so. The specific term of the license can be identified by inquiry made to Contractor or DOE. Neither the United States nor the United States Department of Energy, nor any of their employees, makes any warranty, express or implied, or assumes any legal liability or responsibility for the accuracy, completeness, or usefulness of any data, apparatus, product, or process disclosed, or represents that its use would not infringe privately owned rights.

(End of Notice)

(vi) With respect to any data to which the Contractor has received permission to assert copyright, the DOE has the right, during the five (5) year or specified longer period approved by Patent Counsel as provided for in paragraph (e) of this clause, to request the Contractor to grant a nonexclusive, partially exclusive or exclusive license in any field of use to a responsible applicant(s) upon terms that are reasonable under the circumstances, and if the Contractor refuses such request, to grant such license itself, if the DOE determines that the Contractor has not made a satisfactory demonstration that either it or its licensee(s) is actively pursuing commercialization of the data as set forth in subparagraph (e)(1)(A) of this clause. Before licensing under this subparagraph (vi), DOE shall furnish the Contractor a written request for the Contractor to grant the stated license, and the Contractor shall be allowed thirty (30) days (or such longer period as may be authorized by the contracting officer for good cause shown in writing by the Contractor) after such notice to show cause why the license should not be granted. The Contractor shall have the right to appeal the decision of the DOE to grant the stated license to the Invention Licensing Appeal Board as set forth in 10 CFR 781.65—"Appeals."

(vii) No costs shall be allowable for maintenance of copyrighted data, primarily for the benefit of the Contractor and/or a licensee which exceeds DOE Program needs, except as expressly provided in writing by the contracting officer. The Contractor may use its net royalty income to effect such maintenance costs.

(viii) At any time the Contractor abandons commercialization activities for data for which the Contractor has received permission to assert copyright in accordance with this clause, it shall advise OSTI and Patent Counsel and upon request assign the copyright to the Government so that the Government can distribute the data to the public.

(4) The following notice may be placed on computer software prior to any publication and prior to the Contractor's obtaining permission from the Department of Energy to assert copyright in the computer software pursuant to paragraph (c)(3) of this section.

Notice: This computer software was prepared by [insert the Contractor's name and the individual author], hereinafter the Contractor, under Contract [insert the Contract Number] with the Department of Energy (DOE). All rights in the computer software are reserved by DOE on behalf of the United States Government and the Contractor as provided in the Contract. You are authorized to use this computer software for Governmental purposes but it is not to be released or distributed to the public. NEITHER THE GOVERNMENT NOR THE CONTRACTOR MAKES ANY WARRANTY, EXPRESS OR IMPLIED, OR ASSUMES ANY LIABILITY FOR THE USE OF THIS SOFTWARE. This notice including this sentence must appear on any copies of this computer software.

(End of Notice)

(5) a similar notice can be used for data, other than computer software, upon approval of DOE Patent Counsel.

(f) *Subcontracting.* (1) Unless otherwise directed by the contracting officer, the Contractor agrees to use in subcontracts in which technical data or computer software is expected to be produced or in subcontracts for supplies that contain a requirement for production or delivery of data in accordance with the policy and procedures of 48 CFR Subpart 27.4 as supplemented by 48 CFR 927.401 through 927.409, the clause entitled, "Rights in Data-General" at 48 CFR 52.227-14 modified in accordance with 927.409(a) and including Alternate V. Alternates II through IV of that clause may be included as appropriate with the prior approval of DOE Patent Counsel, and the Contractor shall not acquire rights in a subcontractor's limited rights data or restricted computer software, except through the use of Alternates II or III, respectively, without the prior approval of DOE Patent Counsel. The clause at 48 CFR 52.227-16, Additional Data Requirements, shall be included in subcontracts in accordance with 48 CFR 927.409(h). The Contractor shall use instead the Rights in Data-Facilities clause at 48 CFR 970.5227-1 in subcontracts, including subcontracts for related support services, involving the design or operation of any plants or facilities or specially designed equipment for such plants

or facilities that are managed or operated under its contract with DOE.

(2) It is the responsibility of the Contractor to obtain from its subcontractors technical data and computer software and rights therein, on behalf of the Government, necessary to fulfill the Contractor's obligations to the Government with respect to such data. In the event of refusal by a subcontractor to accept a clause affording the Government such rights, the Contractor shall:

(i) Promptly submit written notice to the contracting officer setting forth reasons or the subcontractor's refusal and other pertinent information which may expedite disposition of the matter, and

(ii) Not proceed with the subcontract without the written authorization of the contracting officer.

(3) Neither the Contractor nor higher-tier subcontractors shall use their power to award subcontracts as economic leverage to acquire rights in a subcontractor's limited rights data and restricted computer software for their private use.

(g) *Rights in Limited Rights Data.* Except as may be otherwise specified in this Contract as data which are not subject to this paragraph, the Contractor agrees to and does hereby grant to the Government an irrevocable nonexclusive, paid-up license by or for the Government, in any limited rights data of the Contractor specifically used in the performance of this Contract, provided, however, that to the extent that any limited rights data when furnished or delivered is specifically identified by the Contractor at the time of initial delivery to the Government or a representative of the Government, such data shall not be used within or outside the Government except as provided in the "Limited Rights Notice" set forth below. All such limited rights data shall be marked with the following "Limited Rights Notice:"

Limited Rights Notice

These data contain "limited rights data," furnished under Contract No. _____ with the United States Department of Energy which may be duplicated and used by the Government with the express limitations that the "limited rights data" may not be disclosed outside the Government or be used for purposes of manufacture without prior permission of the Contractor, except that further disclosure or use may be made solely for the following purposes:

(a) Use (except for manufacture) by support services contractors within the scope of their contracts;

(b) This "limited rights data" may be disclosed for evaluation purposes under the restriction that the "limited rights data" be retained in confidence and not be further disclosed;

(c) This "limited rights data" may be disclosed to other contractors participating in the Government's program of which this Contract is a part for information or use (except for manufacture) in connection with the work performed under their contracts and under the restriction that the "limited rights data" be retained in confidence and not be further disclosed;

(d) This "limited rights data" may be used by the Government or others on its behalf for emergency repair or overhaul work under the

restriction that the "limited rights data" be retained in confidence and not be further disclosed; and

(e) Release to a foreign government, or instrumentality thereof, as the interests of the United States Government may require, for information or evaluation, or for emergency repair or overhaul work by such government.

This Notice shall be marked on any reproduction of this data in whole or in part.

(End of Notice)

(h) *Rights in Restricted Computer Software.*

(1) Except as may be otherwise specified in this Contract as data which are not subject to this paragraph, the Contractor agrees to and does hereby grant to the Government an irrevocable, nonexclusive, paid-up, license by or for the Government, in any restricted computer software of the Contractor specifically used in the performance of this Contract; provided, however, that to the extent that any restricted computer software when furnished or delivered is specifically identified by the Contractor at the time of initial delivery to the Government or a representative of the Government, such data shall not be used within or outside the Government except as provided in the "Restricted Rights Notice" set forth below. All such restricted computer software shall be marked with the following "Restricted Rights Notice:"

Restricted Rights Notice—Long Form

(a) This computer software is submitted with restricted rights under Department of Energy Contract No. _____. It may not be used, reproduced, or disclosed by the Government except as provided in paragraph (b) of this notice.

(b) This computer software may be:

(1) Used or copied for use in or with the computer or computers for which it was acquired, including use at any Government installation to which such computer or computers may be transferred;

(2) Used, copied for use, in a backup or replacement computer if any computer for which it was acquired is inoperative or is replaced;

(3) Reproduced for safekeeping (archives) or backup purposes;

(4) Modified, adapted, or combined with other computer software, provided that only the portions of the derivative software consisting of the restricted computer software are to be made subject to the same restricted rights; and

(5) Disclosed to and reproduced for use by contractors under a service contract (of the type defined in 48 CFR 37.101) in accordance with subparagraphs (b)(1) through (4) of this Notice, provided the Government makes such disclosure or reproduction subject to these restricted rights.

(c) Notwithstanding the foregoing, if this computer software has been published under copyright, it is licensed to the Government, without disclosure prohibitions, with the rights set forth in the restricted rights notice above.

(d) This Notice shall be marked on any reproduction of this computer software, in whole or in part.

(End of Notice)

(2) Where it is impractical to include the Restricted Rights Notice on restricted computer software, the following short-form Notice may be used in lieu thereof:

Restricted Rights Notice—Short Form

Use, reproduction, or disclosure is subject to restrictions set forth in the Long Form Notice of DOE Contract No. _____ with (name of Contractor).

(End of Notice)

(3) If the software is embedded, or if it is commercially impractical to mark it with human readable text, then the symbol R and the clause date (mo/yr) in brackets or a box, a [R-mo/yr], may be used. This will be read to mean restricted computer software, subject to the rights of the Government as described in the Long Form Notice, in effect as of the date indicated next to the symbol. The symbol shall not be used to mark human readable material. In the event this Contract contains any variation to the rights in the Long Form Notice, then the contract number must also be cited.

(4) If restricted computer software is delivered with the copyright notice of 17 U.S.C. 401, the software will be presumed to be published copyrighted computer software licensed to the Government without disclosure prohibitions and with unlimited rights, unless the Contractor includes the following statement with such copyright notice "Unpublished-rights reserved under the Copyright Laws of the United States."

(i) *Relationship to patents.* Nothing contained in this clause creates or is intended to imply a license to the Government in any patent or is intended to be construed as affecting the scope of any licenses or other rights otherwise granted to the Government under any patent.

(End of Clause)

Alternate I (DEC 2000). As prescribed in 48 CFR 970.2704-3(b), where access to Category C-24 restricted data is contemplated in the performance of a contract the contracting officer shall insert the phrase "and except Restricted Data in category C-24, 10 CFR part 725, in which DOE has reserved the right to receive reasonable compensation for the use of its inventions and discoveries, including related data and technology" after "laser isotope separation" and before the comma in paragraph (b)(2)(ii) of the clause at 48 CFR 970.5227-2, Rights in Data—Technology Transfer, as appropriate.

(End of Clause)

970.5227-3 Technology transfer mission.

As prescribed in 48 CFR 970.2770-4(a), insert the following clause: Technology Transfer Mission (DEC 2000)

This clause has as its purpose implementation of the National Competitiveness Technology Transfer Act of 1989 (Sections 3131, 3132, 3133, and 3157 of Pub. L. 101-189 and as amended by Pub. L. 103-160, Sections 3134 and 3160). The Contractor shall conduct technology transfer activities with a purpose of providing benefit from Federal research to U.S. industrial competitiveness.

(a) *Authority.* (1) In order to ensure the full use of the results of research and development efforts of, and the capabilities of, the Laboratory, technology transfer, including Cooperative Research and Development Agreements (CRADAs), is established as a mission of the Laboratory consistent with the policy, principles and purposes of Sections 11(a)(1) and 12(g) of the Stevenson-Wydler Technology Innovation Act of 1980, as amended (15 U.S.C. 3710a); Section 3132(b) of Pub. L. 101-189, Sections 3134 and 3160 of Pub. L. 103-160, and of Chapter 38 of the Patent Laws (35 U.S.C. 200 *et seq.*); Section 152 of the Atomic Energy Act of 1954, as amended (42 U.S.C. 2182); Section 9 of the Federal Nonnuclear Energy Research and Development Act of 1974 (42 U.S.C. 5908); and Executive Order 12591 of April 10, 1987.

(2) In pursuing the technology transfer mission, the Contractor is authorized to conduct activities including but not limited to: identifying and protecting Intellectual Property made, created or acquired at or by the Laboratory; negotiating licensing agreements and assignments for Intellectual Property made, created or acquired at or by the Laboratory that the Contractor controls or owns; bailments; negotiating all aspects of and entering into CRADAs; providing technical consulting and personnel exchanges; conducting science education activities and reimbursable Work for Others (WFO); providing information exchanges; and making available laboratory or weapon production user facilities. It is fully expected that the Contractor shall use all of the mechanisms available to it to accomplish this technology transfer mission, including, but not limited to, CRADAs, user facilities, WFO, science education activities, consulting, personnel, assignments, and licensing in accordance with this clause.

(b) *Definitions.* (1) *Contractor's Laboratory Director* means the individual who has supervision over all or substantially all of the Contractor's operations at the Laboratory.

(2) *Intellectual Property* means patents, trademarks, copyrights, mask works, protected CRADA information, and other forms of comparable property rights protected by Federal Law and other foreign counterparts.

(3) *Cooperative Research and Development Agreement (CRADA)* means any agreement entered into between the Contractor as operator of the Laboratory, and one or more parties including at least one non-Federal party under which the Government, through its laboratory, provides personnel, services, facilities, equipment, intellectual property, or other resources with or without reimbursement (but not funds to non-Federal parties) and the non-Federal parties provide funds, personnel, services, facilities, equipment, intellectual property, or other resources toward the conduct of specified research or development efforts which are consistent with the missions of the Laboratory; except that such term does not include a procurement contract, grant, or cooperative agreement as those terms are used in sections 6303, 6304, and 6305 of Title 31 of the United States Code.

(4) *Joint Work Statement (JWS)* means a proposal for a CRADA prepared by the

Contractor, signed by the Contractor's Laboratory Director or designee which describes the following:

- (i) Purpose;
- (ii) Scope of Work which delineates the rights and responsibilities of the Government, the Contractor and Third Parties, one of which must be a non-Federal party;
- (iii) Schedule for the work; and
- (iv) Cost and resource contributions of the parties associated with the work and the schedule.

(5) *Assignment* means any agreement by which the Contractor transfers ownership of Laboratory Intellectual Property, subject to the Government's retained rights.

(6) *Laboratory Biological Materials* means biological materials capable of replication or reproduction, such as plasmids, deoxyribonucleic acid molecules, ribonucleic acid molecules, living organisms of any sort and their progeny, including viruses, prokaryote and eukaryote cell lines, transgenic plants and animals, and any derivatives or modifications thereof or products produced through their use or associated biological products, made under this contract by Laboratory employees or through the use of Laboratory research facilities.

(7) *Laboratory Tangible Research Product* means tangible material results of research which

- (i) are provided to permit replication, reproduction, evaluation or confirmation of the research effort, or to evaluate its potential commercial utility;
- (ii) are not materials generally commercially available; and
- (iii) were made under this contract by Laboratory employees or through the use of Laboratory research facilities.

(8) *Bailment* means any agreement in which the Contractor permits the commercial or non-commercial transfer of custody, access or use of Laboratory Biological Materials or Laboratory Tangible Research Product for a specified purpose of technology transfer or research and development, including without limitation evaluation, and without transferring ownership to the bailee.

(c) *Allowable Costs.* (1) The Contractor shall establish and carry out its technology transfer efforts through appropriate organizational elements consistent with the requirements for an Office of Research and Technology Applications (ORTA) pursuant to paragraphs (b) and (c) of Section 11 of the Stevenson-Wydler Technology Innovation Act of 1980, as amended (15 U.S.C. 3710). The costs associated with the conduct of technology transfer through the ORTA including activities associated with obtaining, maintaining, licensing, and assigning Intellectual Property rights, increasing the potential for the transfer of technology, and the widespread notice of technology transfer opportunities, shall be deemed allowable provided that such costs meet the other requirements of the allowable costs provisions of this Contract. In addition to any separately designated funds, these costs in any fiscal year shall not exceed an amount equal to 0.5 percent of the operating funds included in the Federal research and

development budget (including Work For Others) of the Laboratory for that fiscal year without written approval of the contracting officer.

(2) The Contractor's participation in litigation to enforce or defend Intellectual Property claims incurred in its technology transfer efforts shall be as provided in the clause entitled "Insurance—Litigation and Claims" of this contract.

(d) *Conflicts of Interest—Technology Transfer.* The Contractor shall have implementing procedures that seek to avoid employee and organizational conflicts of interest, or the appearance of conflicts of interest, in the conduct of its technology transfer activities. These procedures shall apply to other persons participating in Laboratory research or related technology transfer activities. Such implementing procedures shall be provided to the contracting officer for review and approval within sixty (60) days after execution of this contract. The contracting officer shall have thirty (30) days thereafter to approve or require specific changes to such procedures. Such implementing procedures shall include procedures to:

(1) Inform employees of and require conformance with standards of conduct and integrity in connection with the CRADA activity in accordance with the provisions of paragraph (n)(5) of this clause;

(2) Review and approve employee activities so as to avoid conflicts of interest arising from commercial utilization activities relating to Contractor-developed Intellectual Property;

(3) Conduct work performed using royalties so as to avoid interference with or adverse effects on ongoing DOE projects and programs;

(4) Conduct activities relating to commercial utilization of Contractor-developed Intellectual Property so as to avoid interference with or adverse effects on user facility or WFO activities of the Contractor;

(5) Conduct DOE-funded projects and programs so as to avoid the appearance of conflicts of interest or actual conflicts of interest with non-Government funded work;

(6) Notify the contracting officer with respect to any new work to be performed or proposed to be performed under the Contract for DOE or other Federal agencies where the new work or proposal involves Intellectual Property in which the Contractor has obtained or intends to request or elect title;

(7) Except as provided elsewhere in this Contract, obtain the approval of the contracting officer for any licensing of or assignment of title to Intellectual Property rights by the Contractor to any business or corporate affiliate of the Contractor;

(8) Obtain the approval of the contracting officer prior to any assignment, exclusive licensing, or option for exclusive licensing, of Intellectual Property to any individual who has been a Laboratory employee within the previous two years or to the company in which the individual is a principal; and

(9) Notify non-Federal sponsors of WFO activities, or non-Federal users of user facilities, of any relevant Intellectual Property interest of the Contractor prior to execution of WFOs or user agreements.

(10) Notify DOE prior to evaluating a proposal by a third party or DOE, when the subject matter of the proposal involves an elected or waived subject invention under this contract or one in which the Contractor intends to elect to retain title under this contract.

(e) *Fairness of Opportunity.* In conducting its technology transfer activities, the Contractor shall prepare procedures and take all reasonable measures to ensure widespread notice of availability of technologies suited for transfer and opportunities for exclusive licensing and joint research arrangements. The requirement to widely disseminate the availability of technology transfer opportunities does not apply to a specific application originated outside of the Laboratory and by entities other than the Contractor.

(f) *U.S. Industrial Competitiveness.* (1) In the interest of enhancing U.S. Industrial Competitiveness, the Contractor shall, in its licensing and assignments of Intellectual Property, give preference in such a manner as to enhance the accrual of economic and technological benefits to the U.S. domestic economy. The Contractor shall consider the following factors in all of its licensing and assignment decisions involving Laboratory intellectual property where the Laboratory obtains rights during the course of the Contractor's operation of the Laboratory under this contract:

(i) whether any resulting design and development will be performed in the United States and whether resulting products, embodying parts, including components thereof, will be substantially manufactured in the United States; or

(ii) (A) whether the proposed licensee or assignee has a business unit located in the United States and whether significant economic and technical benefits will flow to the United States as a result of the license or assignment agreement; and

(B) in licensing any entity subject to the control of a foreign company or government, whether such foreign government permits United States agencies, organizations or other persons to enter into cooperative research and development agreements and licensing agreements, and has policies to protect United States Intellectual Property rights.

(2) If the Contractor determines that neither of the conditions in paragraphs (f)(1)(i) or (ii) of this clause are likely to be fulfilled, the Contractor, prior to entering into such an agreement, must obtain the approval of the contracting officer. The contracting officer shall act on any such requests for approval within thirty (30) days.

(3) The Contractor agrees to be bound by the provisions of 35 U.S.C. 204 (Preference for United States industry).

(g) *Indemnity—Product Liability.* In entering into written technology transfer agreements, including but not limited to, research and development agreements, licenses, assignments and CRADAs, the Contractor agrees to include in such agreements a requirement that the U.S. Government and the Contractor, except for any negligent acts or omissions of the Contractor, be indemnified for all damages, costs, and expenses, including attorneys'

fees, arising from personal injury or property damage occurring as a result of the making, using or selling of a product, process or service by or on behalf of the Participant, its assignees or licensees which was derived from the work performed under the agreement. The Contractor shall identify and obtain the approval of the contracting officer for any proposed exceptions to this requirement such as where State or local law expressly prohibit the Participant from providing indemnification or where the research results will be placed in the public domain.

(h) *Disposition of Income.* (1) Royalties or other income earned or retained by the Contractor as a result of performance of authorized technology transfer activities herein shall be used by the Contractor for scientific research, development, technology transfer, and education at the Laboratory, consistent with the research and development mission and objectives of the Laboratory and subject to Section 12(b)(5) of the Stevenson-Wydler Technology Innovation Act of 1980, as amended (15 U.S.C. 3710a(b)(5)) and Chapter 38 of the Patent Laws (35 U.S.C. 200 *et seq.*) as amended through the effective date of this contract award or modification. If the net amounts of such royalties and income received from patent licensing after payment of patenting costs, licensing costs, payments to inventors and other expenses incidental to the administration of Subject Inventions during any fiscal year exceed 5 percent of the Laboratory's budget for that fiscal year, 75 percent of such excess amounts shall be paid to the Treasury of the United States, and the remaining amount of such excess shall be used by the Contractor for the purposes as described above in this paragraph. Any inventions arising out of such scientific research and development activities shall be deemed to be Subject Inventions under the Contract.

(2) The Contractor shall include as a part of its annual Laboratory Institutional Plan or other such annual document a plan setting out those uses to which royalties and other income received as a result of performance of authorized technology transfer activities herein will be applied at the Laboratory, and at the end of the year, provide a separate accounting for how the funds were actually used. Under no circumstances shall these royalties and income be used for an illegal augmentation of funds furnished by the U.S. Government.

(3) The Contractor shall establish subject to the approval of the contracting officer a policy for making awards or sharing of royalties with Contractor employees, other coinventors and coauthors, including Federal employee coinventors when deemed appropriate by the contracting officer.

(i) *Transfer to Successor Contractor.* In the event of termination or upon the expiration of this Contract, any unexpended balance of income received for use at the Laboratory shall be transferred, at the contracting officer's request, to a successor contractor, or in the absence of a successor contractor, to such other entity as designated by the contracting officer. The Contractor shall transfer title, as one package, to the extent the

Contractor retains title, in all patents and patent applications, licenses, accounts containing royalty revenues from such license agreements, including equity positions in third party entities, and other Intellectual Property rights which arose at the Laboratory, to the successor contractor or to the Government as directed by the contracting officer.

(j) *Technology Transfer Affecting the National Security.* (1) The Contractor shall notify and obtain the approval of the contracting officer, prior to entering into any technology transfer arrangement, when such technology or any part of such technology is classified or sensitive under Section 148 of the Atomic Energy Act (42 U.S.C. 2168). Such notification shall include sufficient information to enable DOE to determine the extent that commercialization of such technology would enhance or diminish security interests of the United States, or diminish communications within DOE's nuclear weapon production complex. DOE shall use its best efforts to complete its determination within sixty (60) days of the Contractor's notification, and provision of any supporting information, and DOE shall promptly notify the Contractor as to whether the technology is transferable.

(2) The Contractor shall include in all of its technology transfer agreements with third parties, including, but not limited to, CRADAs, licensing agreements and assignments, notice to such third parties that the export of goods and/or Technical Data from the United States may require some form of export control license or other authority from the U.S. Government and that failure to obtain such export control license may result in criminal liability under U.S. laws.

(3) For other than fundamental research as defined in National Security Decision Directive 189, the Contractor is responsible to conduct internal export control reviews and assure that technology is transferred in accordance with applicable law.

(k) *Records.* The Contractor shall maintain records of its technology transfer activities in a manner and to the extent satisfactory to the DOE and specifically including, but not limited to, the licensing agreements, assignments and the records required to implement the requirements of paragraphs (e), (f), and (h) of this clause and shall provide reports to the contracting officer to enable DOE to maintain the reporting requirements of Section 12(c)(6) of the Stevenson-Wydler Technology Innovation Act of 1980, as amended (15 U.S.C. 3710a(c)(6)). Such reports shall be made annually in a format to be agreed upon between the Contractor and DOE and in such a format which will serve to adequately inform DOE of the Contractor's technology transfer activities while protecting any data not subject to disclosure under the Rights in Technical Data clause and paragraph (n) of this clause. Such records shall be made available in accordance with the clauses of this Contract pertaining to inspection, audit and examination of records.

(l) *Reports to Congress.* To facilitate DOE's reporting to Congress, the Contractor is required to submit annually to DOE a

technology transfer plan for conducting its technology transfer function for the upcoming year, including plans for securing Intellectual Property rights in Laboratory innovations with commercial promise and plans for managing such innovations so as to benefit the competitiveness of United States industry. This plan shall be provided to the contracting officer on or before October 1st of each year.

(m) *Oversight and Appraisal.* The Contractor is responsible for developing and implementing effective internal controls for all technology transfer activities consistent with the audit and record requirements of this Contract. Laboratory Contractor performance in implementing the technology transfer mission and the effectiveness of the Contractor's procedures will be evaluated by the contracting officer as part of the annual appraisal process, with input from the cognizant Secretarial Officer or program office.

(n) *Technology Transfer Through Cooperative Research and Development Agreements.* Upon approval of the contracting officer and as provided in a DOE approved Joint Work Statement (JWS), the Laboratory Director, or designee, may enter into CRADAs on behalf of the DOE subject to the requirements set forth in this paragraph.

(1) *Review and Approval of CRADAs.* (i) Except as otherwise directed in writing by the contracting officer, each JWS shall be submitted to the contracting officer for approval. The Contractor's Laboratory Director or designee shall provide a program mission impact statement and shall include an impact statement regarding related Intellectual Property rights known by the Contractor to be owned by the Government to assist the contracting officer in the approval determination.

(ii) The Contractor shall also include (specific to the proposed CRADA), a statement of compliance with the Fairness of Opportunity requirements of paragraph (e) of this clause.

(iii) Within ninety (90) days after submission of a JWS, the contracting officer shall approve, disapprove or request modification to the JWS. If a modification is required, the contracting officer shall approve or disapprove any resubmission of the JWS within thirty (30) days of its resubmission, or ninety (90) days from the date of the original submission, whichever is later. The contracting officer shall provide a written explanation to the Contractor's Laboratory Director or designee of any disapproval or requirement for modification of a JWS.

(iv) Upon approval of a JWS, the Contractor's Laboratory Director or designee may submit a CRADA, based upon the approved JWS, to the contracting officer. The contracting officer, within thirty (30) days of receipt of the CRADA, shall approve or request modification of the CRADA. If the contracting officer requests a modification of the CRADA, an explanation of such request shall be provided to the Laboratory Director or designee.

(v) Except as otherwise directed in writing by the contracting officer, the Contractor

shall not enter into, or begin work under, a CRADA until approval of the CRADA has been granted by the contracting officer. The Contractor may submit its proposed CRADA to the contracting officer at the time of submitting its proposed JWS or any time thereafter. However, the contracting officer is not obligated to respond under paragraph (n)(1)(iv) of this clause until within thirty (30) days after approval of the JWS or thirty (30) days after submittal of the CRADA, whichever is later.

(2) *Selection of Participants.* The Contractor's Laboratory Director or designee in deciding what CRADA to enter into shall:

(i) Give special consideration to small business firms, and consortia involving small business firms;

(ii) Give preference to business units located in the United States which agree that products or processes embodying Intellectual Property will be substantially manufactured or practiced in the United States and, in the case of any industrial organization or other person subject to the control of a foreign company or government, take into consideration whether or not such foreign government permits United States agencies, organizations, or other persons to enter into cooperative research and development agreements and licensing agreements;

(iii) Provide Fairness of Opportunity in accordance with the requirements of paragraph (e) of this clause; and

(iv) Give consideration to the Conflicts of Interest requirements of paragraph (d) of this clause.

(3) *Withholding of Data.* (i) Data that is first produced as a result of research and development activities conducted under a CRADA and that would be a trade secret or commercial or financial data that would be privileged or confidential, if such data had been obtained from a non-Federal third party, may be protected from disclosure under the Freedom of Information Act as provided in the Stevenson-Wylder Technology Innovation Act of 1980, as amended (15 U.S.C. 3710a(c)(7)) for a period as agreed in the CRADA of up to five (5) years from the time the data is first produced. The DOE shall cooperate with the Contractor in protecting such data.

(ii) Unless otherwise expressly approved by the contracting officer in advance for a specific CRADA, the Contractor agrees, at the request of the contracting officer, to transmit such data to other DOE facilities for use by DOE or its Contractors by or on behalf of the Government. When data protected pursuant to paragraph (n)(3)(i) of this clause is so transferred, the Contractor shall clearly mark the data with a legend setting out the restrictions against private use and further dissemination, along with the expiration date of such restrictions.

(iii) In addition to its authority to license Intellectual Property, the Contractor may enter into licensing agreements with third parties for data developed by the Contractor under a CRADA subject to other provisions of this Contract. However, the Contractor shall neither use the protection against dissemination nor the licensing of data as an alternative to the submittal of invention disclosures which include data protected pursuant to paragraph (n)(3)(i) of this clause.

(4) *Work For Others and User Facility Programs.* (i) WFO and User Facility Agreements (UFAs) are not CRADAs and will be available for use by the Contractor in addition to CRADAs for achieving utilization of employee expertise and unique facilities for maximizing technology transfer. The Contractor agrees form prospective CRADA participants, which are intending to substantially pay full cost recovery for the effort under a proposed CRADA, of the availability of alternative forms of agreements, i.e., WFO and UFA, and of the Class Patent Waiver provisions associated therewith.

(ii) Where the Contractor believes that the transfer of technology to the U.S. domestic economy will benefit from, or other equity considerations dictate, an arrangement other than the Class Waiver of patent rights to the sponsor in WFO and UFAs, a request may be made to the contracting officer for an exception to the Class Waivers.

(iii) Rights to inventions made under agreements other than funding agreements with third parties shall be governed by the appropriate provisions incorporated, with DOE approval, in such agreements, and the provisions in such agreements take precedence over any disposition of rights contained in this Contract. Disposition of rights under any such agreement shall be in accordance with any DOE class waiver (including Work for Others and User Class Waivers) or individually negotiated waiver which applies to the agreement.

(5) *Conflicts of Interest.* (i) Except as provided in paragraph (n)(5)(iii) of this clause, the Contractor shall assure that no employee of the Contractor shall have a substantial role (including an advisory role) in the preparation, negotiation, or approval of a CRADA, if, to such employee's knowledge:

(A) Such employee, or the spouse, child, parent, sibling, or partner of such employee, or an organization (other than the Contractor) in which such employee serves as an officer, director, trustee, partner, or employee—

(1) holds financial interest in any entity, other than the Contractor, that has a substantial interest in the preparation, negotiation, or approval of the CRADA;

(2) receives a gift or gratuity from any entity, other than the Contractor, that has a substantial interest in the preparation, negotiation, or approval of the CRADA; or

(B) A financial interest in any entity, other than the Contractor, that has a substantial interest in the preparation, negotiation, or approval of the CRADA, is held by any person or organization with whom such employee is negotiating or has any arrangement concerning prospective employment.

(ii) The Contractor shall require that each employee of the Contractor who has a substantial role (including an advisory role) in the preparation, negotiation, or approval of a CRADA certify through the Contractor to the contracting officer that the circumstances described in paragraph (n)(5)(i) of this clause do not apply to that employee.

(iii) The requirements of paragraphs (n)(5)(i) and (n)(5)(ii) of this clause shall not apply in a case where the contracting officer is advised by the Contractor in advance of the

participation of an employee described in those paragraphs in the preparation, negotiation or approval of a CRADA of the nature of and extent of any financial interest described in paragraph (n)(5)(i) of this clause, and the contracting officer determines that such financial interest is not so substantial as to be considered likely to affect the integrity of the Contractor employee's participation in the process of preparing, negotiating, or approving the CRADA.

(o) *Technology Transfer in Other Cost-Sharing Agreements.* In conducting research and development activities in cost-shared agreements not covered by paragraph (n) of this clause, the Contractor, with prior written permission of the contracting officer, may provide for the withholding of data produced thereunder in accordance with the applicable provisions of paragraph (n)(3) of this clause. (End of clause)

Alternate I (DEC 2000). As prescribed in 48 CFR 970.2770-4(b), add the following definition under paragraph (b) and the following new paragraph (p):

(b)(8) *Privately funded technology transfer* means the prosecuting, maintaining, licensing, and marketing of inventions which are not owned by the Government (and not related to CRADAs) when such activities are conducted entirely without the use of Government funds.

(p) Nothing in paragraphs (c) Allowable Costs, (e) Fairness of Opportunity, (f) U.S. Industrial Competitiveness, (g) Indemnity—Product Liability, (h) Disposition of Income, and (i) Transfer to Successor Contractor of this clause are intended to apply to the contractor's privately funded technology transfer activities if such privately funded activities are addressed elsewhere in the contract.

Alternate II (DEC 2000). As prescribed in 48 CFR 970.2770-4(c), the contracting officer shall substitute the phrase "weapon production facility" wherever the word "laboratory" appears in the clause.

970.5227-4 Authorization and consent.

Insert the following clause in solicitations and contracts in accordance with 970.2702-1: Authorization and Consent (DEC 2000)

(a) The Government authorizes and consents to all use and manufacture of any invention described in and covered by a United States patent in the performance of this contract or any subcontract at any tier.

(b) If the Contractor is sued for copyright infringement or anticipates the filing of such a lawsuit, the Contractor may request authorization and consent to copy a copyrighted work from the contracting officer. Programmatic necessity is a major consideration for DOE in determining whether to grant such request.

(c) The Contractor agrees to include, and require inclusion of, the Authorization and Consent clause at 52.227-1, without Alternate 1, but suitably modified to identify the parties, in all subcontracts at any tier for supplies or services (including construction, architect-engineer services, and materials, supplies, models, samples, and design or testing services expected to exceed \$25,000).

(d) The Contractor agrees to include, and require inclusion of, paragraph (a) of this Authorization and Consent clause, suitably modified to identify the parties, in all subcontracts at any tier for research and development activities. Omission of an authorization and consent clause from any subcontract, including those valued less than \$25,000 does not affect this authorization and consent.

(End of clause)

970.5227-5 Notice and assistance regarding patent and copyright infringement.

Insert the following clause in solicitations and contracts in accordance with 970.2702-2:

Notice and Assistance Regarding Patent and Copyright Infringement (DEC 2000)

(a) The Contractor shall report to the Contracting Officer promptly and in reasonable written detail, each notice or claim of patent or copyright infringement based on the performance of this contract of which the Contractor has knowledge.

(b) If any person files a claim or suit against the Government on account of any alleged patent or copyright infringement arising out of the performance of this contract or out of the use of any supplies furnished or work or services performed hereunder, the Contractor shall furnish to the Government, when requested by the Contracting Officer, all evidence and information in possession of the Contractor pertaining to such suit or claim. Except where the Contractor has agreed to indemnify the Government, the Contractor shall furnish such evidence and information at the expense of the Government.

(c) The Contractor agrees to include, and require inclusion of, this clause suitably modified to identify the parties, in all subcontracts at any tier expected to exceed \$25,000.

(End of clause)

970.5227-6 Patent indemnity—subcontracts.

Insert the following clause in solicitations and contracts in accordance with 970.2702-3:

Patent Indemnity—Subcontracts (DEC 2000)

Except as otherwise authorized by the Contracting Officer, the Contractor shall obtain indemnification of the Government and its officers, agents, and employees against liability, including costs, for infringement of any United States patent (except a patent issued upon an application that is now or may hereafter be withheld from issue pursuant to a secrecy order by the Government) from Contractor's subcontractors for any contract work subcontracted in accordance with FAR 48 CFR 52.227-3.

(End of clause)

970.5227-7 Royalty information.

Insert the following provision in solicitations in accordance with 970.2702-4:

Royalty Information (DEC 2000)

(a) *Cost or charges for royalties.* If the response to this solicitation contains costs or charges for royalties totaling more than \$250, the following information shall be included in the response relating to each separate item of royalty or license fee:

- (1) Name and address of licensor;
- (2) Date of license agreement;
- (3) Patent numbers, patent application serial numbers, or other basis on which the royalty is payable;
- (4) Brief description, including any part or model numbers of each contract item or component on which the royalty is payable;
- (5) Percentage or dollar rate of royalty per unit;
- (6) Unit price of contract item;
- (7) Number of units; and
- (8) Total dollar amount of royalties.

(b) Copies of current licenses. In addition, if specifically requested by the Contracting Officer before execution of the contract, the offeror shall furnish a copy of the current license agreement and an identification of applicable claims of specific patents or other basis upon which the royalty may be payable. (End of provision)

970.5227-8 Refund of royalties.

Insert the following clause in solicitations and contracts in accordance with 970.2702-4:

Refund of Royalties (DEC 2000)

(a) The contract price includes certain amounts for royalties, payable by the Contractor or subcontractors or both, reported to the Contracting Officer in accordance with the Royalty Information provision of the solicitation.

(b) During performance of this contract, if any additional royalty payments are proposed to be charged to the Government as costs under the contract that were not included in the original contract price, the Contractor agrees to submit for approval of the Contracting Officer prior to the execution of any licensing agreement the following information relating to each separate item of royalty or license fee:

- (1) Name and address of licensor;
- (2) Date of license agreement;
- (3) Patent numbers, patent application serial numbers, or other basis on which the royalty is payable;
- (4) Brief description, including any part or model numbers of each contract item or component on which the royalty is payable;
- (5) Percentage or dollar rate of royalty per unit;
- (6) Unit price of contract item;
- (7) Number of units; and
- (8) Total dollar amount of royalties.

(9) In addition, if specifically requested by the Contracting Officer, the contractor shall furnish a copy of the current license agreement and an identification of applicable claims of specific patents.

(c) The term "royalties" as used in this clause refers to any costs or charges in the nature of royalties, license fees, patent or license amortization costs, or the like, for the use of or for rights in patents and patent applications in connection with performing this contract or any subcontract hereunder.

The term also includes any costs or charges associated with the access to, use of, or other right pertaining to data that is represented to be proprietary and is related to the performance of this contract or subcontracts, or the copying of such data or data that is copyrighted.

(d) The Contractor shall furnish to the Contracting Officer, before final payment under this contract, a statement of royalties paid or required to be paid in connection with performing this contract and subcontracts hereunder.

(e) The Contractor is compensated for any royalties reported under paragraph (b) of this clause only to the extent that such royalties were included in the contract price and are determined by the Contracting Officer to be properly chargeable to the Government and allocable to the contract.

(f) The Contracting Officer shall reduce the contract price to the extent any royalties that are included in the contract price are not, in fact, paid by the Contractor or are determined by the Contracting Officer not to be properly chargeable to the Government and allocable to the contract. The Contractor agrees to repay or credit the Government accordingly, as the Contracting Officer directs. Regardless of prior DOE approval of any individual payments or royalties, DOE may contest at any time the enforceability, validity, scope of, or title to, a patent or the proprietary nature of data pursuant to which DOE makes a royalty or other payment.

(g) If at any time within 3 years after final payment under this contract, the Contractor for any reason is relieved in whole or in part from the payment of the royalties included in the final contract price as adjusted pursuant to paragraph (f) of this clause, the Contractor shall promptly notify the Contracting Office of that fact and shall promptly reimburse the Government in a corresponding amount.

(h) The Contractor agrees to include, and require inclusion of, this clause, including this paragraph (h), suitably modified to identify the parties in any subcontract at any tier in which the amount of royalties reported during negotiation of the subcontract exceeds \$250.

(End of clause)

970.5227-9 Notice of right to request patent waiver.

Insert the following provision in solicitations in accordance with 970.2704-6:

Notice of Right to Request Patent Waiver (DEC 2000)

Offerors have the right to request a waiver of all or any part of the rights of the United States in inventions conceived or first actually reduced to practice in performance of the contract, in advance of or within 30 days after the effective date of contracting. If such advance waiver is not requested or the request is denied, the Contractor has a continuing right under the contract to request a waiver of the rights of the Government in identified inventions, *i.e.*, individual inventions conceived or first actually reduced to practice in performance of the contract. Contractors that are domestic small businesses and domestic nonprofit

organizations may not need a waiver and will have included in their contracts a patent clause reflecting their right to elect title to subject inventions pursuant to the Bayh-Dole Act (35 U.S.C. 200 *et seq.*).

(End of provision)

970.5227-10 Patent rights—management and operating contracts, nonprofit organization or small business firm contractor.

As prescribed in 970.2703-1(b)(2), insert the following clause:

Patent Rights-Management and Operating Contracts, Nonprofit Organization or Small Business Firm Contractor (DEC 2000)

(a) Definitions.

(1) *DOE licensing regulations* means the Department of Energy patent licensing regulations at 10 CFR Part 781.

(2) *Exceptional circumstance subject invention* means any subject invention in a technical field or related to a task determined by the Department of Energy to be subject to an exceptional circumstance under 35 U.S.C. 202(a)(ii) and in accordance with 37 CFR 401.3(e).

(3) *Invention* means any invention or discovery which is or may be patentable or otherwise protectable under Title 35 of the United States Code, or any novel variety of plant which is or may be protected under the Plant Variety Protection Act (7 U.S.C. 2321 *et seq.*).

(4) *Made* when used in relation to any invention means the conception or first actual reduction to practice of such invention.

(5) *Nonprofit organization* means a university or other institution of higher education or an organization of the type described in section 501(c)(3) of the Internal Revenue Code of 1954 (26 U.S.C. 501(c)) and exempt from taxation under section 501(a) of the Internal Revenue Code (26 U.S.C. 501(a)) or any nonprofit scientific or educational organization qualified under a state nonprofit organization statute.

(6) *Patent Counsel* means the Department of Energy (DOE) Patent Counsel assisting the DOE contracting activity.

(7) *Practical application* means to manufacture, in the case of a composition or product; to practice, in the case of a process or method; or to operate, in the case of a machine or system; and, in each case, under such conditions as to establish that the invention is being utilized and that its benefits are, to the extent permitted by law or Government regulations, available to the public on reasonable terms.

(8) *Small business firm* means a small business concern as defined at section 2 of Pub. L. 85-536 (15 U.S.C. 632) and implementing regulations of the Administrator of the Small Business Administration. For the purpose of this clause, the size standards for small business concerns involved in Government procurement and subcontracting at 13 CFR 121.3-8 and 13 CFR 121.3-12, respectively, are used.

(9) *Subject Invention* means any invention of the contractor conceived or first actually reduced to practice in the performance of

work under this contract, provided that in the case of a variety of plant, the date of determination (as defined in section 41(d) of the Plant Variety Protection Act, 7 U.S.C. 2401(d)) shall also occur during the period of contract performance.

(b) Allocation of Principal Rights.

(1) Retention of title by the Contractor.

Except for exceptional circumstance subject inventions, the contractor may retain the entire right, title, and interest throughout the world to each subject invention subject to the provisions of this clause and 35 U.S.C. 203. With respect to any subject invention in which the Contractor retains title, the Federal government shall have a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States the subject invention throughout the world.

(2) *Exceptional circumstance subject inventions.* Except to the extent that rights are retained by the Contractor in a determination of exceptional circumstances or granted to a contractor through a determination of greater rights in accordance with subparagraph (b)(4) of this clause, the Contractor does not have a right to retain title to any exceptional circumstance subject inventions and agrees to assign to the Government the entire right, title, and interest, throughout the world, in and to any exceptional circumstance subject inventions.

(i) Inventions within or relating to the following fields of technology are exceptional circumstance subject inventions:

(A) uranium enrichment technology;

(B) storage and disposal of civilian high-level nuclear waste and spent fuel technology; and

(C) national security technologies classified or sensitive under Section 148 of the Atomic Energy Act (42 U.S.C. 2168).

(ii) Inventions made under any agreement, contract or subcontract related to the following are exceptional circumstance subject inventions:

(A) DOE Steel Initiative and Metals Initiative;

(B) U.S. Advanced Battery Consortium; and

(C) any funding agreement which is funded in part by the Electric Power Research Institute (EPRI) or the Gas Research Institute (GRI).

(iii) DOE reserves the right to unilaterally amend this contract to modify, by deletion or insertion, technical fields, tasks, or other classifications for the purpose of determining DOE exceptional circumstance subject inventions.

(3) Treaties and international agreements.

Any rights acquired by the Contractor in subject inventions are subject to any disposition of right, title, or interest in or to subject inventions provided for in treaties or international agreements identified at Appendix [Insert Reference] to this contract. DOE reserves the right to unilaterally amend this contract to identify specific treaties or international agreements entered into or to be entered into by the Government after the effective date of this contract and to effectuate those license or other rights which are necessary for the Government to meet its obligations to foreign governments, their nationals and international organizations

under such treaties or international agreements with respect to subject inventions made after the date of the amendment.

(4) *Contractor request for greater rights in exceptional circumstance subject inventions.* The Contractor may request rights greater than allowed by the exceptional circumstance determination in an exceptional circumstance subject invention by submitting such a request in writing to Patent Counsel at the time the exceptional circumstance subject invention is disclosed to DOE or within eight (8) months after conception or first actual reduction to practice of the exceptional circumstance subject invention, whichever occurs first, unless a longer period is authorized in writing by the Patent Counsel for good cause shown in writing by the Contractor. DOE may, in its discretion, grant or refuse to grant such a request by the Contractor.

(5) *Contractor employee-inventor rights.* If the Contractor does not elect to retain title to a subject invention or does not request greater rights in an exceptional circumstance subject invention, a Contractor employee-inventor, after consultation with the Contractor and with written authorization from the Contractor in accordance with 10 CFR 784.9(b)(4), may request greater rights, including title, in the subject invention or the exceptional circumstance invention from DOE, and DOE may, in its discretion, grant or refuse to grant such a request by the Contractor employee-inventor.

(6) *Government assignment of rights in Government employees' subject inventions.* If a Government employee is a joint inventor of a subject invention or of an exceptional circumstance subject invention to which the Contractor has rights, the Government may assign or refuse to assign to the Contractor any rights in the subject invention or exceptional circumstance subject invention acquired by the Government from the Government employee, in accordance with 48 CFR 27.304-1(d). The rights assigned to the Contractor are subject to any provision of this clause that is applicable to subject inventions in which the Contractor retains title, including reservation by the Government of a nonexclusive, nontransferable, irrevocable, paid-up license, except that the Contractor shall file its initial patent application claiming the subject invention or exceptional circumstance invention within one (1) year after the assignment of such rights. The Contractor shall share royalties collected for the manufacture, use or sale of the subject invention with the Government employee, as DOE deems appropriate.

(c) *Subject Invention Disclosure, Election of Title and Filing of Patent Application by Contractor.*

(1) *Subject invention disclosure.* The contractor will disclose each subject invention to the Patent Counsel within two months after the inventor discloses it in writing to contractor personnel responsible for patent matters. The disclosure to the agency shall be in the form of a written report and shall identify the contract under which the invention was made and the inventor(s) and all sources of funding by B&R code for the invention. It shall be sufficiently

complete in technical detail to convey a clear understanding to the extent known at the time of the disclosure, of the nature, purpose, operation, and the physical, chemical, biological or electrical characteristics of the invention. The disclosure shall also identify any publication, on sale or public use of the invention and whether a manuscript describing the invention has been submitted for publication and, if so, whether it has been accepted for publication at the time of disclosure. The disclosure shall include a written statement as to whether the invention falls within an exceptional circumstance field. DOE will make a determination and advise the Contractor within 30 days of receipt of an invention disclosure as to whether the invention is an exceptional circumstance subject invention. In addition, after disclosure to the Patent Counsel, the Contractor will promptly notify the agency of the acceptance of any manuscript describing the invention for publication or of any on sale or public use planned by the contractor. The Contractor shall obtain approval from Patent Counsel prior to any release or publication of information concerning any nonelectable subject invention such as an exceptional circumstance subject invention or any subject invention related to a treaty or international agreement.

(2) *Election by the Contractor.* Except as provided in paragraph (b)(2) of this clause, the Contractor will elect in writing whether or not to retain title to any such invention by notifying the Federal agency within two years of disclosure to the Federal agency. However, in any case where publication, on sale or public use has initiated the one year statutory period wherein valid patent protection can still be obtained in the United States, the period for election of title may be shortened by the agency to a date that is no more than 60 days prior to the end of the statutory period.

(3) *Filing of patent applications by the Contractor.* The Contractor will file its initial patent application on a subject invention to which it elects to retain title within one year after election of title or, if earlier, or prior to the end of any 1-year statutory period wherein valid patent protection can be obtained in the United States after a publication, on sale, or public use. The Contractor will file patent applications in additional countries or international patent offices within either ten months of the corresponding initial patent application or six months from the date permission is granted by the Commissioner of Patents and Trademarks to file foreign patent applications where such filing has been prohibited by a Secrecy Order.

(4) *Contractor's request for an extension of time.* Requests for an extension of the time for disclosure, election, and filing under subparagraphs (c)(1), (2) and (3) may, at the discretion of Patent Counsel, be granted.

(5) *Publication Approval.* During the course of the work under this contract, the Contractor or its employees may desire to release or publish information regarding scientific or technical developments conceived or first actually reduced to practice in the course of or under this contract. In order that public disclosure of

such information will not adversely affect the patent interest of DOE or the Contractor, approval for release or publication shall be secured from the Contractor personnel responsible for patent matters prior to any such release or publication. Where DOE's approval of publication is requested, DOE's response to such requests for approval shall normally be provided within 90 days except in circumstances in which a domestic patent application must be filed in order to protect foreign rights. In the case involving foreign patent rights, DOE shall be granted an additional 180 days with which to respond to the request for approval, unless extended by mutual agreement.

(d) *Conditions When the Government May Obtain Title.*

The Contractor will convey to the DOE, upon written request, title to any subject invention—

(1) If the Contractor fails to disclose or elect title to the subject invention within the times specified in paragraph (c) of this clause, or elects not to retain title; provided, that DOE may only request title within sixty (60) days after learning of the failure of the Contractor to disclose or to elect within the specified times.

(2) In those countries in which the Contractor fails to file a patent application within the times specified in subparagraph (c) of this clause; provided, however, that if the Contractor has filed a patent application in a country after the times specified in subparagraph (c) above, but prior to its receipt of the written request of the DOE, the Contractor shall continue to retain title in that country.

(3) In any country in which the Contractor decides not to continue the prosecution of any application for, to pay the maintenance fees on, or defend in a reexamination or opposition proceeding on, a patent on a subject invention.

(4) If the Contractor requests that DOE acquire title or rights from the Contractor in a subject invention to which the Contractor had initially retained title or rights, or in an exceptional circumstance subject invention to which the Contractor was granted greater rights, DOE may acquire such title or rights from the Contractor, or DOE may decide against acquiring such title or rights from the Contractor, at DOE's sole discretion.

(e) *Minimum Rights of the Contractor and Protection of the Contractor's Right to File.*

(1) *Request for a Contractor license.* The Contractor may request the right to reserve a revocable, nonexclusive, royalty-free license throughout the world in each subject invention to which the Government obtains title, except if the Contractor fails to disclose the invention within the times specified in paragraph (c) of this clause. DOE may grant or refuse to grant such a request by the Contractor. When DOE approves such reservation, the Contractor's license will normally extend to its domestic subsidiaries and affiliates, if any, within the corporate structure of which the Contractor is a party and includes the right to grant sublicenses of the same scope to the extent the Contractor was legally obligated to do so at the time the contract was awarded. The license is transferable only with the approval of DOE,

except when transferred to the successor of that part of the contractor's business to which the invention pertains.

(2) *Revocation or modification of a Contractor license.* The Contractor's domestic license may be revoked or modified by DOE to the extent necessary to achieve expeditious practical application of the subject invention pursuant to an application for an exclusive license submitted in accordance with applicable provisions at 37 CFR Part 404 and DOE licensing regulations at 10 CFR Part 781. This license will not be revoked in the field of use or the geographical areas in which the Contractor has achieved practical application and continues to make the benefits of the subject invention reasonably accessible to the public. The license in any foreign country may be revoked or modified at the discretion of DOE to the extent the Contractor, its licensees, or the domestic subsidiaries or affiliates have failed to achieve practical application of the subject invention in that foreign country.

(3) *Notice of revocation or modification of a Contractor license.* Before revocation or modification of the license, DOE will furnish the Contractor a written notice of its intention to revoke or modify the license, and the Contractor will be allowed thirty days (or such other time as may be authorized by DOE for good cause shown by the Contractor) after the notice to show cause why the license should not be revoked or modified. The Contractor has the right to appeal, in accordance with applicable regulations in 37 CFR part 404 and DOE licensing regulations at 10 CFR part 781 concerning the licensing of Government owned inventions, any decision concerning the revocation or modification of the license.

(f) Contractor Action to Protect the Government's Interest.

(1) *Execution of delivery of title or license instruments.* The Contractor agrees to execute or to have executed, and promptly deliver to the Patent Counsel all instruments necessary to accomplish the following actions:

(i) establish or confirm the rights the Government has throughout the world in those subject inventions to which the Contractor elects to retain title, and

(ii) convey title to DOE when requested under subparagraphs (b) or paragraph (d) of this clause and to enable the Government to obtain patent protection throughout the world in that subject invention.

(2) *Contractor employee agreements.* The Contractor agrees to require, by written agreement, its employees, other than clerical and nontechnical employees, to disclose promptly in writing to Contractor personnel identified as responsible for the administration of patent matters and in a format suggested by the Contractor, each subject invention made under this contract in order that the Contractor can comply with the disclosure provisions of paragraph (c) of this clause, and to execute all papers necessary to file patent applications on subject inventions and to establish the Government's rights in the subject inventions. This disclosure format should require, as a minimum, the information required by subparagraph (c)(1) of this clause. The Contractor shall instruct such

employees, through employee agreements or other suitable educational programs, on the importance of reporting inventions in sufficient time to permit the filing of patent applications prior to U.S. or foreign statutory bars.

(3) *Notification of discontinuation of patent protection.* The contractor will notify the Patent Counsel of any decision not to continue the prosecution of a patent application, pay maintenance fees, or defend in a reexamination or opposition proceeding on a patent, in any country, not less than thirty days before the expiration of the response period required by the relevant patent office.

(4) *Notification of Government rights.* The contractor agrees to include, within the specification of any United States patent applications and any patent issuing thereon covering a subject invention, the following statement, "This invention was made with government support under (identify the contract) awarded by (identify the Federal agency). The government has certain rights in the invention."

(5) *Invention Identification Procedures.* The Contractor shall establish and maintain active and effective procedures to ensure that subject inventions are promptly identified and timely disclosed and shall submit a written description of such procedures to the Contracting Officer so that the Contracting Officer may evaluate and determine their effectiveness.

(6) *Invention Filing Documentation.* If the Contractor files a domestic or foreign patent application claiming a subject invention, the Contractor shall promptly submit to Patent Counsel, upon request, the following information and documents:

(i) the filing date, serial number, title, and a copy of the patent application (including an English-language version if filed in a language other than English);

(ii) an executed and approved instrument fully confirmatory of all Government rights in the subject invention; and

(iii) the patent number, issue date, and a copy of any issued patent claiming the subject invention.

(7) *Duplication and disclosure of documents.* The Government may duplicate and disclose subject invention disclosures and all other reports and papers furnished or required to be furnished pursuant to this clause; provided, however, that any such duplication or disclosure by the Government is subject to the confidentiality provision at 35 U.S.C. 205 and 37 CFR Part 40.

(g) Subcontracts.

(1) *Subcontractor subject inventions.* The Contractor shall not obtain rights in the subcontractor's subject inventions as part of the consideration for awarding a subcontract.

(2) *Inclusion of patent rights clause—non-profit organization or small business firm subcontractors.* Unless otherwise authorized or directed by the Contracting Officer, the Contractor shall include the patent rights clause at 48 CFR 952.227-11, suitably modified to identify the parties, in all subcontracts, at any tier, for experimental, developmental, demonstration or research work to be performed by a small business firm or domestic nonprofit organization,

except subcontracts which are subject to exceptional circumstances in accordance with 35 U.S.C. 202 and subparagraph (b)(2) of this clause. The subcontractor retains all rights provided for the contractor in the patent rights clause at 48 CFR 952.227-11.

(3) *Inclusion of patent rights clause—subcontractors other than non-profit organizations and small business firms.* Except for the subcontracts described in subparagraph (g)(2) of this clause, the Contractor shall include the patent rights clause at 48 CFR 952.227-13, suitably modified to identify the parties, in any contract for experimental, developmental, demonstration or research work. For subcontracts subject to exceptional circumstances, the contractor must consult with DOE patent counsel with respect to the appropriate patent clause.

(4) *DOE and subcontractor contract.* With respect to subcontracts at any tier, DOE, the subcontractor, and the Contractor agree that the mutual obligations of the parties created by this clause constitute a contract between the subcontractor and DOE with respect to the matters covered by the clause; provided, however, that nothing in this paragraph is intended to confer any jurisdiction under the Contract Disputes Act in connection with proceedings under paragraph (j) of this clause.

(5) *Subcontractor refusal to accept terms of patent clause.* If a prospective subcontractor refuses to accept the terms of a patent rights clause, the Contractor shall promptly submit a written notice to the Contracting Officer stating the subcontractor's reasons for such a refusal, including any relevant information for expediting disposition of the matter, and the Contractor shall not proceed with the subcontract without the written authorization of the Contracting Officer.

(6) *Notification of award of subcontract.* Upon the award of any subcontract at any tier containing a patent rights clause, the Contractor shall promptly notify the Contracting Officer in writing and identify the subcontractor, the applicable patent rights clause, the work to be performed under the subcontract, and the dates of award and estimated completion. Upon request of the Contracting Officer, the Contractor shall furnish a copy of a subcontract.

(7) *Identification of subcontractor subject inventions.* If the Contractor in the performance of this contract becomes aware of a subject invention made under a subcontract, the Contractor shall promptly notify Patent Counsel and identify the subject invention.

(h) *Reporting on Utilization of Subject Inventions.* The Contractor agrees to submit to DOE on request, periodic reports, no more frequently than annually, on the utilization of a subject invention or on efforts at obtaining such utilization that are being made by the Contractor or its licensees or assignees. Such reports shall include information regarding the status of development, date of first commercial sale or use, gross royalties received by the Contractor, and such other data and information as DOE may reasonably specify. The Contractor also agrees to provide additional reports as may be requested by

DOE in connection with any march-in proceeding undertaken by DOE in accordance with paragraph (j) of this clause. As required by 35 U.S.C. 202(c)(5), DOE agrees it will not disclose such information to persons outside the Government without permission of the Contractor.

(i) *Preference for United States Industry.* Notwithstanding any other provision of this clause, the Contractor agrees that neither it nor any assignee will grant to any person the exclusive right to use or sell any subject invention in the United States unless such person agrees that any product embodying the subject invention or produced through the use of the subject invention will be manufactured substantially in the United States. However, in individual cases, the requirement for such an agreement may be waived by DOE upon a showing by the Contractor or its assignee that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible.

(j) *March-in Rights.* The Contractor agrees that, with respect to any subject invention in which it has acquired title, DOE has the right in accordance with the procedures in 37 CFR 401.6 and any DOE supplemental regulations to require the Contractor, an assignee or exclusive licensee of a subject invention to grant a nonexclusive, partially exclusive, or exclusive license in any field of use to a responsible applicant or applicants, upon terms that are reasonable under the circumstances, and, if the Contractor, assignee or exclusive licensee refuses such a request, DOE has the right to grant such a license itself if DOE determines that—

(1) Such action is necessary because the Contractor or assignee has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention in such field of use;

(2) Such action is necessary to alleviate health or safety needs which are not reasonably satisfied by the Contractor, assignee, or their licensees;

(3) Such action is necessary to meet requirements for public use specified by Federal regulations and such requirements are not reasonably satisfied by the Contractor, assignee, or licensees; or

(4) Such action is necessary because the agreement required by paragraph (i) of this clause has not been obtained or waived, or because a licensee of the exclusive right to use or sell any subject invention in the United States is in breach of such agreement.

(k) *Special Provisions for Contracts With Nonprofit Organizations.* If the Contractor is a nonprofit organization, it agrees that—

(1) *DOE approval of assignment of rights.* Rights to a subject invention in the United States may not be assigned by the Contractor without the approval of DOE, except where such assignment is made to an organization which has as one of its primary functions the management of inventions; provided, that such assignee will be subject to the same provisions of this clause as the Contractor.

(2) *Small business firm licensees.* It will make efforts that are reasonable under the

circumstances to attract licensees of subject inventions that are small business firms, and that it will give a preference to a small business firm when licensing a subject invention if the Contractor determines that the small business firm has a plan or proposal for marketing the invention which, if executed, is equally as likely to bring the invention to practical application as any plans or proposals from applicants that are not small business firms; provided, that the Contractor is also satisfied that the small business firm has the capability and resources to carry out its plan or proposal. The decision whether to give a preference in any specific case will be at the discretion of the Contractor. However, the Contractor agrees that the Secretary of Commerce may review the Contractor's licensing program and decisions regarding small business firm applicants, and the Contractor will negotiate changes to its licensing policies, procedures, or practices with the Secretary of Commerce when that Secretary's review discloses that the Contractor could take reasonable steps to more effectively implement the requirements of this subparagraph (k)(2).

(3) *Contractor licensing of subject inventions.* To the extent that it provides the most effective technology transfer, licensing of subject inventions shall be administered by Contractor employees on location at the facility.

(l) *Communications.* The Contractor shall direct any notification, disclosure or request provided for in this clause to the Patent Counsel assisting the DOE contracting activity.

(m) *Reports.*

(1) *Interim reports.* Upon DOE's request, the Contractor shall submit to DOE, no more frequently than annually, a list of subject inventions disclosed to DOE during a specified period, or a statement that no subject inventions were made during the specified period; and a list of subcontracts containing a patent clause and awarded by the Contractor during a specified period, or a statement that no such subcontracts were awarded during the specified period.

(2) *Final reports.* Upon DOE's request, the Contractor shall submit to DOE, prior to closeout of the contract, a list of all subject inventions disclosed during the performance period of the contract, or a statement that no subject inventions were made during the contract performance period; and a list of all subcontracts containing a patent clause and awarded by the Contractor during the contract performance period, or a statement that no such subcontracts were awarded during the contract performance period.

(n) *Examination of Records Relating to Subject Inventions.* (1) *Contractor compliance.* Until the expiration of three (3) years after final payment under this contract, the Contracting Officer or any authorized representative may examine any books (including laboratory notebooks), records, documents, and other supporting data of the Contractor, which the Contracting Officer or authorized representative deems reasonably pertinent to the discovery or identification of subject inventions, including exceptional circumstance subject inventions, or to determine Contractor compliance with any requirement of this clause.

(2) *Unreported inventions.* If the Contracting Officer is aware of an invention that is not disclosed by the Contractor to DOE, and the Contracting Officer believes the unreported invention may be a subject invention, including exceptional circumstance subject inventions, DOE may require the Contractor to submit to DOE a disclosure of the invention for a determination of ownership rights.

(3) *Confidentiality.* Any examination of records under this paragraph is subject to appropriate conditions to protect the confidentiality of the information involved.

(4) *Power of inspection.* With respect to a subject invention for which the Contractor has responsibility for patent prosecution, the Contractor shall furnish the Government, upon request by DOE, an irrevocable power to inspect and make copies of a prosecution file for any patent application claiming the subject invention.

(o) *Facilities License.* In addition to the rights of the parties with respect to inventions or discoveries conceived or first actually reduced to practice in the course of or under this contract, the Contractor agrees to and does hereby grant to the Government an irrevocable, nonexclusive, paid-up license in and to any inventions or discoveries regardless of when conceived or actually reduced to practice or acquired by the Contractor at any time through completion of this contract and which are incorporated or embodied in the construction of the facility or which are utilized in the operation of the facility or which cover articles, materials, or product manufactured at the facility (1) to practice or have practiced by or for the Government at the facility, and (2) to transfer such license with the transfer of that facility. Notwithstanding the acceptance or exercise by the Government of these rights, the Government may contest at any time the enforceability, validity or scope of, or title to, any rights or patents herein licensed.

(p) *Atomic Energy.*

(1) *Pecuniary awards.* No claim for pecuniary award of compensation under the provisions of the Atomic Energy Act of 1954, as amended, may be asserted with respect to any invention or discovery made or conceived in the course of or under this contract.

(2) *Patent agreements.* Except as otherwise authorized in writing by the Contracting Officer, the Contractor shall obtain patent agreements to effectuate the provisions of subparagraph (p)(1) of this clause from all persons who perform any part of the work under this contract, except nontechnical personnel, such as clerical employees and manual laborers.

(q) *Classified Inventions.* (1) *Approval for filing a foreign patent application.* The Contractor shall not file or cause to be filed an application or registration for a patent disclosing a subject invention related to classified subject matter in any country other than the United States without first obtaining the written approval of the Contracting Officer.

(2) *Transmission of classified subject matter.* If in accordance with this clause the Contractor files a patent application in the United States disclosing a subject invention

that is classified for reasons of security, the Contractor shall observe all applicable security regulations covering the transmission of classified subject matter. If the Contractor transmits a patent application disclosing a classified subject invention to the United States Patent and Trademark Office (USPTO), the Contractor shall submit a separate letter to the USPTO identifying the contract or contracts by agency and agreement number that require security classification markings to be placed on the patent application.

(3) *Inclusion of clause in subcontracts.* The Contractor agrees to include the substance of this clause in subcontracts at any tier that cover or are likely to cover subject matter classified for reasons of security.

(r) *Patent Functions.* Upon the written request of the Contracting Officer or Patent Counsel, the Contractor agrees to make reasonable efforts to support DOE in accomplishing patent-related functions for work arising out of the contract, including, but not limited to, the prosecution of patent applications, and the determination of questions of novelty, patentability, and inventorship.

(s) *Educational Awards Subject to 35 U.S.C. 212.* The Contractor shall notify the Contracting Officer prior to the placement of any person subject to 35 U.S.C. 212 in an area of technology or task (1) related to exceptional circumstance technology or (2) which is subject to treaties or international agreements as set forth in paragraph (b)(3) of this clause or agreements other than funding agreements. The Contracting Officer may disapprove of any such placement.

(t) *Annual Appraisal by Patent Counsel.* Patent Counsel may conduct an annual appraisal to evaluate the Contractor's effectiveness in identifying and protecting subject inventions in accordance with DOE policy.

(End of clause)

Alternate 1 Weapons Related Subject Inventions. As prescribed at 970.2703-2(g), insert the following as subparagraphs (a)(10) and (b)(7), respectively:

(a) *Definitions.* (10) *Weapons Related Subject Invention* means any subject invention conceived or first actually reduced to practice in the course of or under work funded by or through defense programs, including Department of Defense and intelligence reimbursable work, or the Naval Nuclear Propulsion Program of the Department of Energy.

(b) *Allocation of Principal Rights.* (7) *Weapons related subject inventions.* Except to the extent that DOE is solely satisfied that the Contractor meets certain procedural requirements and DOE grants rights to the Contractor in weapons related subject inventions, the Contractor does not have the right to retain title to any weapons related subject inventions.

(End of Alternate)

970.5227-11 Patent rights—management and operating contracts, for-profit contractor, non-technology transfer.

Insert the following clause in solicitations and contracts in accordance with 970.2703-1(b)(4):

Patent Rights—Management and Operating Contracts, for-Profit Contractor, Non-Technology Transfer (DEC 2000)

(a) *Definitions.* (1) *DOE licensing regulations* means the Department of Energy patent licensing regulations at 10 CFR Part 781.

(2) *DOE patent waiver regulations* means the Department of Energy patent waiver regulations at 10 CFR Part 784.

(3) *Invention* means any invention or discovery which is or may be patentable or otherwise protectable under title 35 of the United States Code, or any novel variety of plant which is or may be protected under the Plant Variety Protection Act (7 U.S.C. 2321, et seq.).

(4) *Made* when used in relation to any invention means the conception or first actual reduction to practice of such invention.

(5) *Patent Counsel* means DOE Patent Counsel assisting the contracting activity.

(6) *Practical application* means to manufacture, in the case of a composition or product; to practice, in the case of a process or method; or to operate, in the case of a machine or system; and, in each case, under such conditions as to establish that the invention is being utilized and that its benefits are, to the extent permitted by law or Government regulations, available to the public on reasonable terms.

(7) *Subject Invention* means any invention of the contractor conceived or first actually reduced to practice in the course of or under this contract, provided that in the case of a variety of plant, the date of determination (as defined in section 41(d) of the Plant Variety Protection Act, 7 U.S.C. 2401(d)) shall also occur during the period of contract performance.

(b) *Allocation of Principal Rights.* (1) *Assignment to the Government.* Except to the extent that rights are retained by the Contractor by a determination of greater rights in accordance with subparagraph (b)(2) of this clause or by a request for foreign patent rights in accordance with subparagraph (d)(2) of this clause, the Contractor agrees to assign to the Government the entire right, title, and interest throughout the world in and to each subject invention.

(2) *Greater rights determinations.* The Contractor, or an Contractor employee-inventor after consultation with the Contractor and with the written authorization of the Contractor in accordance with DOE patent waiver regulations, may request greater rights, including title, in an identified subject invention than the nonexclusive license and the foreign patent rights provided for in paragraph (d) of this clause, in accordance with the DOE patent waiver regulations. Such a request shall be submitted in writing to Patent Counsel with a copy to the Contracting Officer at the time the subject invention is first disclosed to DOE in accordance with subparagraph (c)(2) of this clause, or not later than eight (8) months after such disclosure, unless a longer period is authorized in writing by the Contracting Officer for good cause shown in writing by the Contractor. DOE may grant or refuse to grant such a request by the Contractor or

Contractor employee-inventor. Unless otherwise provided in the greater rights determination, any rights in a subject invention obtained by the Contractor pursuant to a determination of greater rights are subject to a nonexclusive, nontransferable, irrevocable, paid-up license to the Government to practice or have practiced the subject invention throughout the world by or on behalf of the Government of the United States (including any Government agency), and to any reservations and conditions deemed appropriate by the Secretary of Energy or designee.

(c) *Subject Invention Disclosures.* (1) *Contractor procedures for reporting subject inventions to Contractor personnel.* Subject inventions shall be reported to Contractor personnel responsible for patent matters within six (6) months of conception and/or first actual reduction to practice, whichever occurs first in the performance of work under this contract. Accordingly, the Contractor shall establish and maintain effective procedures for ensuring such prompt identification and timely disclosure of subject inventions to Contractor personnel responsible for patent matters, and the procedures shall include the maintenance of laboratory notebooks, or equivalent records, and other records that are reasonably necessary to document the conception and/or the first actual reduction to practice of subject inventions, and the maintenance of records demonstrating compliance with such procedures. The Contractor shall submit a written description of such procedures to the Contracting Officer, upon request, for evaluation of the effectiveness of such procedures by the Contracting Officer.

(2) *Subject invention disclosure.* The Contractor shall disclose each subject invention to Patent Counsel with a copy to the Contracting Officer within two (2) months after the subject invention is reported to Contractor personnel responsible for patent matters, in accordance with subparagraph (c)(1) of this clause, or, if earlier, within six (6) months after the Contractor has knowledge of the subject invention, but in any event before any on sale, public use, or publication of the subject invention. The disclosure to DOE shall be in the form of a written report and shall include:

- (i) the contract number under which the subject invention was made;
- (ii) the inventor(s) of the subject invention;
- (iii) a description of the subject invention in sufficient technical detail to convey a clear understanding of the nature, purpose and operation of the subject invention, and of the physical, chemical, biological or electrical characteristics of the subject invention, to the extent known by the Contractor at the time of the disclosure;
- (iv) the date and identification of any publication, on sale or public use of the invention;
- (v) the date and identification of any submissions for publication of any manuscripts describing the invention, and a statement of whether the manuscript is accepted for publication, to the extent known by the Contractor at the time of the disclosure;

(vi) a statement indicating whether the subject invention concerns exceptional circumstances pursuant to 35 U.S.C. 202(ii), related to national security, or subject to a treaty or an international agreement, to the extent known or believed by Contractor at the time of the disclosure;

(vii) all sources of funding by Budget and Resources (B&R) code; and

(viii) the identification of any agreement relating to the subject invention, including Cooperative Research and Development Agreements and Work-for-Others agreements. Unless the Contractor contends otherwise in writing at the time the invention is disclosed, inventions disclosed to DOE under this paragraph are deemed made in the manner specified in Sections (a)(1) and (a)(2) of 42 U.S.C. 5908.

(3) *Publication after disclosure.* After disclosure of the subject invention to the DOE, the Contractor shall promptly notify Patent Counsel of the acceptance for publication of any manuscript describing the subject invention or of any expected or on sale or public use of the subject invention, known by the Contractor.

(4) *Contractor employee agreements.* The Contractor agrees to require, by written agreement, its employees, other than clerical and nontechnical employees, to disclose promptly in writing to Contractor personnel identified as responsible for the administration of patent matters and in a format suggested by the Contractor, each subject invention made under this contract, and to execute all papers necessary to file patent applications claiming subject inventions or to establish the Government's rights in the subject inventions. This disclosure format shall at a minimum include the information required by subparagraph (c)(2) of this clause. The Contractor shall instruct such employees, through employee agreements or other suitable educational programs, on the importance of reporting inventions in sufficient time to permit the filing of patent applications prior to U.S. or foreign statutory bars.

(5) *Contractor procedures for reporting subject inventions to DOE.* The Contractor agrees to establish and maintain effective procedures for ensuring the prompt identification and timely disclosure of subject inventions to DOE. The Contractor shall submit a written description of such procedures to the Contracting Officer, upon request, for evaluation of the effectiveness of such procedures by the Contracting Officer.

(6) *Duplication and disclosure of documents.* The Government may duplicate and disclose subject invention disclosures and all other reports and papers furnished or required to be furnished pursuant to this clause; provided, however, that any such duplication or disclosure by the Government is subject to 35 U.S.C. 205 and 37 CFR 401.13.

(d) *Minimum Rights of the Contractor.* (1) Contractor License. (i) *Request for a Contractor license.* Except for subject inventions that the Contractor fails to disclose within the time periods specified at subparagraph (c)(2) of this clause, the Contractor may request a revocable, nonexclusive, royalty-free license in each

patent application filed in any country claiming a subject invention and any resulting patent in which the Government obtains title, and DOE may grant or refuse to grant such a request by the Contractor. If DOE grants the Contractor's request for a license, the Contractor's license extends to its domestic subsidiaries and affiliates, if any, within the corporate structure of which the Contractor is a party and includes the right to grant sublicenses of the same scope to the extent the Contractor was legally obligated to do so at the time the contract was awarded.

(ii) *Transfer of a Contractor license.* DOE shall approve any transfer of the Contractor's license in a subject invention, and DOE may determine the Contractor's license is non-transferable, on a case-by-case basis.

(iii) *Revocation or modification of a Contractor license.* DOE may revoke or modify the Contractor's domestic license to the extent necessary to achieve expeditious practical application of the subject invention pursuant to an application for an exclusive license submitted in accordance with applicable provisions in 37 CFR Part 404 and DOE licensing regulations. DOE may not revoke the Contractor's domestic license in that field of use or the geographical areas in which the Contractor, its licensee, or its domestic subsidiaries or affiliates achieved practical applications and continues to make the benefits of the invention reasonably accessible to the public. DOE may revoke or modify the Contractor's license in any foreign country to the extent the Contractor, its licensees, or its domestic subsidiaries or affiliates failed to achieve practical application in that foreign country.

(iv) *Notice of revocation or modification of a Contractor license.* Before revocation or modification of the license, DOE shall furnish the Contractor a written notice of its intention to revoke or modify the license, and the Contractor shall be allowed thirty (30) days from the date of the notice (or such other time as may be authorized by DOE for good cause shown by the Contractor) to show cause why the license should not be revoked or modified. The Contractor has the right to appeal any decision concerning the revocation or modification of its license, in accordance with applicable regulations in 37 CFR Part 404 and DOE licensing regulations.

(2) *Contractor's right to request foreign patent rights.* If the Government has title to a subject invention and the Government decides against securing patent rights in a foreign country for the subject invention, the Contractor may request such foreign patent rights from DOE, and DOE may grant the Contractor's request, subject to a nonexclusive, nontransferable, irrevocable, paid-up license to the Government to practice or have practiced the subject invention in the foreign country, and any reservations and conditions deemed appropriate by the Secretary of Energy or designee. Such a request shall be submitted in writing to the Patent Counsel as part of the disclosure required by subparagraph (c)(2) of this clause, with a copy to the DOE Contracting Officer, unless a longer period is authorized in writing by the Contracting Officer for good cause shown in writing by the Contractor. DOE may grant or refuse to

grant such a request, and may consider whether granting the Contractor's request best serves the interests of the United States.

(e) *Examination of Records Relating to Inventions.* (1) *Contractor compliance.* Until the expiration of three (3) years after final payment under this contract, the Contracting Officer or any authorized representative may examine any books (including laboratory notebooks), records, and documents and other supporting data of the Contractor, which the Contracting Officer or authorized representative deems reasonably pertinent to the discovery or identification of subject inventions, or to determine Contractor (and inventor) compliance with the requirements of this clause, including proper identification and disclosure of subject inventions, and establishment and maintenance of invention disclosure procedures.

(2) *Unreported inventions.* If the Contracting Officer is aware of an invention that is not disclosed by the Contractor to DOE, and the Contracting Officer believes the unreported invention may be a subject invention, DOE may require the Contractor to submit to DOE a disclosure of the invention for a determination of ownership rights.

(3) *Confidentiality.* Any examination of records under this paragraph is subject to appropriate conditions to protect the confidentiality of the information involved.

(f) *Subcontracts.* (1) *Subcontractor subject inventions.* The Contractor shall not obtain rights in the subcontractor's subject inventions as part of the consideration for awarding a subcontract.

(2) *Inclusion of patent rights clause—non-profit organization or small business firm subcontractors.* Unless otherwise authorized or directed by the Contracting Officer, the Contractor shall include the patent rights clause at 48 CFR 952.227-11, suitably modified to identify the parties in all subcontracts, at any tier, for experimental, developmental, demonstration or research work to be performed by a small business firm or domestic nonprofit organization, except subcontracts which are subject to exceptional circumstances in accordance with 35 U.S.C. 202(a)(ii).

(3) *Inclusion of patent rights clause—subcontractors other than non-profit organizations and small business firms.* Except for the subcontracts described in subparagraph (f)(2) of this clause, the Contractor shall include the patent rights clause at 48 CFR 952.227-13, suitably modified to identify the parties, in any contract for experimental, developmental, demonstration or research work.

(4) *DOE and subcontractor contract.* With respect to subcontracts at any tier, DOE, the subcontractor, and the Contractor agree that the mutual obligations of the parties created by this clause constitute a contract between the subcontractor and DOE with respect to those matters covered by this clause.

(5) *Subcontractor refusal to accept terms of patent rights clause.* If a prospective subcontractor refuses to accept the terms of a patent rights clause, the Contractor shall promptly submit a written notice to the Contracting Officer stating the subcontractor's reasons for such a refusal, including any relevant information for

expediting disposition of the matter, and the Contractor shall not proceed with the subcontract without the written authorization of the Contracting Officer.

(6) *Notification of award of subcontract.* Upon the award of any subcontract at any tier containing a patent rights clause, the Contractor shall promptly notify the Contracting Officer in writing and identify the subcontractor, the applicable patent rights clause, the work to be performed under the subcontract, and the dates of award and estimated completion. Upon request of the Contracting Officer, the Contractor shall furnish a copy of a subcontract.

(7) *Identification of subcontractor subject inventions.* If the Contractor in the performance of this contract becomes aware of a subject invention made under a subcontract, the Contractor shall promptly notify Patent Counsel and identify the subject invention, with a copy of the notification and identification to the Contracting Officer.

(g) *Atomic Energy.* (1) *Pecuniary awards.* No claim for pecuniary award of compensation under the provisions of the Atomic Energy Act of 1954, as amended, may be asserted with respect to any invention or discovery made or conceived in the course of or under this contract.

(2) *Patent Agreements.* Except as otherwise authorized in writing by the Contracting Officer, the Contractor shall obtain patent agreements to effectuate the provisions of subparagraph (g)(1) of this clause from all persons who perform any part of the work under this contract, except nontechnical personnel, such as clerical employees and manual laborers.

(h) *Publication.* The Contractor shall receive approval from Patent Counsel prior to releasing or publishing information regarding scientific or technical developments conceived or first actually reduced to practice in the course of or under this contract, to ensure such release or publication does not adversely affect the patent interests of DOE or the Contractor.

(i) *Communications.* The Contractor shall direct any notification, disclosure, or request provided for in this clause to the Patent Counsel assisting the DOE contracting activity, with a copy of the communication to the Contracting Officer.

(j) *Reports.* (1) *Interim reports.* Upon DOE's request, the Contractor shall submit to DOE, no more frequently than annually, a list of subject inventions disclosed to DOE during a specified period, or a statement that no subject inventions were made during the specified period; and/or a list of subcontracts containing a patent clause and awarded by the Contractor during a specified period, or a statement that no such subcontracts were awarded during the specified period. The interim report shall state whether the Contractor's invention disclosures were submitted to DOE in accordance with the requirements of subparagraphs (c)(1) and (c)(5) of this clause.

(2) *Final reports.* Upon DOE's request, the Contractor shall submit to DOE, prior to closeout of the contract or within three (3)

months of the date of completion of the contracted work, a list of all subject inventions disclosed during the performance period of the contract, or a statement that no subject inventions were made during the contract performance period; and/or a list of all subcontracts containing a patent clause and awarded by the Contractor during the contract performance period, or a statement that no such subcontracts were awarded during the contract performance period.

(k) *Facilities License.* In addition to the rights of the parties with respect to inventions or discoveries conceived or first actually reduced to practice in the course of or under this contract, the Contractor agrees to and does hereby grant to the Government an irrevocable, nonexclusive, paid-up license in and to any inventions or discoveries regardless of when conceived or actually reduced to practice or acquired by the contractor at any time through completion of this contract and which are incorporated or embodied in the construction of the facility or which are utilized in the operation of the facility or which cover articles, materials, or products manufactured at the facility (1) to practice or have practiced by or for the Government at the facility, and (2) to transfer such license with the transfer of that facility. Notwithstanding the acceptance or exercise by the Government of these rights, the Government may contest at any time the enforceability, validity or scope of, or title to, any rights or patents herein licensed.

(l) *Classified Inventions.* (1) *Approval for filing a foreign patent application.* The Contractor shall not file or cause to be filed an application or registration for a patent disclosing a subject invention related to classified subject matter in any country other than the United States without first obtaining the written approval of the Contracting Officer.

(2) *Transmission of classified subject matter.* If in accordance with this clause the Contractor files a patent application in the United States disclosing a subject invention that is classified for reasons of security, the Contractor shall observe all applicable security regulations covering the transmission of classified subject matter. If the Contractor transmits a patent application disclosing a classified subject invention to the United States Patent and Trademark Office (USPTO), the Contractor shall submit a separate letter to the USPTO identifying the contract or contracts by agency and agreement number that require security classification markings to be placed on the patent application.

(3) *Inclusion of clause in subcontracts.* The Contractor agrees to include the substance of this clause in subcontracts at any tier that cover or are likely to cover subject matter classified for reasons of security.

(m) *Patent Functions.* Upon the written request of the Contracting Officer or Patent Counsel, the Contractor agrees to make reasonable efforts to support DOE in accomplishing patent-related functions for work arising out of the contract, including, but not limited to, the prosecution of patent

applications, and the determination of questions of novelty, patentability, and inventorship.

(n) *Annual Appraisal by Patent Counsel.* Patent Counsel may conduct an annual appraisal to evaluate the Contractor's effectiveness in identifying and protecting subject inventions in accordance with DOE policy.

(End of Clause)

970.5227-12 Patent rights—management and operating contracts, for-profit contractor, advance class waiver.

Insert the following clause in solicitations and contracts in accordance with 970.2703-1(b)(3):

Patent Rights—Management and Operating Contracts, For-Profit Contractor, Advance Class Waiver (DEC 2000)

(a) *Definitions.* (1) *DOE licensing regulations* means the Department of Energy patent licensing regulations at 10 CFR Part 781.

(2) *DOE patent waiver regulations* means the Department of Energy patent waiver regulations at 10 CFR Part 784.

(3) *Exceptional Circumstance Subject Invention* means any subject invention in a technical field or related to a task determined by the Department of Energy to be subject to an exceptional circumstance under 35 U.S.C. 202(a)(ii), and in accordance with 37 CFR 401.3(e).

(4) *Invention* means any invention or discovery which is or may be patentable or otherwise protectable under title 35 of the United States Code, or any novel variety of plant which is or may be protected under the Plant Variety Protection Act (7 U.S.C. 2321, *et seq.*).

(5) *Made* when used in relation to any invention means the conception or first actual reduction to practice of such invention.

(6) *Patent Counsel* means DOE Patent Counsel assisting the contracting activity.

(7) *Practical application* means to manufacture, in the case of a composition or product; to practice, in the case of a process or method; or to operate, in the case of a machine or system; and, in each case, under such conditions as to establish that the invention is being utilized and that its benefits are, to the extent permitted by law or Government regulations, available to the public on reasonable terms.

(8) *Subject Invention* means any invention of the contractor conceived or first actually reduced to practice in the course of or under this contract, provided that in the case of a variety of plant, the date of determination (as defined in section 41(d) of the Plant Variety Protection Act, 7 U.S.C. 2401(d)) shall also occur during the period of contract performance.

(b) *Allocation of Principal Rights.* (1) *Assignment to the Government.* Except to the extent that rights are retained by

the Contractor by the granting of an advance class waiver pursuant to subparagraph (b)(2) of this clause or a determination of greater rights pursuant to subparagraph (b)(7) of this clause, the Contractor agrees to assign to the Government the entire right, title, and interest throughout the world in and to each subject invention.

(2) *Advance class waiver of Government rights to the Contractor.* DOE may grant to the Contractor an advance class waiver of Government rights in any or all subject inventions, at the time of execution of the contract, such that the Contractor may elect to retain the entire right, title and interest throughout the world to such waived subject inventions, in accordance with the terms and conditions of the advance class waiver. Unless otherwise provided by the terms of the advance class waiver, any rights in a subject invention retained by the Contractor under an advance class waiver are subject to 35 U.S.C. 203 and the provisions of this clause, including the Government license provided for in subparagraph (b)(3) of this clause, and any reservations and conditions deemed appropriate by the Secretary of Energy or designee.

(3) *Government license.* With respect to any subject invention to which the Contractor retains title, either under an advance class waiver pursuant to subparagraph (b)(2) or a determination of greater rights pursuant to subparagraph (b)(7) of this clause, the Government has a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States the subject invention throughout the world.

(4) *Foreign patent rights.* If the Government has title to a subject invention and the Government decides against securing patent rights in a foreign country for the subject invention, the Contractor may request such foreign patent rights from DOE, and DOE may grant the Contractor's request, subject to 35 U.S.C. 203 and the provisions of this clause, including the Government license provided for in subparagraph (b)(3) of this clause, and any reservations and conditions deemed appropriate by the Secretary of Energy or designee.

(5) *Exceptional circumstance subject inventions.* Except to the extent that rights are retained by the Contractor by a determination of greater rights in accordance with subparagraph (b)(7) of this clause, the Contractor does not have the right to retain title to any exceptional circumstance subject inventions and agrees to assign to the Government the entire right, title, and

interest, throughout the world, in and to any exceptional circumstance subject inventions.

(i) Inventions within or relating to the following fields of technology are exceptional circumstance subject inventions:

- (A) uranium enrichment technology;
- (B) storage and disposal of civilian high-level nuclear waste and spent fuel technology; and
- (C) national security technologies classified or sensitive under Section 148 of the Atomic Energy Act (42 U.S.C. 2168).

(ii) Inventions made under any agreement, contract or subcontract related to the following initiatives or programs are exceptional circumstance subject inventions:

- (A) DOE Steel Initiative and Metals Initiative;
- (B) U.S. Advanced Battery Consortium; and
- (C) any funding agreement which is funded in part by the Electric Power Research Institute (EPRI) or the Gas Research Institute (GRI).

(iii) DOE reserves the right to unilaterally amend this contract to modify, by deletion or insertion, technical fields, programs, initiatives, and/or other classifications for the purpose of defining DOE exceptional circumstance subject inventions.

(6) *Treaties and international agreements.* Any rights acquired by the Contractor in subject inventions are subject to any disposition of right, title, or interest in or to subject inventions provided for in treaties or international agreements identified at Appendix [Insert Reference], to this contract. DOE reserves the right to unilaterally amend this contract to identify specific treaties or international agreements entered into or to be entered into by the Government after the effective date of this contract and to effectuate those license or other rights which are necessary for the Government to meet its obligations to foreign governments, their nationals and international organizations under such treaties or international agreements with respect to subject inventions made after the date of the amendment.

(7) *Contractor request for greater rights.* The Contractor may request greater rights in an identified subject invention, including an exceptional circumstance subject invention, to which the Contractor does not have the right to elect to retain title, in accordance with the DOE patent waiver regulations, by submitting such a request in writing to Patent Counsel with a copy to the Contracting Officer at the time the subject invention is first disclosed to DOE pursuant to subparagraph (c)(1) of this clause, or not later than eight (8) months after such disclosure,

unless a longer period is authorized in writing by the Contracting Officer for good cause shown in writing by the Contractor. DOE may grant or refuse to grant such a request by the Contractor. Unless otherwise provided in the greater rights determination, any rights in a subject invention obtained by the Contractor under a determination of greater rights is subject to 35 U.S.C. 203 and the provisions of this clause, including the Government license provided for in subparagraph (b)(3) of this clause, and to any reservations and conditions deemed appropriate by the Secretary of Energy or designee.

(8) *Contractor employee-inventor rights.* If the Contractor does not elect to retain title to a subject invention or does not request greater rights in a subject invention, including an exceptional circumstance subject invention, to which the Contractor does not have the right to elect to retain title, a Contractor employee-inventor, after consultation with the Contractor and with written authorization from the Contractor in accordance with 10 CFR 784.9(b)(4), may request greater rights, including title, in the subject invention or the exceptional circumstance invention from DOE, and DOE may grant or refuse to grant such a request by the Contractor employee-inventor.

(9) *Government assignment of rights in Government employees' subject inventions.* If a DOE employee is a joint inventor of a subject invention to which the Contractor has rights, DOE may assign or refuse to assign any rights in the subject invention acquired by the Government from the DOE employee to the Contractor, consistent with 48 CFR 27.304-1(d). Unless otherwise provided in the assignment, the rights assigned to the Contractor are subject to the Government license provided for in subparagraph (b)(3) of this clause, and to any provision of this clause applicable to subject inventions in which rights are retained by the Contractor, and to any reservations and conditions deemed appropriate by the Secretary of Energy or designee. The Contractor shall share royalties collected for the manufacture, use or sale of the subject invention with the DOE employee, as DOE deems appropriate.

(c) *Subject Invention Disclosure, Election of Title, and Filing of Patent Application by Contractor.* (1) *Subject invention disclosure.* The Contractor shall disclose each subject invention to Patent Counsel with a copy to the Contracting Officer within two (2) months after an inventor discloses it in

writing to Contractor personnel responsible for patent matters or, if earlier, within six (6) months after the Contractor has knowledge of the subject invention, but in any event before any on sale, public use, or publication of the subject invention. The disclosure to DOE shall be in the form of a written report and shall include:

- (i) the contract number under which the subject invention was made;
- (ii) the inventor(s) of the subject invention;
- (iii) a description of the subject invention in sufficient technical detail to convey a clear understanding of the nature, purpose and operation of the subject invention, and of the physical, chemical, biological or electrical characteristics of the subject invention, to the extent known by the Contractor at the time of the disclosure;
- (iv) the date and identification of any publication, on sale or public use of the invention;
- (v) the date and identification of any submissions for publication of any manuscripts describing the invention, and a statement of whether the manuscript is accepted for publication, to the extent known by the Contractor at the time of the disclosure;
- (vi) a statement indicating whether the subject invention is an exceptional circumstance subject invention, related to national security, or subject to a treaty or an international agreement, to the extent known or believed by Contractor at the time of the disclosure;
- (vii) all sources of funding by Budget and Resources (B&R) code; and
- (viii) the identification of any agreement relating to the subject invention, including Cooperative Research and Development Agreements and Work-for-Others agreements.

Unless the Contractor contends otherwise in writing at the time the invention is disclosed, inventions disclosed to DOE under this paragraph are deemed made in the manner specified in Sections (a)(1) and (a)(2) of 42 U.S.C. 5908.

(2) *Publication after disclosure.* After disclosure of the subject invention to the DOE, the Contractor shall promptly notify Patent Counsel of the acceptance for publication of any manuscript describing the subject invention or of any expected or on sale or public use of the subject invention, known by the Contractor. The Contractor shall obtain approval from Patent Counsel prior to any release or publication of information concerning an exceptional circumstance subject invention or any subject invention related to a treaty or international agreement.

(3) *Election by the Contractor under an advance class waiver.* If the Contractor has the right to elect to retain title to subject inventions under an advance class waiver granted in accordance with subparagraph (b)(2) of this clause, and unless otherwise provided for by the terms of the advance class waiver, the Contractor shall elect in writing whether or not to retain title to any subject invention by notifying DOE within two (2) years of the date of the disclosure of the subject invention to DOE, in accordance with subparagraph (c)(1) of this clause. The notification shall identify the advance class waiver, state the countries, including the United States, in which rights are retained, and certify that the subject invention is not an exceptional circumstance subject invention or subject to a treaty or international agreement. If a publication, on sale or public use of the subject invention has initiated the 1-year statutory period under 35 U.S.C. 102(b), the period for election may be shortened by DOE to a date that is no more than sixty (60) days prior to the end of the 1-year statutory period.

(4) *Filing of patent applications by the Contractor under an advance class waiver.* If the Contractor has the right to retain title to a subject invention in accordance with an advance class waiver pursuant to subparagraph (b)(2) of this clause or a determination of greater rights pursuant to paragraph (b)(7) of this clause, and unless otherwise provided for by the terms of the advance class waiver or greater rights determination, the Contractor shall file an initial patent application claiming the subject invention to which it retains title either within one (1) year after the Contractor's election to retain or grant of title to the subject invention or prior to the end of any 1-year statutory period under 35 U.S.C. 102(b), whichever occurs first. Any patent applications filed by the Contractor in foreign countries or international patent offices shall be filed within either ten (10) months of the corresponding initial patent application or, if such filing has been prohibited by a Secrecy Order, within six (6) months from the date permission is granted by the Commissioner of Patents and Trademarks to file foreign patent applications.

(5) *Submission of patent information and documents.* If the Contractor files a domestic or foreign patent application claiming a subject invention, the Contractor shall promptly submit to Patent Counsel the following information and documents:

- (i) The filing date, serial number, title, and a copy of the patent application (including an

English-language version if filed in a language other than English);

- (ii) An executed and approved instrument fully confirmatory of all Government rights in the subject invention; and

- (iii) The patent number, issue date, and a copy of any issued patent claiming the subject invention.

(6) *Contractor's request for an extension of time.* Requests for an extension of the time to disclose a subject invention, to elect to retain title to a subject invention, or to file a patent application under subparagraphs (c)(1), (3), and (4) of this clause may be granted at the discretion of Patent Counsel or DOE.

(7) *Duplication and disclosure of documents.* The Government may duplicate and disclose subject invention disclosures and all other reports and papers furnished or required to be furnished pursuant to this clause; provided, however, that any such duplication or disclosure by the Government is subject to 35 U.S.C. 205 and 37 CFR Part 40.

(d) *Conditions When the Government May Obtain Title Notwithstanding an Advance Class Waiver.* (1) *Return of title to a subject invention.* If the Contractor requests that DOE acquire title or rights from the Contractor in a subject invention, including an exceptional circumstance subject invention, to which the Contractor retained title or rights under subparagraph (b)(2) or subparagraph (b)(7) of this clause, DOE may acquire such title or rights from the Contractor, or DOE may decide against acquiring such title or rights from the Contractor, at DOE's sole discretion.

(2) *Failure to disclose or elect to retain title.* Title vests in DOE and DOE may request, in writing, a formal assignment of title to a subject invention from the Contractor, and the Contractor shall convey title to the subject invention to DOE, if the Contractor elects not to retain title to the subject invention under an advance class waiver, or the Contractor fails to disclose or fails to elect to retain title to the subject invention within the times specified in subparagraphs (c)(1) and (c)(3) of this clause.

(3) *Failure to file domestic or foreign patent applications.* In those countries in which the Contractor fails to file a patent application within the times specified in subparagraph (c)(4) of this clause, DOE may request, in writing, title to the subject invention from the Contractor, and the Contractor shall convey title to the subject invention to

DOE; provided, however, that if the Contractor has filed a patent application in any country after the times specified in subparagraph (c)(4) of this clause, but prior to its receipt of DOE's written request for title, the Contractor continues to retain title in that country.

(4) *Discontinuation of patent protection by the Contractor.* If the Contractor decides to discontinue the prosecution of a patent application, the payment of maintenance fees, or the defense of a subject invention in a reexamination or opposition proceeding, in any country, DOE may request, in writing, title to the subject invention from the Contractor, and the Contractor shall convey title to the subject invention to DOE.

(5) *Termination of advance class waiver.* DOE may request, in writing, title to any subject inventions from the Contractor, and the Contractor shall convey title to the subject inventions to DOE, if the advance class waiver granted under subparagraph (b)(2) of this clause is terminated under paragraph (u) of this clause.

(e) *Minimum Rights of the Contractor.* (1) *Request for a Contractor license.* Except for subject inventions that the Contractor fails to disclose within the time periods specified at subparagraph (c)(1) of this clause, the Contractor may request a revocable, nonexclusive, royalty-free license in each patent application filed in any country claiming a subject invention and any resulting patent in which the Government obtains title, and DOE may grant or refuse to grant such a request by the Contractor. If DOE grants the Contractor's request for a license, the Contractor's license extends to its domestic subsidiaries and affiliates, if any, within the corporate structure of which the Contractor is a party and includes the right to grant sublicenses of the same scope to the extent the Contractor was legally obligated to do so at the time the contract was awarded.

(2) *Transfer of a Contractor license.* DOE shall approve any transfer of the Contractor's license in a subject invention, and DOE may determine that the Contractor's license is non-transferrable, on a case-by-case basis.

(3) *Revocation or modification of a Contractor license.* DOE may revoke or modify the Contractor's domestic license to the extent necessary to achieve expeditious practical application of the subject invention pursuant to an application for an exclusive license submitted in accordance with applicable provisions in 37 CFR Part 404 and DOE licensing regulations. DOE may not revoke the Contractor's domestic license in that field of use or the geographical areas in

which the Contractor, its licensees or its domestic subsidiaries or affiliates have achieved practical applications and continues to make the benefits of the invention reasonably accessible to the public. DOE may revoke or modify the Contractor's license in any foreign country to the extent the Contractor, its licensees, or its domestic subsidiaries or affiliates failed to achieve practical application in that foreign country.

(4) *Notice of revocation or modification of a Contractor license.* Before revocation or modification of the license, DOE shall furnish the Contractor a written notice of its intention to revoke or modify the license, and the Contractor shall be allowed thirty (30) days from the date of the notice (or such other time as may be authorized by DOE for good cause shown by the Contractor) to show cause why the license should not be revoked or modified. The Contractor has the right to appeal any decision concerning the revocation or modification of its license, in accordance with applicable regulations in 37 CFR Part 404 and DOE licensing regulations.

(f) *Contractor Action to Protect the Government's Interest.* (1) *Execution and delivery of title or license instruments.* The Contractor agrees to execute or have executed, and to deliver promptly to DOE all instruments necessary to accomplish the following actions:

(i) establish or confirm the Government's rights throughout the world in subject inventions to which the Contractor elects to retain title;

(ii) convey title in a subject invention to DOE pursuant to subparagraph (b)(5) and paragraph (d) of this clause; or

(iii) enable the Government to obtain patent protection throughout the world in a subject invention to which the Government has title.

(2) *Contractor employee agreements.* The Contractor agrees to require, by written agreement, its employees, other than clerical and nontechnical employees, to disclose promptly in writing to Contractor personnel identified as responsible for the administration of patent matters and in a format suggested by the Contractor, each subject invention made under this contract, and to execute all papers necessary to file patent applications claiming subject inventions or to establish the Government's rights in the subject inventions. This disclosure format shall at a minimum include the information required by subparagraph (c)(1) of this clause. The Contractor shall instruct such employees, through employee agreements or other suitable educational

programs, on the importance of reporting inventions in sufficient time to permit the filing of patent applications prior to U.S. or foreign statutory bars.

(3) *Contractor procedures for reporting subject inventions to DOE.* The Contractor agrees to establish and maintain effective procedures for ensuring the prompt identification and timely disclosure of subject inventions to DOE. The Contractor shall submit a written description of such procedures to the Contracting Officer, upon request, for evaluation and approval of the effectiveness of such procedures by the Contracting Officer.

(4) *Notification of discontinuation of patent protection.* With respect to any subject invention for which the Contractor has responsibility for patent prosecution, the Contractor shall notify Patent Counsel of any decision to discontinue the prosecution of a patent application, payment of maintenance fees, or defense of a subject invention in a reexamination or opposition proceeding, in any country, not less than thirty (30) days before the expiration of the response period for any action required by the corresponding patent office.

(5) *Notification of Government rights.* With respect to any subject invention to which the Contractor has title, the Contractor agrees to include, within the specification of any United States patent application and within any patent issuing thereon claiming a subject invention, the following statement, "This invention was made with Government support under (identify the contract) awarded by the United States Department of Energy. The Government has certain rights in the invention."

(6) *Avoidance of Royalty Charges.* If the Contractor licenses a subject invention, the Contractor agrees to avoid royalty charges on acquisitions involving Government funds, including funds derived through a Military Assistance Program of the Government or otherwise derived through the Government, to refund any amounts received as royalty charges on a subject invention in acquisitions for, or on behalf of, the Government, and to provide for such refund in any instrument transferring rights in the subject invention to any party.

(7) *DOE approval of assignment of rights.* Rights in a subject invention in the United States may not be assigned by the Contractor without the approval of DOE.

(8) *Small business firm licensees.* The Contractor shall make efforts that are reasonable under the circumstances to attract licensees of subject inventions

that are small business firms, and may give a preference to a small business firm when licensing a subject invention if the Contractor determines that the small business firm has a plan or proposal for marketing the invention which, if executed, is equally as likely to bring the invention to practical application as any plans or proposals from applicants that are not small business firms; provided, the Contractor is also satisfied that the small business firm has the capability and resources to carry out its plan or proposal. The decision as to whether to give a preference in any specific case is at the discretion of the Contractor.

(9) *Contractor licensing of subject inventions.* To the extent that it provides the most effective technology transfer, licensing of subject inventions shall be administered by Contractor employees on location at the facility.

(g) *Subcontracts.* (1) *Subcontractor subject inventions.* The Contractor shall not obtain rights in the subcontractor's subject inventions as part of the consideration for awarding a subcontract.

(2) *Inclusion of patent rights clause—non-profit organization or small business firm subcontractors.* Unless otherwise authorized or directed by the Contracting Officer, the Contractor shall include the patent rights clause at 48 CFR 952.227–11, suitably modified to identify the parties, in all subcontracts, at any tier, for experimental, developmental, demonstration or research work to be performed by a small business firm or domestic nonprofit organization, except subcontracts which are subject to exceptional circumstances in accordance with 35 U.S.C. 202 and subparagraph (b)(5) of this clause.

(3) *Inclusion of patent rights clause—subcontractors other than non-profit organizations or small business firms.* Except for the subcontracts described in subparagraph (g)(2) of this clause, the Contractor shall include the patent rights clause at 48 CFR 952.227–13, suitably modified to identify the parties and any applicable exceptional circumstance, in any contract for experimental, developmental, demonstration or research work.

(4) *DOE and subcontractor contract.* With respect to subcontracts at any tier, DOE, the subcontractor and Contractor agree that the mutual obligations of the parties created by this clause constitute a contract between the subcontractor and DOE with respect to those matters covered by this clause; provided, however, that nothing in this paragraph is intended to confer any jurisdiction under the

Contract Disputes Act in connection with proceedings under paragraph (j) of this clause.

(5) Subcontractor refusal to accept terms of patent rights clause. If a prospective subcontractor refuses to accept the terms of a patent rights clause, the Contractor shall promptly submit a written notice to the Contracting Officer stating the subcontractor's reasons for such refusal and including relevant information for expediting disposition of the matter; and the Contractor shall not proceed with the subcontract without the written authorization of the Contracting Officer.

(6) *Notification of award of subcontract.* Upon the award of any subcontract at any tier containing a patent rights clause, the Contractor shall promptly notify the Contracting Officer in writing and identify the subcontractor, the applicable patent rights clause, the work to be performed under the subcontract, and the dates of award and estimated completion. Upon request of the Contracting Officer, the Contractor shall furnish a copy of a subcontract.

(7) *Identification of subcontractor subject inventions.* If the Contractor in the performance of this contract becomes aware of a subject invention made under a subcontract, the Contractor shall promptly notify Patent Counsel and identify the subject invention, with a copy of the notification and identification to the Contracting Officer.

(h) *Reporting on Utilization of Subject Inventions.* Upon request by DOE, the Contractor agrees to submit periodic reports, no more frequently than annually, describing the utilization of a subject invention or efforts made by the Contractor or its licensees or assignees to obtain utilization of the subject invention. The reports shall include information regarding the status of development, date of first commercial sale or use, gross royalties received by the Contractor, and other data and information reasonably specified by DOE. Upon request by DOE, the Contractor also agrees to provide reports in connection with any march-in proceedings undertaken by DOE, in accordance with paragraph (j) of this clause. If any data or information reported by the Contractor in accordance with this provision is considered privileged and confidential by the Contractor, its licensee, or assignee and the Contractor properly marks the data or information privileged or confidential, DOE agrees not to disclose such information to persons outside the Government, to the extent permitted by law.

(i) *Preference for United States Industry.* Notwithstanding any other provision of this

clause the Contractor agrees that with respect to any subject invention in which it retains title, neither it nor any assignee may grant to any person the exclusive right to use or sell any subject invention in the United States unless such person agrees that any products embodying the subject invention or produced through the use of the subject invention will be manufactured substantially in the United States. However, in individual cases, DOE may waive the requirement for such an agreement upon a showing by the Contractor or its assignee that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible.

(j) *March-In Rights.* With respect to any subject invention to which the Contractor has elected to retain or is granted title, DOE may, in accordance with the procedures in the DOE patent waiver regulations, require the Contractor, an assignee or exclusive licensee of a subject invention to grant a nonexclusive, partially exclusive or exclusive license in any field of use to a responsible applicant or applicants, upon terms that are reasonable under the circumstances. If the Contractor, assignee or exclusive licensee refuses such a request, DOE has the right to grant such a license itself if DOE determines that—

(1) Such action is necessary because the Contractor or assignee has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention in such field of use;

(2) Such action is necessary to alleviate health or safety needs that are not reasonably satisfied by the Contractor, assignee, or their licensees;

(3) Such action is necessary to meet requirements for public use specified by government regulations and such requirements are not reasonably satisfied by the Contractor, assignee, or licensees; or

(4) Such action is necessary because the agreement to substantially manufacture in the United States and required by paragraph (i) of this clause has neither been obtained nor waived or because a licensee of the exclusive right to use or sell any subject invention in the United States is in breach of such agreement.

(k) *Communications.* The Contractor shall direct any notification, disclosure, or request provided for in this clause to

the Patent Counsel identified in the contract.

(l) *Reports.* (1) *Interim reports.* Upon DOE's request, the Contractor shall submit to DOE, no more frequently than annually, a list of subject inventions disclosed to DOE during a specified period, or a statement that no subject inventions were made during the specified period; and/or a list of subcontracts containing a patent clause and awarded by the Contractor during a specified period, or a statement that no such subcontracts were awarded during the specified period. The interim report shall state whether the Contractor's invention disclosures were submitted to DOE in accordance with the requirements of subparagraphs (f)(3) and (f)(4) of this clause.

(2) *Final reports.* Upon DOE's request, the Contractor shall submit to DOE, prior to closeout of the contract or within three (3) months of the date of completion of the contracted work, a list of all subject inventions disclosed during the performance period of the contract, or a statement that no subject inventions were made during the contract performance period; and/or a list of all subcontracts containing a patent clause and awarded by the Contractor during the contract performance period, or a statement that no such subcontracts were awarded during the contract performance period.

(m) *Facilities License.* In addition to the rights of the parties with respect to inventions or discoveries conceived or first actually reduced to practice in the course of or under this contract, the Contractor agrees to and does hereby grant to the Government an irrevocable, nonexclusive, paid-up license in and to any inventions or discoveries regardless of when conceived or actually reduced to practice or acquired by the contractor at any time through completion of this contract and which are incorporated or embodied in the construction of the facility or which are utilized in the operation of the facility or which cover articles, materials, or products manufactured at the facility (1) to practice or have practiced by or for the Government at the facility, and (2) to transfer such license with the transfer of that facility. Notwithstanding the acceptance or exercise by the Government of these rights, the Government may contest at any time the enforceability, validity or scope of, or title to, any rights or patents herein licensed.

(n) *Atomic Energy.* (1) *Pecuniary awards.* No claim for pecuniary award of compensation under the provisions of the Atomic Energy Act of 1954, as amended, may be asserted with respect to any invention or discovery made or conceived in the course of or under this contract.

(2) *Patent Agreements.* Except as otherwise authorized in writing by the Contracting Officer, the Contractor shall obtain patent agreements to effectuate the provisions of subparagraph (o)(1) of this clause from all persons who perform any part of the work under this contract, except nontechnical personnel, such as clerical employees and manual laborers.

(o) *Classified Inventions.* (1) *Approval for filing a foreign patent application.* The Contractor shall not file or cause to be filed an application or registration for a patent disclosing a subject invention related to classified subject matter in any country other than the United States without first obtaining the written approval of the Contracting Officer.

(2) *Transmission of classified subject matter.* If in accordance with this clause the Contractor files a patent application in the United States disclosing a subject invention that is classified for reasons of security, the Contractor shall observe all applicable security regulations covering the transmission of classified subject matter. If the Contractor transmits a patent application disclosing a classified subject invention to the United States Patent and Trademark Office (USPTO), the Contractor shall submit a separate letter to the USPTO identifying the contract or contracts by agency and agreement number that require security classification markings to be placed on the patent application.

(3) *Inclusion of clause in subcontracts.* The Contractor agrees to include the substance of this clause in subcontracts at any tier that cover or are likely to cover subject matter classified for reasons of security.

(p) *Examination of Records Relating to Inventions.* (1) *Contractor compliance.* Until the expiration of three (3) years after final payment under this contract, the Contracting Officer or any authorized representative may examine any books (including laboratory notebooks), records, and documents and other supporting data of the Contractor, which the Contracting Officer or authorized representative deems reasonably pertinent to the discovery or identification of subject inventions, including exceptional circumstance subject inventions, or to determine Contractor (and inventor) compliance with the requirements of this clause, including proper identification and disclosure of subject inventions, and establishment and maintenance of invention disclosure procedures.

(2) *Unreported inventions.* If the Contracting Officer is aware of an invention

that is not disclosed by the Contractor to DOE, and the Contracting Officer believes the unreported invention may be a subject invention, DOE may require the Contractor to submit to DOE a disclosure of the invention for a determination of ownership rights.

(3) *Confidentiality.* Any examination of records under this paragraph is subject to appropriate conditions to protect the confidentiality of the information involved.

(4) *Power of inspection.* With respect to a subject invention for which the Contractor has responsibility for patent prosecution, the Contractor shall furnish the Government, upon request by DOE, an irrevocable power to inspect and make copies of a prosecution file for any patent application claiming the subject invention.

(q) *Patent Functions.* Upon the written request of the Contracting Officer or Patent Counsel, the Contractor agrees to make reasonable efforts to support DOE in accomplishing patent-related functions for work arising out of the contract, including, but not limited to, the prosecution of patent applications, and the determination of questions of novelty, patentability, and inventorship.

(r) *Educational Awards Subject to 35 U.S.C. 212.* The Contractor shall notify the Contracting Officer prior to the placement of any person subject to 35 U.S.C. 212 in an area of technology or task (1) related to exceptional circumstance technology or (2) any person who is subject to treaties or international agreements as set forth in paragraph (b)(6) of this clause or to agreements other than funding agreements. The Contracting Officer may disapprove of any such placement.

(s) *Annual Appraisal by Patent Counsel.* Patent Counsel may conduct an annual appraisal to evaluate the Contractor's effectiveness in identifying and protecting subject inventions in accordance with DOE policy.

(t) *Publication.* The Contractor shall receive approval from Patent Counsel prior to releasing or publishing information regarding scientific or technical developments conceived or first actually reduced to practice in the course of or under this contract, to ensure such release or publication does not adversely affect the patent rights of DOE or the Contractor.

(u) *Termination of Contractor's Advance Class Waiver.* If a request by the Contractor for an advance class waiver pursuant to subparagraph (b)(2) of this clause or a determination of

greater rights pursuant to paragraph (c) of this clause contains false material statements or fails to disclose material facts, and DOE relies on the false statements or omissions in granting the Contractor's request, the waiver or grant of any Government rights (in whole or in part) to the subject invention(s) may be terminated at the discretion of the Secretary of Energy or designee. Prior to termination, DOE shall provide the Contractor with written notification of the termination, including a statement of facts in support of the termination, and the Contractor shall be allowed thirty (30) days, or a longer period authorized by the Secretary of Energy or designee for good cause shown in writing by the Contractor, to show cause for not terminating the waiver or grant. Any termination of an advance class waiver or a determination of greater rights is subject to the Contractor's license as provided for in paragraph (f) of this clause.

(End of Clause)

Alternate 1 Weapons Related Subject Inventions. As prescribed at 970.2703-2(g), insert the following as subparagraphs (a)(9) and (b)(10), respectively:

(a) *Definitions.* (9) *Weapons Related Subject Invention* means any subject invention conceived or first actually reduced to practice in the course of or under work funded by or through defense programs, including Department of Defense and intelligence reimbursable work, or the Naval Nuclear Propulsion Program of the Department of Energy.

(b) *Allocation of Principal Rights.* (10) *Weapons related subject inventions.* Except to the extent that DOE is solely satisfied that the Contractor meets certain procedural requirements and DOE grants rights to the Contractor in weapons related subject inventions, the Contractor does not have a right to retain title to any weapons related subject inventions.

(End of Alternate)

970.5228-1 Insurance-litigation and claims.

As prescribed in 48 CFR 970.2803-2, insert the following clause:

Insurance—Litigation and Claims (DEC 2000)

(a) The contractor may, with the prior written authorization of the contracting officer, and shall, upon the request of the Government, initiate litigation against third parties, including proceedings before administrative agencies, in connection with this contract. The contractor shall proceed with such litigation in good faith and as directed from time to time by the contracting officer.

(b) The contractor shall give the contracting officer immediate notice in writing of any legal proceeding, including any proceeding before an administrative agency, filed against the contractor arising out of the performance of this contract. Except as otherwise directed by the contracting officer, in writing, the contractor shall furnish immediately to the contracting

officer copies of all pertinent papers received by the contractor with respect to such action. The contractor, with the prior written authorization of the contracting officer, shall proceed with such litigation in good faith and as directed from time to time by the contracting officer.

(c)(1) Except as provided in paragraph (c)(2) of this clause, the contractor shall procure and maintain such bonds and insurance as required by law or approved in writing by the contracting officer.

(2) The contractor may, with the approval of the contracting officer, maintain a self-insurance program; provided that, with respect to workers' compensation, the contractor is qualified pursuant to statutory authority.

(3) All bonds and insurance required by this clause shall be in a form and amount and for those periods as the contracting officer may require or approve and with sureties and insurers approved by the contracting officer.

(d) The contractor agrees to submit for the contracting officer's approval, to the extent and in the manner required by the contracting officer, any other bonds and insurance that are maintained by the contractor in connection with the performance of this contract and for which the contractor seeks reimbursement. If an insurance cost (whether a premium for commercial insurance or related to self-insurance) includes a portion covering costs made unallowable elsewhere in the contract, and the share of the cost for coverage for the unallowable cost is determinable, the portion of the cost that is otherwise an allowable cost under this contract is reimbursable to the extent determined by the contracting officer.

(e) Except as provided in subparagraphs (g) and (h) of this clause, or specifically disallowed elsewhere in this contract, the contractor shall be reimbursed—

(1) For that portion of the reasonable cost of bonds and insurance allocable to this contract required in accordance with contract terms or approved under this clause, and

(2) For liabilities (and reasonable expenses incidental to such liabilities, including litigation costs) to third persons not compensated by insurance or otherwise without regard to and as an exception to the clause of this contract entitled, "Obligation of Funds."

(f) The Government's liability under paragraph (e) of this clause is subject to the availability of appropriated funds. Nothing in this contract shall be construed as implying that the Congress will, at a later date, appropriate funds sufficient to meet deficiencies.

(g) Notwithstanding any other provision of this contract, the contractor shall not be reimbursed for liabilities (and expenses incidental to such liabilities, including litigation costs, counsel fees, judgment and settlements)—

(1) Which are otherwise unallowable by law or the provisions of this contract; or

(2) For which the contractor has failed to insure or to maintain insurance as required by law, this contract, or by the written direction of the contracting officer.

(h) In addition to the cost reimbursement limitations contained in 48 CFR Part 31, as supplemented by 48 CFR 970.31, and notwithstanding any other provision of this contract, the contractor's liabilities to third persons, including employees but excluding costs incidental to worker's compensation actions, (and any expenses incidental to such liabilities, including litigation costs, counsel fees, judgments and settlements) shall not be reimbursed if such liabilities were caused by contractor managerial personnel's—

(1) Willful misconduct,

(2) Lack of good faith, or

(3) Failure to exercise prudent business judgment, which means failure to act in the same manner as a prudent person in the conduct of competitive business; or, in the case of a non-profit educational institution, failure to act in the manner that a prudent person would under the circumstances prevailing at the time the decision to incur the cost is made.

(i) The burden of proof shall be upon the contractor to establish that costs covered by paragraph (h) of this clause are allowable and reasonable if, after an initial review of the facts, the contracting officer challenges a specific cost or informs the contractor that there is reason to believe that the cost results from willful misconduct, lack of good faith, or failure to exercise prudent business judgment by contractor managerial personnel.

(j)(1) All litigation costs, including counsel fees, judgments and settlements shall be differentiated and accounted for by the contractor so as to be separately identifiable. If the contracting officer provisionally disallows such costs, then the contractor may not use funds advanced by DOE under the contract to finance the litigation.

(2) Punitive damages are not allowable unless the act or failure to act which gave rise to the liability resulted from compliance with specific terms and conditions of the contract or written instructions from the contracting officer.

(3) The portion of the cost of insurance obtained by the contractor that is allocable to coverage of liabilities referred to in paragraph (g)(1) of this clause is not allowable.

(4) The term "contractor's managerial personnel" is defined in clause paragraph (j) of 48 CFR 970.5245-1.

(k) The contractor may at its own expense and not as an allowable cost procure for its own protection insurance to compensate the contractor for any unallowable or unreimbursable costs incurred in connection with contract performance.

(l) If any suit or action is filed or any claim is made against the contractor, the cost and expense of which may be reimbursable to the contractor under this contract, and the risk of which is then uninsured or is insured for less than the amount claimed, the contractor shall—

(1) Immediately notify the contracting officer and promptly furnish copies of all pertinent papers received;

(2) Authorize Department representatives to collaborate with: in-house or DOE-approved outside counsel in settling or defending the claim; or counsel for the insurance carrier in settling or defending the claim if the amount of the liability claimed exceeds the amount of coverage, unless precluded by the terms of the insurance contract; and

(3) Authorize Department representatives to settle the claim or to defend or represent the contractor in and/or to take charge of any litigation, if required by the Department, if the liability is not insured or covered by bond. In any action against more than one Department contractor, the Department may require the contractor to be represented by common counsel. Counsel for the contractor may, at the contractor's own expense, be associated with the Department representatives in any such claim or litigation.

(m) Reasonable litigation and other legal expenses are allowable when incurred in accordance with the DOE approved contractor legal management procedures (including cost guidelines) as such procedures may be revised from time to time, and if not otherwise made unallowable by law or the provisions of this contract.

(End of Clause)

970.5229-1 State and local taxes.

As prescribed in 48 CFR 970.2904-1(b), insert the following clause in management and operating contracts. The requirement for the notice prescribed in paragraph (a) of the clause may be broadened to include all State and local taxes which may be claimed as allowable costs when considered to be appropriate.

State and Local Taxes (DEC 2000)

(a) The contractor agrees to notify the contracting officer of any State or local tax, fee, or charge levied or purported to be levied on or collected from the contractor with respect to the contract work, any transaction thereunder, or property in the custody or control of the contractor and constituting an allowable item of cost if due and payable, but which the contractor has reason to believe, or the contracting officer has advised the contractor, is or may be inapplicable or invalid; and the contractor further agrees to refrain from paying any such tax, fee, or charge unless authorized in writing by the contracting officer. Any State or local tax, fee, or charge paid with the approval of the contracting officer or on the basis of advice from the contracting officer that such tax, fee, or charge is applicable and valid, and which would otherwise be an allowable item of cost, shall not be disallowed as an item of cost by reason of any subsequent ruling or determination that such tax, fee, or charge was in fact inapplicable or invalid.

(b) The contractor agrees to take such action as may be required or approved by the contracting officer to cause any State or local tax, fee, or charge which would be an allowable cost to be paid under protest; and to take such action as may be required or approved by the contracting officer to seek

recovery of any payments made, including assignment to the Government or its designee of all rights to an abatement or refund thereof, and granting permission for the Government to join with the contractor in any proceedings for the recovery thereof or to sue for recovery in the name of the contractor. If the contracting officer directs the contractor to institute litigation to enjoin the collection of or to recover payment of any such tax, fee, or charge referred to above, or if a claim or suit is filed against the contractor for a tax, fee, or charge it has refrained from paying in accordance with this clause, the procedures and requirements of the clause entitled "Insurance-Litigation and Claims" shall apply and the costs and expenses incurred by the contractor shall be allowable items of costs, as provided in this contract, together with the amount of any judgment rendered against the contractor.

(c) The Government shall hold the contractor harmless from penalties and interest incurred through compliance with this clause. All recoveries or credits in respect of the foregoing taxes, fees, and charges (including interest) shall inure to and be for the sole benefit of the Government.

(End of Clause)

970.5231-4 Preexisting conditions.

As prescribed in 48 CFR 970.3170, insert the following clause:

Preexisting Conditions (DEC 2000)

(a) The Department of Energy agrees to reimburse the contractor, and the contractor shall not be held responsible, for any liability (including without limitation, a claim involving strict or absolute liability and any civil fine or penalty), expense, or remediation cost, but limited to those of a civil nature, which may be incurred by, imposed on, or asserted against the contractor arising out of any condition, act, or failure to act which occurred before the contractor assumed responsibility on [Insert date contract began]. To the extent the acts or omissions of the contractor cause or add to any liability, expense or remediation cost resulting from conditions in existence prior to [Insert date contract began], the contractor shall be responsible in accordance with the terms and conditions of this contract.

(b) The obligations of the Department of Energy under this clause are subject to the availability of appropriated funds.

(End of Clause)

Alternate I (DEC 2000). As prescribed in 48 CFR 970.3170 (a), in contracts with incumbent management and operating contractors, substitute the following for paragraph (a) of the basic clause:

(a) Any liability, obligation, loss, damage, claim (including without limitation, a claim involving strict or absolute liability), action, suit, civil fine or penalty, cost, expense or disbursement, which may be incurred or imposed, or asserted by any party and arising out of any condition, act or failure to act which occurred before [Insert date this clause was included in contract], in conjunction with the management and operation of [Insert name of facility], shall be deemed incurred under Contract No. [Insert number of prior contract].

Alternate II (DEC 2000). As prescribed in 48 CFR 970.3170 (b), add the following paragraph (c) to the basic clause in contracts with management and operating contractors not previously working at that particular site or facility:

(c) The contractor has the duty to inspect the facilities and sites and timely identify to the contracting officer those conditions which it believes could give rise to a liability, obligation, loss, damage, penalty, fine, claim, action, suit, cost, expense, or disbursement or areas of actual or potential noncompliance with the terms and conditions of this contract or applicable law or regulation. The contractor has the responsibility to take corrective action, as directed by the contracting officer and as required elsewhere in this contract.

(End of Clause)

970.5232-1 Reduction or suspension of advance, partial, or progress payments upon finding of substantial evidence of fraud.

As prescribed in 48 CFR 970.3200-1-1, insert the following clause:

Reduction or Suspension of Advance, Partial, or Progress Payments (DEC 2000)

(a) The contracting officer may reduce or suspend further advance, partial, or progress payments to the contractor upon a written determination by the Senior Procurement Executive that substantial evidence exists that the contractor's request for advance, partial, or progress payment is based on fraud.

(b) The contractor shall be afforded a reasonable opportunity to respond in writing. (End of Clause)

970.5232-2 Payments and advances.

As prescribed in 48 CFR 970.3270(a)(1), insert the following clause:

Payments and Advances (DEC 2000)

(a) *Installments of fixed-fee.* The fixed-fee payable under this contract shall become due and payable in periodic installments in accordance with a schedule determined by the contracting officer. Fixed-fee payments shall be made by direct payment or withdrawn from funds advanced or available under this contract, as determined by the contracting officer. The contracting officer may offset against any such fee payment the amounts owed to the Government by the contractor, including any amounts owed for disallowed costs under this contract. No fixed-fee payment may be withdrawn against the payments cleared financing arrangement without prior written approval of the contracting officer.

(b) *Payments on Account of Allowable Costs.* The contracting officer and the contractor shall agree as to the extent to which payment for allowable costs or payments for other items specifically approved in writing by the contracting officer (for example, negotiated fixed amounts) shall be made from advances of Government funds. When pension contributions are paid by the contractor to the retirement fund less frequently than quarterly, accrued costs

therefor shall be excluded from costs for payment purposes until such costs are paid. If pension contribution are paid on a quarterly or more frequent basis, accrual therefor may be included in costs for payment purposes, provided that they are paid to the fund within 30 days after the close of the period covered. If payments are not made to the fund within such 30-day period, pension contribution costs shall be excluded from cost for payment purposes until payment has been made.

(c) *Special financial institution account—use.* All advances of Government funds shall be withdrawn pursuant to a payments cleared financing arrangement prescribed by DOE in favor of the financial institution or, at the option of the Government, shall be made by direct payment or other payment mechanism to the contractor, and shall be deposited only in the special financial institution account referred to in the Special Financial Institution Account Agreement, which is incorporated into this contract as Appendix—. No part of the funds in the special financial institution account shall be commingled with any funds of the contractor or used for a purpose other than that of making payments for costs allowable and, if applicable, fees earned under this contract, negotiated fixed amounts, or payments for other items specifically approved in writing by the contracting officer. If the contracting officer determines that the balance of such special financial institution account exceeds the contractor's current needs, the contractor shall promptly make such disposition of the excess as the contracting officer may direct.

(d) *Title to funds advanced.* Title to the unexpended balance of any funds advanced and of any special financial institution account established pursuant to this clause shall remain in the Government and be superior to any claim or lien of the financial institution of deposit or others. It is understood that an advance to the contractor hereunder is not a loan to the contractor, and will not require the payment of interest by the contractor, and that the contractor acquires no right, title or interest in or to such advance other than the right to make expenditures therefrom, as provided in this clause.

(e) *Financial settlement.* The Government shall promptly pay to the contractor the unpaid balance of allowable costs (or other items specifically approved in writing by the contracting officer) and fee upon termination of the work, expiration of the term of the contract, or completion of the work and its acceptance by the Government after:

(1) Compliance by the contractor with DOE's patent clearance requirements, and

(2) The furnishing by the contractor of:

(i) An assignment of the contractor's rights to any refunds, rebates, allowances, accounts receivable, collections accruing to the contractor in connection with the work under this contract, or other credits applicable to allowable costs under the contract;

(ii) A closing financial statement;

(iii) The accounting for Government-owned property required by the clause entitled "Property"; and

(iv) A release discharging the Government, its officers, agents, and employees from all

liabilities, obligations, and claims arising out of or under this contract subject only to the following exceptions:

(A) Specified claims in stated amounts or in estimated amounts where the amounts are not susceptible to exact statement by the contractor;

(B) Claims, together with reasonable expenses incidental thereto, based upon liabilities of the contractor to third parties arising out of the performance of this contract; provided that such claims are not known to the contractor on the date of the execution of the release; and provided further that the contractor gives notice of such claims in writing to the contracting officer promptly, but not more than one (1) year after the contractor's right of action first accrues. In addition, the contractor shall provide prompt notice to the contracting officer of all potential claims under this clause, whether in litigation or not (see also Contract Clause____, DEAR 970.5228-1, "Insurance—Litigation and Claims");

(C) Claims for reimbursement of costs (other than expenses of the contractor by reason of any indemnification of the Government against patent liability), including reasonable expenses incidental thereto, incurred by the contractor under the provisions of this contract relating to patents; and

(D) Claims recognizable under the clause entitled, Nuclear Hazards Indemnity Agreement.

(3) In arriving at the amount due the contractor under this clause, there shall be deducted,

(i) Any claim which the Government may have against the contractor in connection with this contract, and

(ii) Deductions due under the terms of this contract, and not otherwise recovered by or credited to the Government. The unliquidated balance of the special financial institution account may be applied to the amount due and any balance shall be returned to the Government forthwith.

(f) *Claims.* Claims for credit against funds advanced for payment shall be accompanied by such supporting documents and justification as the contracting officer shall prescribe.

(g) *Discounts.* The contractor shall take and afford the Government the advantage of all known and available cash and trade discounts, rebates, allowances, credits, salvage, and commissions unless the contracting officer finds that action is not in the best interest of the Government.

(h) *Collections.* All collections accruing to the contractor in connection with the work under this contract, except for the contractor's fee and royalties or other income accruing to the contractor from technology transfer activities in accordance with this contract, shall be Government property and shall be processed and accounted for in accordance with applicable requirements imposed by the contracting officer pursuant to the Laws, regulations, and DOE directives clause of this contract and, to the extent consistent with those requirements, shall be deposited in the special financial institution account or otherwise made available for payment of allowable costs under this

contract, unless otherwise directed by the contracting officer.

(i) *Direct payment of charges.* The Government reserves the right, upon ten days written notice from the contracting officer to the contractor, to pay directly to the persons concerned, all amounts due which otherwise would be allowable under this contract. Any payment so made shall discharge the Government of all liability to the contractor therefor.

(j) *Determining allowable costs.* The contracting officer shall determine allowable costs in accordance with the Federal Acquisition Regulation subpart 31.2 and the Department of Energy Acquisition Regulation subpart 48 CFR 970.31 in effect on the date of this contract and other provisions of this contract.

Alternate I (DEC 2000). As prescribed in 48 CFR 970.3270(a)(1)(i), if a separate fixed-fee is provided for a separate item of work, paragraph (a) of the basic clause should be modified to permit payment of the entire fixed-fee upon completion of that item.

Alternate II (DEC 2000). As prescribed in 48 CFR 970.3270(a)(1)(ii), when total available fee provisions are used, replace paragraph (a) of the basic clause with the following paragraph (a):

(a) *Payment of Total available fee: Base Fee and Performance Fee.* The base fee amount, if any, is payable in equal monthly installments. Total available fee amount earned is payable following the Government's Determination of Total Available Fee Amount Earned in accordance with the clause of this contract entitled "Total Available Fee: Base Fee Amount and Performance Fee Amount." Base fee amount and total available fee amount earned payments shall be made by direct payment or withdrawn from funds advanced or available under this contract, as determined by the contracting officer. The contracting officer may offset against any such fee payment the amounts owed to the Government by the contractor, including any amounts owed for disallowed costs under this contract. No base fee amount or total available fee amount earned payment may be withdrawn against the payments cleared financing arrangement without the prior written approval of the contracting officer.

Alternate III (DEC 2000). As prescribed in 48 CFR 970.3270(a)(1)(iii), the following paragraph (k) shall be included in management and operating contracts with integrated accounting systems:

(k) Review and approval of costs incurred. The contractor shall prepare and submit annually as of September 30, a "Statement of Costs Incurred and Claimed" (Cost Statement) for the total of net expenditures accrued (i.e., net costs incurred) for the period covered by the Cost Statement. The contractor shall certify the Cost Statement subject to the penalty provisions for unallowable costs as stated in sections 306(b) and (i) of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 256), as amended. DOE, after audit and appropriate adjustment, will approve such Cost Statement. This approval by DOE will constitute an acknowledgment by DOE that the net costs incurred are allowable

under the contract and that they have been recorded in the accounts maintained by the contractor in accordance with DOE accounting policies, but will not relieve the contractor of responsibility for DOE's assets in its care, for appropriate subsequent adjustments, or for errors later becoming known to DOE.

Alternate IV (DEC 2000). As prescribed in 48 CFR 970.3270(a)(1)(iv), the following paragraph (k) shall be included in management and operating contracts without integrated accounting systems:

(k) *Certification and penalties.* The contractor shall prepare and submit a "Statement of Costs Incurred and Claimed" (Cost Statement) for the total of net expenditures incurred for the period covered by the Cost Statement. It is anticipated that this will be an annual submission unless otherwise agreed to by the contracting officer. The contractor shall certify the Cost Statement subject to the penalty provisions for unallowable costs as stated in sections 306(b) and (i) of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 256), as amended.

970.5232-3 Accounts, records, and inspection.

As prescribed in 48 CFR 970.3270(a)(2), insert the following clause:

Accounts, Records, and Inspection (DEC 2000)

(a) *Accounts.* The contractor shall maintain a separate and distinct set of accounts, records, documents, and other evidence showing and supporting: all allowable costs incurred; collections accruing to the contractor in connection with the work under this contract, other applicable credits, negotiated fixed amounts, and fee accruals under this contract; and the receipt, use, and disposition of all Government property coming into the possession of the contractor under this contract. The system of accounts employed by the contractor shall be satisfactory to DOE and in accordance with generally accepted accounting principles consistently applied.

(b) *Inspection and audit of accounts and records.* All books of account and records relating to this contract shall be subject to inspection and audit by DOE or its designees in accordance with the provisions of Clause ____, Access to and ownership of records, at all reasonable times, before and during the period of retention provided for in paragraph (d) of this clause, and the contractor shall afford DOE proper facilities for such inspection and audit.

(c) *Audit of subcontractors' records.* The contractor also agrees, with respect to any subcontracts (including fixed-price or unit-price subcontracts or purchase orders) where, under the terms of the subcontract, costs incurred are a factor in determining the amount payable to the subcontractor of any tier, to either conduct an audit of the subcontractor's costs or arrange for such an audit to be performed by the cognizant government audit agency through the contracting officer.

(d) *Disposition of records.* Except as agreed upon by the Government and the contractor,

all financial and cost reports, books of account and supporting documents, system files, data bases, and other data evidencing costs allowable, collections accruing to the contractor in connection with the work under this contract, other applicable credits, and fee accruals under this contract, shall be the property of the Government, and shall be delivered to the Government or otherwise disposed of by the contractor either as the contracting officer may from time to time direct during the progress of the work or, in any event, as the contracting officer shall direct upon completion or termination of this contract and final audit of accounts hereunder. Except as otherwise provided in this contract, including provisions of Clause ____, Access to and ownership of records, all other records in the possession of the contractor relating to this contract shall be preserved by the contractor for a period of three years after final payment under this contract or otherwise disposed of in such manner as may be agreed upon by the Government and the contractor.

(e) *Reports.* The contractor shall furnish such progress reports and schedules, financial and cost reports, and other reports concerning the work under this contract as the contracting officer may from time to time require.

(f) *Inspections.* The DOE shall have the right to inspect the work and activities of the contractor under this contract at such time and in such manner as it shall deem appropriate.

(g) *Subcontracts.* The contractor further agrees to require the inclusion of provisions similar to those in paragraphs (a) through (g) and paragraph (h) of this clause in all subcontracts (including fixed-price or unit-price subcontracts or purchase orders) of any tier entered into hereunder where, under the terms of the subcontract, costs incurred are a factor in determining the amount payable to the subcontractor.

(h) *Comptroller General.* (1) The Comptroller General of the United States, or an authorized representative, shall have access to and the right to examine any of the contractor's directly pertinent records involving transactions related to this contract or a subcontract hereunder.

(2) This paragraph may not be construed to require the contractor or subcontractor to create or maintain any record that the contractor or subcontractor does not maintain in the ordinary course of business or pursuant to a provision of law.

(3) Nothing in this contract shall be deemed to preclude an audit by the General Accounting Office of any transaction under this contract.

(End of Clause)

Alternate I (DEC 2000). As prescribed in 48 CFR 970.3270(a)(2)(i), if the contract includes the clause at 48 CFR 52.215-11, Price Reduction for Defective Cost or Pricing Data, the basic clause shall be modified as follows:

(a) Paragraph (a) of the basic clause shall be modified by adding the words "or anticipated to be incurred" after the words "allowable costs incurred."

(b) Paragraph (g) of the basic clause shall be modified by adding the following:

The contractor further agrees to include an "Audit" clause, the substance of which is the "Audit" clause set forth at 48 CFR 52.215-2, in each subcontract which does not include provisions similar to those in paragraph (a) through paragraph (g) and paragraph (h) of this clause, but which contains a "defective cost or pricing data" clause.

Alternate II (DEC 2000). As prescribed in 48 CFR 970.3270(a)(2)(ii), in cost-reimbursement contracts involving an estimated cost exceeding \$5 million and expected to run for more than 2 years, and any other cost-reimbursement contract determined by the Head of the Contracting Activity in which the contractor has an established internal audit organization, add the following paragraph (i) to the basic clause:

(i) *Internal audit.* The contractor agrees to conduct an internal audit and examination satisfactory to DOE of the records, operations, expenses, and the transactions with respect to costs claimed to be allowable under this contract annually and at such other times as may be mutually agreed upon. The results of such audit, including the working papers, shall be submitted or made available to the contracting officer. The contractor shall include this paragraph (i) in all cost-reimbursement subcontracts with an estimated cost exceeding \$5 million and expected to run for more than 2 years, and any other cost-reimbursement subcontract determined by the Head of the Contracting Activity.

970.5232-4 Obligation of funds.

As prescribed in 48 CFR 970.3270(a)(3), insert the following clause:

Obligation of Funds (DEC 2000)

(a) *Obligation of funds.* The amount presently obligated by the Government with respect to this contract is ____ dollars (\$____). Such amount may be increased unilaterally by DOE by written notice to the contractor and may be increased or decreased by written agreement of the parties (whether or not by formal modification of this contract). Estimated collections from others for work and services to be performed under this contract are not included in the amount presently obligated. Such collections, to the extent actually received by the contractor, shall be processed and accounted for in accordance with applicable requirements imposed by the contracting officer pursuant to the Laws, regulations, and DOE directives clause of this contract. Nothing in this paragraph is to be construed as authorizing the contractor to exceed limitations stated in financial plans established by DOE and furnished to the contractor from time to time under this contract.

(b) *Limitation on payment by the Government.* Except as otherwise provided in this contract and except for costs which may be incurred by the contractor pursuant to the Termination clause of this contract or costs of claims allowable under the contract occurring after completion or termination and not released by the contractor at the time of financial settlement of the contract in

accordance with the clause entitled "Payments and Advances," payment by the Government under this contract on account of allowable costs shall not, in the aggregate, exceed the amount obligated with respect to this contract, less the contractor's fee and any negotiated fixed amount. Unless expressly negated in this contract, payment on account of those costs excepted in the preceding sentence which are in excess of the amount obligated with respect to this contract shall be subject to the availability of:

(1) collections accruing to the contractor in connection with the work under this contract and processed and accounted for in accordance with applicable requirements imposed by the contracting officer pursuant to the Laws, regulations, and DOE directives clause of this contract, and

(2) other funds which DOE may legally use for such purpose, provided DOE will use its best efforts to obtain the appropriation of funds for this purpose if not otherwise available.

(c) *Notices—Contractor excused from further performance.* The contractor shall notify DOE in writing whenever the unexpended balance of available funds (including collections available under paragraph (a) of this clause), plus the contractor's best estimate of collections to be received and available during the ____ day period hereinafter specified, is in the contractor's best judgment sufficient to continue contract operations at the programmed rate for only ____ days and to cover the contractor's unpaid fee and any negotiated fixed amounts, and outstanding encumbrances and liabilities on account of costs allowable under the contract at the end of such period. Whenever the unexpended balance of available funds (including collections available under paragraph (a) of this clause), less the amount of the contractor's fee then earned but not paid and any negotiated fixed amounts, is in the contractor's best judgment sufficient only to liquidate outstanding encumbrances and liabilities on account of costs allowable under this contract, the contractor shall immediately notify DOE and shall make no further encumbrances or expenditures (except to liquidate existing encumbrances and liabilities), and, unless the parties otherwise agree, the contractor shall be excused from further performance (except such performance as may become necessary in connection with termination by the Government) and the performance of all work hereunder will be deemed to have been terminated for the convenience of the Government in accordance with the provisions of the Termination clause of this contract.

(d) *Financial plans; cost and encumbrance limitations.* In addition to the limitations provided for elsewhere in this contract, DOE may, through financial plans, such as Approved Funding Programs, or other directives issued to the contractor, establish controls on the costs to be incurred and encumbrances to be made in the performance of the contract work. Such plans and directives may be amended or supplemented from time to time by DOE. The contractor agrees

(1) to comply with the specific limitations (ceilings) on costs and encumbrances set forth in such plans and directives,

(2) to comply with other requirements of such plans and directives, and

(3) to notify DOE promptly, in writing, whenever it has reason to believe that any limitation on costs and encumbrances will be exceeded or substantially underrun.

(e) *Government's right to terminate not affected.* The giving of any notice under this clause shall not be construed to waive or impair any right of the Government to terminate the contract under the provisions of the Termination clause of this contract.

(End of Clause)

Alternate I (DEC 2000). As prescribed in 48 CFR 970.3270(a)(3)(i), paragraph (d) of the clause may be omitted in contracts which, expressly or otherwise, provide a contractual basis for equivalent controls in a separate clause.

970.5232-5 Liability with respect to cost accounting standards.

As prescribed in 48 CFR 970.3270(a)(5), insert the following clause:

Liability With Respect to Cost Accounting Standards (DEC 2000)

(a) The contractor is not liable to the Government for increased costs or interest resulting from its failure to comply with the clauses of this contract entitled, "Cost Accounting Standards," and "Administration of Cost Accounting Standards," if its failure to comply with the clauses is caused by the contractor's compliance with published DOE financial management policies and procedures or other requirements established by the Department's Chief Financial Officer or Procurement Executive.

(b) The contractor is not liable to the Government for increased costs or interest resulting from its subcontractors' failure to comply with the clauses at FAR 52.230-2, "Cost Accounting Standards," and FAR 52.230-6, "Administration of Cost Accounting Standards," if the contractor includes in each covered subcontract a clause making the subcontractor liable to the Government for increased costs or interest resulting from the subcontractor's failure to comply with the clauses; and the contractor seeks the subcontract price adjustment and cooperates with the Government in the Government's attempts to recover from the subcontractor.

970.5232-6 Work for others funding authorization.

As prescribed in 48 CFR 970.3270(a)(6), insert the following clause:

Work for Others Funding Authorization (DEC 2000)

Any uncollectible receivables resulting from the contractor utilizing contractor corporate funding for reimbursable work shall be the responsibility of the contractor, and the United States Government shall have no liability to the contractor for the contractor's uncollected receivables. The contractor is permitted to provide advance

payment utilizing contractor corporate funds for reimbursable work to be performed by the contractor for a non-Federal entity in instances where advance payment from that entity is required under the Laws, regulations, and DOE directives clause of this contract and such advance cannot be obtained. The contractor is also permitted to provide advance payment utilizing contractor corporate funds to continue reimbursable work to be performed by the contractor for a Federal entity when the term or the funds on a Federal interagency agreement required under the Laws, regulations, and DOE directives clause of this contract have elapsed. The contractor's utilization of contractor corporate funds does not relieve the contractor of its responsibility to comply with all requirements for Work for Others applicable to this contract.

970.5232-7 Financial management system.

As prescribed in 48 CFR 970.3270(b)(1), insert the following clause:

Financial Management System (DEC 2000)

The contractor shall maintain and administer a financial management system that is suitable to provide proper accounting in accordance with DOE requirements for assets, liabilities, collections accruing to the contractor in connection with the work under this contract, expenditures, costs, and encumbrances; permits the preparation of accounts and accurate, reliable financial and statistical reports; and assures that accountability for the assets can be maintained. The contractor shall submit to DOE for written approval an annual plan for new financial management systems and/or subsystems and major enhancements and/or upgrades to the currently existing financial systems and/or subsystems. The contractor shall notify DOE thirty (30) days in advance of any planned implementation of any substantial deviation from this plan and, as requested by the contracting officer, shall submit any such deviation to DOE for written approval before implementation.

970.5232-8 Integrated accounting.

As prescribed in 48 CFR 970.3270(b)(2), insert the following clause:

Integrated Accounting (DEC 2000)

Integrated accounting procedures are required for use under this contract. The contractor's financial management system shall include an integrated accounting system that is linked to DOE's accounts through the use of reciprocal accounts and that has electronic capability to transmit monthly and year-end self-balancing trial balances to the Department's Primary Accounting System for reporting financial activity under this contract in accordance with requirements imposed by the contracting officer pursuant to the Laws, regulations, and DOE directives clause of this contract.

970.5235-1 Federally funded research and development center sponsoring agreement.

As prescribed in 48 CFR 970.3501-4, the contracting officer shall insert the following clause:

Federally Funded Research and Development Center Sponsoring Agreement (DEC 2000)

(a) Pursuant to 48 CFR 35.017-1, this contract constitutes the sponsoring agreement between the Department of Energy and the contractor, which establishes the relationship for the operation of a Department of Energy sponsored Federally Funded Research and Development Center (FFRDC).

(b) In the operation of this FFRDC, the contractor may be provided access beyond that which is common to the normal contractual relationship, to Government and supplier data, including sensitive and proprietary data, and to Government employees and facilities needed to discharge its responsibilities efficiently and effectively. Because of this special relationship, it is essential that the FFRDC be operated in the public interest with objectivity and independence, be free from organizational conflicts of interest, and have full disclosure of its affairs to the Department of Energy.

(c) Unless otherwise provided by the contract, the contractor may accept work from a nonsponsor (as defined in 48 CFR 35.017) in accordance with the requirements and limitations of DOE Order 481.1, Work for Others (Non-Department of Energy Funded Work) (see current version).

(d) As an FFRDC, the contractor shall not use its privileged information or access to government facilities to compete with the private sector. Specific guidance on restricted activities is contained in DOE Order 481.1. (End of Clause)

970.5236-1 Government facility subcontract approval.

As prescribed in 48 CFR 970.3605-2, insert the following clause:

Government Facility Subcontract Approval (DEC 2000)

Upon request of the contracting officer and acceptance thereof by the contractor, the contractor shall procure, by subcontract, the construction of new facilities or the alteration or repair of Government-owned facilities at the plant. Any subcontract entered into under this paragraph shall be subject to the written approval of the contracting officer and shall contain the provisions relative to labor and wages required by law to be included in contracts for the construction, alteration, and/or repair, including painting and decorating, of a public building or public work.

(End of Clause)

970.5237-2 Facilities management.

As prescribed in 48 CFR 970.3770-2, insert the following clause:

Facilities Management (DEC 2000)

Copies of DOE Directives referenced herein are available from the contracting officer.

(a) *Site development planning.* The Government shall provide to the contractor

site development guidance for the facilities and lands for which the contractor is responsible under the terms and conditions of this contract. Based upon this guidance, the contractor shall prepare, and maintain through annual updates, a Long-Range Site Development Plan (Plan) to reflect those actions necessary to keep the development of these facilities current with the needs of the Government and allow the contractor to successfully accomplish the work required under this contract. In developing this Plan, the contractor shall follow the procedural guidance set forth in the applicable DOE Directives in the Life Cycle Facility Operations Series listed elsewhere in this contract. The contractor shall use the Plan to manage and control the development of facilities and lands. All plans and revisions shall be approved by the Government.

(b) *General design criteria.* The general design criteria which shall be utilized by the contractor in managing the site for which it is responsible under this contract are those specified in the applicable DOE Directives in the 6430, Design Criteria, series listed elsewhere in this contract. The contractor shall comply with these mandatory, minimally acceptable requirements for all facility designs with regard to any building acquisition, new facility, facility addition or alteration or facility lease undertaken as part of the site development activities of paragraph (a) of this clause. This includes on-site constructed buildings, pre-engineered buildings, plan-fabricated modular buildings, and temporary facilities. For existing facilities, original design criteria apply to the structure in general; however, additions or modifications shall comply with this directive and the associated latest editions of the references therein. An exception may be granted for off-site office space being leased by the contractor on a temporary basis.

(c) *Energy management.* The contractor shall manage the facilities for which it is responsible under the terms and conditions of this contract in an energy efficient manner in accordance with the applicable DOE Directives in the Life Cycle Facility Operations Series listed elsewhere in this contract. The contractor shall develop a 10-year energy management plan for each site with annual reviews and revisions. The contractor shall submit an annual report on progress toward achieving the goals of the 10-year plan for each individual site, and an energy conservation analysis report for each new building or building addition project. Any acquisition of utility services by the contractor shall be conducted in accordance with 48 CFR 970.41.

(d) *Subcontract Requirements.* To the extent the contractor subcontracts performance of any of the responsibilities discussed in this clause, the subcontract shall contain the requirements of this clause relative to the subcontracted responsibilities. (End of Clause)

970.5242-1 Penalties for unallowable costs.

As prescribed in 48 CFR 970.4207-03-70, insert the following clause:

Penalties for Unallowable Costs (DEC 2000)

(a) Contractors which include unallowable cost in a submission for settlement for cost incurred, may be subject to penalties.

(b) If, during the review of a submission for settlement of cost incurred, the contracting officer determines that the submission contains an expressly unallowable cost or a cost determined to be unallowable prior to the submission, the contracting officer shall assess a penalty.

(c) Unallowable costs are either expressly unallowable or determined unallowable.

(1) An expressly unallowable cost is a particular item or type of cost which, under the express provisions of an applicable law, regulation, or this contract, is specifically named and stated to be unallowable.

(2) A cost determined unallowable is one which, for that contractor,

(i) was subject to a contracting officer's final decision and not appealed;

(ii) the Department's Board of Contract Appeals or a court has previously ruled as unallowable; or

(iii) was mutually agreed to be unallowable.

(d) If the contracting officer determines that a cost submitted by the contractor in its submission for settlement of cost incurred is:

(1) expressly unallowable, then the contracting officer shall assess a penalty in an amount equal to the disallowed cost allocated to this contract plus interest on the paid portion of the disallowed cost. Interest shall be computed from the date of overpayment to the date of repayment using the interest rate specified by the Secretary of the Treasury pursuant to Pub. L. 92-41 (85 Stat. 97); or

(2) determined unallowable, then the contracting officer shall assess a penalty in an amount equal to two times the amount of the disallowed cost allocated to this contract.

(e) The contracting officer may waive the penalty provisions when

(1) the contractor withdraws the submission before the formal initiation of an audit of the submission and submits a revised submission;

(2) the amount of the unallowable costs allocated to covered contracts is \$10,000 or less; or

(3) the contractor demonstrates to the contracting officer's satisfaction that:

(i) it has established appropriate policies, personnel training, and an internal control and review system that provides assurances that unallowable costs subject to penalties are precluded from the contractor's submission for settlement of costs; and

(ii) the unallowable costs subject to the penalty were inadvertently incorporated into the submission.

(End of clause)

970.5243-1 Changes.

As prescribed in 48 CFR 970.4302-1, the contracting officer shall insert the following clause in all management and operating contracts:

Changes (DEC 2000)

(a) *Changes and adjustment of fee.* The contracting officer may at any time and

without notice to the sureties, if any, issue written directions within the general scope of this contract requiring additional work or directing the omission of, or variation in, work covered by this contract. If any such direction results in a material change in the amount or character of the work described in the "Statement of Work," an equitable adjustment of the fee, if any, shall be made in accordance with the agreement of the parties and the contract shall be modified in writing accordingly. Any claim by the contractor for an adjustment under this clause must be asserted in writing within 30 days from the date of receipt by the contractor of the notification of change; provided, however, that the contracting officer, if it is determined that the facts justify such action, may receive and act upon any such claim asserted at any time prior to final payment under this contract. A failure to agree on an equitable adjustment under this clause shall be deemed to be a dispute within the meaning of the clause entitled "Disputes."

(b) *Work to continue.* Nothing contained in this clause shall excuse the contractor from proceeding with the prosecution of the work in accordance with the requirements of any direction hereunder.

(End of Clause)

970.5244-1 Contractor purchasing system.

As prescribed in 48 CFR 970.4402-5, insert the following clause:

Contractor Purchasing System (DEC 2000)

(a) *General.* The contractor shall develop, implement, and maintain formal policies, practices, and procedures to be used in the award of subcontracts consistent with this clause and 48 CFR 970.44. The contractor's purchasing system and methods shall be fully documented, consistently applied, and acceptable to DOE in accordance with 48 CFR 970.4401-1. The contractor shall maintain file documentation which is appropriate to the value of the purchase and is adequate to establish the propriety of the transaction and the price paid. The contractor's purchasing performance will be evaluated against such performance criteria and measures as may be set forth elsewhere in this contract. DOE reserves the right at any time to require that the contractor submit for approval any or all purchases under this contract. The contractor shall not purchase any item or service the purchase of which is expressly prohibited by the written direction of DOE and shall use such special and directed sources as may be expressly required by the DOE contracting officer. DOE will conduct periodic appraisals of the contractor's management of all facets of the purchasing function, including the contractor's compliance with its approved system and methods. Such appraisals will be performed through the conduct of Contractor Purchasing System Reviews in accordance with 48 CFR subpart 44.3, or, when approved by the contracting officer, through the contractor's participation in the conduct of the Balanced Scorecard performance measurement and performance management system. The contractor's approved

purchasing system and methods shall include the requirements set forth in paragraphs (b) through (x) of this clause.

(b) *Acquisition of utility services.* Utility services shall be acquired in accordance with the requirements of 48 CFR 970.41.

(c) *Acquisition of Real Property.* Real property shall be acquired in accordance with 48 CFR Subpart 917.74.

(d) *Advance Notice of Proposed Subcontract Awards.* Advance notice shall be provided in accordance with 48 CFR 970.4401-3.

(e) *Audit of Subcontractors.* (1) The contractor shall provide for:

(i) periodic post-award audit of cost-reimbursement subcontractors at all tiers, and

(ii) audits, where necessary, to provide a valid basis for pre-award or cost or price analysis.

(2) Responsibility for determining the costs allowable under each cost-reimbursement subcontract remains with the contractor or next higher-tier subcontractor. The contractor shall provide, in appropriate cases, for the timely involvement of the contractor and the DOE contracting officer in resolution of subcontract cost allowability.

(3) Where audits of subcontractors at any tier are required, arrangements may be made to have the cognizant Federal agency perform the audit of the subcontract. These arrangements shall be made administratively between DOE and the other agency involved and shall provide for the cognizant agency to audit in an appropriate manner in light of the magnitude and nature of the subcontract. In no case, however, shall these arrangements preclude determination by the DOE contracting officer of the allowability or unallowability of subcontractor costs claimed for reimbursement by the contractor.

(4) Allowable costs for cost reimbursable subcontracts are to be determined in accordance with the cost principles of 48 CFR Part 31, appropriate for the type of organization to which the subcontract is to be awarded, as supplemented by 48 CFR Part 931. Allowable costs in the purchase or transfer from contractor-affiliated sources shall be determined in accordance with 48 CFR 970.4402-3 and 48 CFR 970.3102-3-21(b).

(f) *Bonds and Insurance.* (1) The contractor shall require performance bonds in penal amounts as set forth in 48 CFR 28.102-2(a) for all fixed priced and unit-priced construction subcontracts in excess of \$100,000. The contractor shall consider the use of performance bonds in fixed price nonconstruction subcontracts, where appropriate.

(2) For fixed-price, unit-priced and cost reimbursement construction subcontracts in excess of \$100,000 a payment bond shall be obtained on Standard Form 25A modified to name the contractor as well as the United States of America as obligees. The penal amounts shall be determined in accordance with 48 CFR 28.102-2(b).

(3) For fixed-price, unit-priced and cost-reimbursement construction subcontracts, greater than \$25,000, but not greater than \$100,000, the contractor shall select two or more of the payment protections at 48 CFR

28.102-1(b), giving particular consideration to the inclusion of an irrevocable letter of credit as one of the selected alternatives.

(4) A subcontractor may have more than one acceptable surety in both construction and other subcontracts, provided that in no case will the liability of any one surety exceed the maximum penal sum for which it is qualified for any one obligation. For subcontracts other than construction, a co-surety (two or more sureties together) may reinsure amounts in excess of their individual capacity, with each surety having the required underwriting capacity that appears on the list of acceptable corporate sureties.

(g) *Buy American.* The contractor shall comply with the provisions of the Buy American Act as reflected in 48 CFR 52.225-3 and 48 CFR 52.225-5. The contractor shall forward determinations of nonavailability of individual items to the DOE contracting officer for approval. Items in excess of \$100,000 require the prior concurrence of the Head of Contracting Activity. If, however, the contractor has an approved purchasing system, the Head of the Contracting Activity may authorize the contractor to make determinations of nonavailability for individual items valued at \$100,000 or less.

(h) *Construction and Architect-Engineer Subcontracts.* (1) *Independent Estimates.* A detailed, independent estimate of costs shall be prepared for all construction work to be subcontracted.

(2) *Specifications.* Specifications for construction shall be prepared in accordance with the DOE publication entitled "General Design Criteria Manual."

(3) *Prevention of Conflict of Interest.* (i) The contractor shall not award a subcontract for construction to the architect-engineer firm or an affiliate that prepared the design. This prohibition does not preclude the award of a "turnkey" subcontract so long as the subcontractor assumes all liability for defects in design and construction and consequential damages.

(ii) The contractor shall not award both a cost-reimbursement subcontract and a fixed-price subcontract for construction or architect-engineer services or any combination thereof to the same firm where those subcontracts will be performed at the same site.

(iii) The contractor shall not employ the construction subcontractor or an affiliate to inspect the firm's work. The contractor shall assure that the working relationships of the construction subcontractor and the subcontractor inspecting its work and the authority of the inspector are clearly defined.

(i) *Contractor-Affiliated Sources.* Equipment, materials, supplies, or services from a contractor-affiliated source shall be purchased or transferred in accordance with 48 CFR 970.4402-3.

(j) *Contractor-Subcontractor Relationship.* The obligations of the contractor under paragraph (a) of this clause, including the development of the purchasing system and methods, and purchases made pursuant thereto, shall not relieve the contractor of any obligation under this contract (including, among other things, the obligation to properly supervise, administer, and

coordinate the work of subcontractors). Subcontracts shall be in the name of the contractor, and shall not bind or purport to bind the Government.

(k) *Government Property*. Identification, inspection, maintenance, protection, and disposition of Government property shall conform with the policies and principles of 48 CFR Part 45, 48 CFR 945, the Federal Property Management Regulations 41 CFR Chapter 101, the DOE Property Management Regulations 41 CFR Chapter 109, and their contracts.

(l) *Indemnification*. Except for Price-Anderson Nuclear Hazards Indemnity, no subcontractor may be indemnified except with the prior approval of the Senior Procurement Executive.

(m) *Leasing of Motor Vehicles*. Contractors shall comply with 48 CFR 8.11 and 48 CFR 908.11.

(n) *Make-or-Buy Plans*. Acquisition of property and services shall be obtained on a least-cost basis, consistent with the requirements of the "Make-or-Buy Plan" clause of this contract and the contractor's approved make-or-buy plan.

(o) *Management, Acquisition and Use of Information Resources*. Requirements for automatic data processing resources and telecommunications facilities, services, and equipment, shall be reviewed and approved in accordance with applicable DOE Orders and regulations regarding information resources.

(p) *Priorities, Allocations and Allotments*. Priorities, allocations and allotments shall be extended to appropriate subcontracts in accordance with the clause or clauses of this contract dealing with priorities and allocations.

(q) *Purchase of Special Items*. Purchase of the following items shall be in accordance with the following provisions of 48 CFR 908.71 and the Federal Property Management Regulations, 41 CFR Chapter 101:

- (1) Motor vehicles—48 CFR 908.7101
 - (2) Aircraft—48 CFR 908.7102
 - (3) Security Cabinets—48 CFR 908.7106
 - (4) Alcohol—48 CFR 908.7107
 - (5) Helium—48 CFR 908.7108
 - (6) Fuels and packaged petroleum products—48 CFR 908.7109
 - (7) Coal—48 CFR 908.7110
 - (8) Arms and Ammunition—48 CFR 908.7111
 - (9) Heavy Water—48 CFR 908.7121(a)
 - (10) Precious Metals—48 CFR 908.7121(b)
 - (11) Lithium—48 CFR 908.7121(c)
 - (12) Products and services of the blind and severely handicapped—41 CFR 101-26.701
 - (13) Products made in Federal penal and correctional institutions—41 CFR 101-26.702
- (r) *Purchase vs. Lease Determinations*. Contractors shall determine whether required equipment and property should be purchased or leased, and establish appropriate thresholds for application of lease vs. purchase determinations. Such determinations shall be made:
- (1) at time of original acquisition;
 - (2) when lease renewals are being considered; and
 - (3) at other times as circumstances warrant.
- (s) *Quality Assurance*. Contractors shall provide no less protection for the

Government in its subcontracts than is provided in the prime contract.

(t) *Setoff of Assigned Subcontractor Proceeds*. Where a subcontractor has been permitted to assign payments to a financial institution, the assignment shall treat any right of setoff in accordance with 48 CFR 932.803.

(u) *Strategic and Critical Materials*. The contractor may use strategic and critical materials in the National Defense Stockpile.

(v) *Termination*. When subcontracts are terminated as a result of the termination of all or a portion of this contract, the contractor shall settle with subcontractors in conformity with the policies and principles relating to settlement of prime contracts in 48 CFR Subparts 49.1, 49.2 and 49.3. When subcontracts are terminated for reasons other than termination of this contract, the contractor shall settle such subcontracts in general conformity with the policies and principles in 48 CFR Subparts 49.1, 49.2, 49.3 and 49.4. Each such termination shall be documented and consistent with the terms of this contract. Terminations which require approval by the Government shall be supported by accounting data and other information as may be directed by the contracting officer.

(w) *Unclassified Controlled Nuclear Information*. Subcontracts involving unclassified uncontrolled nuclear information shall be treated in accordance with 10 CFR part 1017.

(x) *Subcontract Flowdown Requirements*. In addition to terms and conditions that are included in the prime contract which direct application of such terms and conditions in appropriate subcontracts, the contractor shall include the following clauses in subcontracts, as applicable:

- (1) Davis-Bacon clauses prescribed in 48 CFR 22.407.
- (2) Foreign Travel clause prescribed in 48 CFR 952.247-70.
- (3) Counterintelligence clause prescribed in 48 CFR 970.0404-4(a).
- (4) Service Contract Act clauses prescribed in 48 CFR 22.1006.
- (5) State and local taxes clause prescribed in 48 CFR 970.2904-1.
- (6) Cost or pricing data clauses prescribed in 48 CFR 970.1504-3-1(b).

(End of Clause)

970.5245-1 Property.

As prescribed in 48 CFR 970.4501-1(a), insert the following clause:
Property (DEC 2000)

(a) *Furnishing of Government property*. The Government reserves the right to furnish any property or services required for the performance of the work under this contract.

(b) *Title to property*. Except as otherwise provided by the contracting officer, title to all materials, equipment, supplies, and tangible personal property of every kind and description purchased by the contractor, for the cost of which the contractor is entitled to be reimbursed as a direct item of cost under this contract, shall pass directly from the vendor to the Government. The Government reserves the right to inspect, and to accept or reject, any item of such property. The

contractor shall make such disposition of rejected items as the contracting officer shall direct. Title to other property, the cost of which is reimbursable to the contractor under this contract, shall pass to and vest in the Government upon (1) issuance for use of such property in the performance of this contract, or (2) commencement of processing or use of such property in the performance of this contract, or (3) reimbursement of the cost thereof by the Government, whichever first occurs. Property furnished by the Government and property purchased or furnished by the contractor, title to which vests in the Government, under this paragraph are hereinafter referred to as Government property. Title to Government property shall not be affected by the incorporation of the property into or the attachment of it to any property not owned by the Government, nor shall such Government property or any part thereof, be or become a fixture or lose its identity as personality by reason of affixation to any realty.

(c) *Identification*. To the extent directed by the contracting officer, the contractor shall identify Government property coming into the contractor's possession or custody, by marking and segregating in such a way, satisfactory to the contracting officer, as shall indicate its ownership by the Government.

(d) *Disposition*. The contractor shall make such disposition of Government property which has come into the possession or custody of the contractor under this contract as the contracting officer may direct during the progress of the work or upon completion or termination of this contract. The contractor may, upon such terms and conditions as the contracting officer may approve, sell, or exchange such property, or acquire such property at a price agreed upon by the contracting officer and the contractor as the fair value thereof. The amount received by the contractor as the result of any disposition, or the agreed fair value of any such property acquired by the contractor, shall be applied in reduction of costs allowable under this contract or shall be otherwise credited to account to the Government, as the contracting officer may direct. Upon completion of the work or the termination of this contract, the contractor shall render an accounting, as prescribed by the contracting officer, of all government property which had come into the possession or custody of the contractor under this contract.

(e) *Protection of government property—management of high-risk property and classified materials*. (1) The contractor shall take all reasonable precautions, and such other actions as may be directed by the contracting officer, or in the absence of such direction, in accordance with sound business practice, to safeguard and protect government property in the contractor's possession or custody.

(2) In addition, the contractor shall ensure that adequate safeguards are in place, and adhered to, for the handling, control and disposition of high-risk property and classified materials throughout the life cycle of the property and materials consistent with the policies, practices and procedures for

property management contained in the Federal Property Management regulations (41 CFR chapter 101), the Department of Energy Property Management regulations (41 CFR chapter 109), and other applicable regulations.

(3) High-risk property is property, the loss, destruction, damage to, or the unintended or premature transfer of which could pose risks to the public, the environment, or the national security interests of the United States. High-risk property includes proliferation sensitive, nuclear related dual use, export controlled, chemically or radioactively contaminated, hazardous, and specially designed and prepared property, including property on the militarily critical technologies list.

(f) *Risk of loss of Government property.*

(1)(i) The contractor shall not be liable for the loss or destruction of, or damage to, Government property unless such loss, destruction, or damage was caused by any of the following:

(A) Willful misconduct or lack of good faith on the part of the contractor's managerial personnel;

(B) Failure of the contractor's managerial personnel to take all reasonable steps to comply with any appropriate written direction of the contracting officer to safeguard such property under paragraph (e) of this clause; or

(C) Failure of contractor managerial personnel to establish, administer, or properly maintain an approved property management system in accordance with paragraph (i)(1) of this clause.

(ii) If, after an initial review of the facts, the contracting officer informs the contractor that there is reason to believe that the loss, destruction of, or damage to the government property results from conduct falling within one of the categories set forth above, the burden of proof shall be upon the contractor to show that the contractor should not be required to compensate the government for the loss, destruction, or damage.

(2) In the event that the contractor is determined liable for the loss, destruction or damage to Government property in accordance with (f)(1) of this clause, the contractor's compensation to the Government shall be determined as follows:

(i) For damaged property, the compensation shall be the cost of repairing such damaged property, plus any costs incurred for temporary replacement of the damaged property. However, the value of repair costs shall not exceed the fair market value of the damaged property. If a fair market value of the property does not exist, the contracting officer shall determine the value of such property, consistent with all relevant facts and circumstances.

(ii) For destroyed or lost property, the compensation shall be the fair market value of such property at the time of such loss or destruction, plus any costs incurred for

temporary replacement and costs associated with the disposition of destroyed property. If a fair market value of the property does not exist, the contracting officer shall determine the value of such property, consistent with all relevant facts and circumstances.

(3) The portion of the cost of insurance obtained by the contractor that is allocable to coverage of risks of loss referred to in paragraph (f)(1) of this clause is not allowable.

(g) *Steps to be taken in event of loss.* In the event of any damage, destruction, or loss to Government property in the possession or custody of the contractor with a value above the threshold set out in the contractor's approved property management system, the contractor:

(1) Shall immediately inform the contracting officer of the occasion and extent thereof,

(2) Shall take all reasonable steps to protect the property remaining, and

(3) Shall repair or replace the damaged, destroyed, or lost property in accordance with the written direction of the contracting officer. The contractor shall take no action prejudicial to the right of the Government to recover therefore, and shall furnish to the Government, on request, all reasonable assistance in obtaining recovery.

(h) *Government property for Government use only.* Government property shall be used only for the performance of this contract.

(i) *Property Management.* (1) *Property Management System.* (i) The contractor shall establish, administer, and properly maintain an approved property management system of accounting for and control, utilization, maintenance, repair, protection, preservation, and disposition of Government property in its possession under the contract. The contractor's property management system shall be submitted to the contracting officer for approval and shall be maintained and administered in accordance with sound business practice, applicable Federal Property Management regulations and Department of Energy Property Management regulations, and such directives or instructions which the contracting officer may from time to time prescribe.

(ii) In order for a property management system to be approved, it must provide for:

(A) Comprehensive coverage of property from the requirement identification, through its life cycle, to final disposition;

(B) Employee personal responsibility and accountability for Government-owned property;

(C) Full integration with the contractor's other administrative and financial systems; and

(D) A method for continuously improving property management practices through the identification of best practices established by "best in class" performers.

(iii) Approval of the contractor's property management system shall be contingent upon

the completion of the baseline inventory as provided in subparagraph (i)(2) of this clause.

(2) *Property Inventory.* (i) Unless otherwise directed by the contracting officer, the contractor shall within six months after execution of the contract provide a baseline inventory covering all items of Government property.

(ii) If the contractor is succeeding another contractor in the performance of this contract, the contractor shall conduct a joint reconciliation of the property inventory with the predecessor contractor. The contractor agrees to participate in a joint reconciliation of the property inventory at the completion of this contract. This information will be used to provide a baseline for the succeeding contract as well as information for closeout of the predecessor contract.

(j) The term "contractor's managerial personnel" as used in this clause means the contractor's directors, officers and any of its managers, superintendents, or other equivalent representatives who have supervision or direction of:

(1) All or substantially all of the contractor's business; or

(2) All or substantially all of the contractor's operations at any one facility or separate location to which this contract is being performed; or

(3) A separate and complete major industrial operation in connection with the performance of this contract; or

(4) A separate and complete major construction, alteration, or repair operation in connection with performance of this contract; or

(5) A separate and discrete major task or operation in connection with the performance of this contract.

(k) The contractor shall include this clause in all cost reimbursable subcontracts.

(End of Clause)

Alternate I (DEC 2000). As prescribed in 48 CFR 970.4501-1(b), when the award is to a nonprofit contractor, replace paragraph (j) of the basic clause with the following paragraph (j):

(j) The term "contractor's managerial personnel" as used in this clause means the contractor's directors, officers and any of its managers, superintendents, or other equivalent representatives who have supervision or direction of all or substantially all of:

(1) The contractor's business; or

(2) The contractor's operations at any one facility or separate location at which this contract is being performed; or

(3) The contractor's Government property system and/or a Major System Acquisition or Major Project as defined in DOE Order 4700.1 (Version in effect on effective date of contract).

[FR Doc. 00-31542 Filed 12-21-00; 8:45 am]

BILLING CODE 6450-01-P



Federal Register

**Friday,
December 22, 2000**

Part III

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 201

**Requirements on Content and Format of
Labeling for Human Prescription Drugs
and Biologics; Requirements for
Prescription Drug Product Labels;
Proposed Rule**

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 201

[Docket No. 00N-1269]

RIN 0910-AA94

Requirements on Content and Format of Labeling for Human Prescription Drugs and Biologics; Requirements for Prescription Drug Product Labels

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend its regulations governing the format and content of labeling for human prescription drug and biologic products. This proposal would revise current regulations to require that the labeling of new and recently approved products include a section containing highlights of prescribing information and a section containing an index to prescribing information, reorder currently required information and make minor changes to its content, and establish minimum graphical requirements. These revisions would make it easier for health care practitioners to access, read, and use information in prescription drug labeling and would enhance the safe and effective use of prescription drug products. This proposal would also amend prescription drug labeling requirements for older drugs to require that certain types of statements currently appearing in labeling be removed if they are not sufficiently supported. Finally, the proposal would eliminate certain unnecessary statements that are currently required to appear on prescription drug product labels and move other, less important information to labeling. These changes would simplify drug product labels and reduce the possibility of medication errors.

DATES: Submit written comments by March 22, 2001. Submit written comments on the information collection requirements by January 22, 2001.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20857. Submit written comments on the information collection requirements to the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), New Executive Office Bldg., 725

17th St. NW., rm. 10235, Washington, DC 20503, ATTN: Wendy Taylor.

FOR FURTHER INFORMATION CONTACT: *For information on drug product labeling:*

Nancy M. Ostrove, Center for Drug Evaluation and Research (HFD-42), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-2828, e-mail: Ostrove@CDER.FDA.GOV

or

Lee D. Korb, Center for Drug Evaluation and Research (HFD-7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-2041, e-mail: Korb1@CDER.FDA.GOV

For information on biologics labeling:

Toni M. Stifano, Center for Biologics Evaluation and Research (HFM-600), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20856, 301-827-6190, e-mail: Stifano@CBER.FDA.GOV

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I. Background

The part of a prescription drug product's approved labeling directed to health care practitioners (also known as its "package insert," "direction circular," or "package circular") is the primary mechanism through which FDA and drug manufacturers communicate essential, science-based prescribing information to health care professionals. This part of approved labeling is a compilation of information based on a thorough analysis of the new drug application (NDA) or biologics license application (BLA) submitted by the applicant. The regulations governing the format and content of labeling for prescription drugs and biologics appear at §§ 201.56 and 201.57 (21 CFR 201.56 and 201.57).¹ Under § 201.100(d) (21 CFR 201.100(d)), any labeling, as defined in section 201(m) of the act (21 U.S.C. 321(m)), that is distributed by or on behalf of the manufacturer, packer, or distributor of the drug, that furnishes or purports to furnish information for use of the drug, or that prescribes, recommends, or suggests a dosage for the use of the drug, must meet the content and format requirements contained in §§ 201.56 and 201.57. Thus, §§ 201.56 and 201.57 apply to the labeling for all prescription drugs approved under an NDA, abbreviated new drug application (ANDA), or BLA, including labeling on or within the package from which the drug is to be dispensed and "promotional" labeling described in § 202.1(l)(2) (21 CFR 202.1(l)(2)).

Regulations proposing §§ 201.56 and 201.57 were published in the **Federal Register** of April 7, 1975 (40 FR 15392). At the time of the proposal, agency regulations required that certain section headings appear in prescription drug labeling, but did not, for the most part, specify the type of information required under those headings. The purpose of the proposal was to improve prescription drug labeling by ensuring that it contained more specific, comprehensive, and accurate information. The agency determined

¹ Although current §§ 201.56 and 201.57 do not specifically refer to biologics, under the Federal Food, Drug, and Cosmetic Act (the act), most biologics are drugs that require a prescription and thus are subject to these regulations.

that the primary purpose of prescription drug labeling is to provide practitioners with the essential information they need to prescribe the drug safely and effectively for the care of patients, and that revision of labeling requirements was necessary to achieve this objective for all products. Among other things, the proposal set forth standards for the content of labeling information required under the then-existing section headings, provided for a new section in prescription drug labeling entitled "Clinical Pharmacology," revised the format and expanded the content requirements for the "Indications and Usage" and "Adverse Reactions" sections of prescription drug labeling, and reformatted and expanded required information related to possible hazards of use in pregnant women and in children.

Regulations finalizing §§ 201.56 and 201.57 were published in the **Federal Register** of June 26, 1979 (44 FR 37434). These regulations were revised in 1994 by amending the requirements relating to the inclusion of data relevant to use in pediatric populations (59 FR 64240, December 13, 1994) and in 1997 by amending the requirements relating to the inclusion of data relevant to use in geriatric populations (62 FR 45313, August 27, 1997).

Current § 201.56 requires that prescription drug labeling contain the required information in the format specified in current § 201.57. Section 201.56 also sets forth general requirements for prescription drug labeling, including the requirement that labeling contain a summary of the essential scientific information needed for the safe and effective use of the drug, that it be informative and accurate and neither promotional in tone nor false or misleading, and that labeling be based whenever possible on data derived from human experience. In addition, § 201.56 sets forth required and optional section headings for prescription drug labeling and specifies the order in which those headings must appear. Required section headings include: "Description," "Clinical Pharmacology," "Indications and Usage," "Contraindications," "Warnings," "Precautions," "Adverse Reactions," "Drug Abuse and Dependence," "Overdosage," "Dosage and Administration," and "How Supplied." Section headings that may be included under certain circumstances include: "Animal Pharmacology and/or Animal Toxicology," "Clinical Studies," and "References."

Current § 201.57 specifies the kind of information that is required to appear under each of the section headings set

forth in § 201.56. This information is intended to help ensure that health care practitioners are provided with a complete and accurate explanation of prescription drugs to facilitate their safe and effective prescribing. Thus, the regulations require prescription drug labeling to contain detailed information on various topics that may be important to practitioners.

In addition to these regulations, the National Childhood Vaccine Injury Act (Public Law 103-66) requires FDA to monitor the adequacy of labeling for children's vaccines.

In addition to the requirements for prescription drug labeling discussed above, current §§ 201.55 (21 CFR 201.55) and 201.100(b) set forth certain requirements for prescription drug product labels. As discussed in section V of this document, the agency is proposing certain amendments to these requirements that would simplify prescription drug product labels and reduce the possibility of medication errors.

II. The Need for Revised Prescription Drug Labeling

Although the format and content requirements for prescription drug labeling in §§ 201.56 and 201.57 have enabled health care practitioners to prescribe drugs more safely and effectively, the requirements, together with various developments in recent years, have contributed to an increase in the amount, detail, and complexity of labeling information. This has made it harder for health care practitioners to find specific information and to discern the most critical information in product labeling.

Nonregulatory developments that have affected the length and complexity of drug labeling include technological advances in the drug products themselves and recognition of the importance of including new or additional labeling information, such as information on drug/drug interactions and information necessary to optimize use in various subpopulations. In addition, the use of labeling in product liability and medical malpractice lawsuits, together with increasing litigation costs, has caused manufacturers to become more cautious and include virtually all known adverse event information, regardless of its importance or its plausible relationship to the drug. Finally, accelerated approval of certain drugs for serious or life-threatening illnesses has resulted in the rapid availability of products for which expanded information about benefits and risks is necessary to help ensure safe and effective prescribing.

In response to the resulting increase in the length and complexity of prescription drug labeling and to anecdotal evidence suggesting that current prescription drug labeling does not optimally communicate its information (Ref. 1), FDA evaluated the usefulness of prescription drug labeling for its principal audience to determine whether, and how, its format and content can be improved. As discussed below, the agency conducted two initial focus groups and a national physician survey to ascertain how prescription drug labeling is used by health care practitioners, what labeling information is most important to practitioners, and how prescription drug labeling can be improved. Based on the results of the physician survey, FDA developed two prototype revisions to the format of prescription drug labeling ("Prototypes 1 and 2") and examined the value of these prototypes in four physician focus groups. Based on these results, FDA developed a third prototype ("Prototype 3") and held a public meeting to solicit public comments on Prototype 3. FDA revised the prototype ("Prototype 4") based on the public meeting and written comments submitted to the agency on Prototype 3. Prototype 4 serves as the model for this proposal and is included as Appendix 1.²

A discussion follows of the agency's prescription drug labeling development efforts, including the focus groups, physician surveys, public meeting, and prototype development.

A. Initial Focus Groups

In February 1992, FDA conducted two physician focus groups (Ref. 2) to ascertain how practitioners use prescription drug labeling, which aspects of labeling are most important to practitioners, and how current labeling can be improved. The focus groups indicated that the Physicians' Desk Reference (PDR) was the most common source of labeling information. The practitioners expressed concern about the lack of ease in locating specific information among the extensive information presented. They stated that the most important information needed to make a confident decision about prescribing a particular drug for a particular individual is contraindications (especially when the patient is a member of a special population), side effects, drug interactions, dosage, comparative efficacy, and cost information. The

² All prototypes may be seen at the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday (see Docket No. 95N-0314).

focus groups' recommendations with regard to improving the format included: (1) Using graphical devices to highlight important information; (2) adding an abstract of important information; (3) placing packaging and dosing information earlier in labeling; (4) enlarging the type size; and (5) reducing or eliminating anecdotal, marginal information.

B. Physician Surveys

Between October 1993 and March 1994, FDA conducted a telephone interview survey of a national probability sample of office-based physicians to determine how physicians perceive and use drug product labeling and to ascertain how labeling (the drug package insert) could be made more useful (the DPI survey). FDA designed the DPI survey to examine specific issues, including what is the perceived importance of the various labeling sections and what formatting alterations could make labeling more useful to practicing physicians.

Results of the DPI survey demonstrated that office-based physicians use drug product labeling primarily to answer specific questions about patient care rather than as a general educational tool and that labeling (generally in its reprinted form in the PDR) is consulted after the physician has made a tentative prescribing decision. The DPI survey further demonstrated that:

(1) The labeling sections physicians read most often and perceive as most important are: Dosage and Administration, Contraindications, Warnings, Adverse Reactions, and Precautions;

(2) Overall, the Clinical Pharmacology section, and the Abuse and Dependence and Overdosage sections, are referred to relatively infrequently;

(3) Physicians are prompted to refer to labeling most often by negative product experiences and newness of the product; and

(4) Physicians believe that labeling overly stresses the occurrence of extremely rare events. They also asserted that although they can generally find the information they need, the usefulness of labeling could be improved by highlighting and providing an abstract of the most important information.

In addition to the DPI survey that addressed drug package inserts generally, the agency conducted a physician survey from October 1994 to October 1995 to obtain information specifically regarding physicians' use of and perceptions about vaccine package inserts (the VPI survey). The VPI survey

was conducted by the agency's Center for Biologics Evaluation and Research (CBER) in an effort to improve the utility of vaccine package inserts in communicating the nature and extent of risks associated with vaccines. Among other things, the VPI survey was designed to examine whether changes can be made to vaccine package inserts to increase their usefulness.

Although the objectives of and the methodology used in the VPI survey were different than those used in the DPI survey, the VPI survey helped to confirm the findings of the DPI survey. For example, the VPI survey found that, overall, the vaccine package insert sections that are perceived as most useful by physicians include Dosage and Administration, Indications and Usage, Contraindications, Warnings, and Adverse Reactions. The Clinical Pharmacology and References sections were found to be among the least useful sections. Of the physicians surveyed, 71 percent indicated that they would increase their use of vaccine package inserts if a summary of prescribing information were used in the inserts. Eighty percent of physicians surveyed indicated that the summary should be no more than one-half page in length, 64 percent wanted the summary to have large print, and 56 percent wanted the summary to list serious reactions and be printed in bold type. The physicians also indicated that the following information (listed in order of preference) should be included in a summary: (1) Indications/usage, contraindications, and warnings; (2) adverse reactions, precautions, and dosage/administration; (3) a description of the vaccine; and (4) storage.

C. Initial Prototype Development

Based on the results of the DPI survey, FDA developed two prototypes of revised labeling formats for each of three prescription drug products (Prototypes 1 and 2). Both prototypes incorporated three major differences from the current labeling requirements. The first and most visible difference was the addition of a short section, entitled "Summary of Prescribing Information," inserted at the very beginning of the labeling. It included brief excerpts from the content areas that physicians felt included the most important labeling information. The second major difference was the reordering and reorganization of the presentation of information topics in the current labeling. For example, one of the sections judged by survey participants to be most important and most often used, "Dosage and Administration," is currently required to be placed toward

the end of labeling. This section was placed more toward the beginning of labeling in the prototypes. The "Clinical Pharmacology" section, judged by physicians as one of the least frequently used and least important, is currently placed at the beginning of labeling. This section and other less highly rated sections were moved toward the end of the labeling in the prototypes.

The prototypes also combined the current "Warnings" and "Precautions" sections into a single section entitled "Special Considerations" because of anecdotal information that physicians do not make meaningful distinctions between these two categories. The prototypes also included the subheadings "Hypersensitivity Reactions" and "Major Toxicities" to distinguish potentially serious reactions from "General Precautions," which included drug interactions. Subsections currently required to be included under the "Precautions" section concerning use of a drug in special populations (e.g., "Pediatrics," "Labor and Delivery," "Nursing Mothers") and the section entitled "Information for Patients" were reorganized in the prototype into separate headings entitled "Use in Specific Populations" and "Patient Counseling Information."

The third major difference between the prototypes and current labeling was the use of a paragraph identification system to make detailed information more accessible. This system was designed to be used together with a listing of the contents of the comprehensive information, inserted immediately before the comprehensive section. The system was also designed to provide "pointers" within the summary section that would refer readers desiring additional information to the proper place in the comprehensive section. The system is analogous to the hypertext linkage systems currently used on the Internet in which a user can select a particular word or phrase within other text to have more detailed information about the selected word or phrase automatically displayed.

The only difference between Prototypes 1 and 2 was the length of their "summary" sections. Prototype 1 included a two-column page-length summary while the summary of Prototype 2 was one and one-half pages in length.

D. Qualitative Testing of Initial Prototypes

FDA conducted qualitative testing of the revised labeling format prototypes (Prototypes 1 and 2) in four physician focus groups. The focus group results

showed that the physicians preferred the prototype with the one-page summary section (Prototype 1), but believed (consistent with the VPI survey results) that it was still too lengthy, which might discourage its use. The physicians stated that the availability of a short summary would not decrease the likelihood of reading the detailed labeling sections, but would direct them more efficiently to needed detailed information in the comprehensive section. The physicians also found the contents listing very helpful.

The focus group results confirmed the agency's belief that it is important to include the following sections prominently in the summary of prescription drug information:

"Indications and Usage," "Dosage and Administration," and "How Supplied." It is also important that the summary include information about the negative attributes of a drug product—its contraindications, warnings, precautions, and adverse drug reactions (ADR's), and that drug interactions be listed under a separate major heading.

The focus groups also recommended that summary information be presented in a short, bulleted format and include pointers indicating where in the labeling they should go for additional information. Many physicians preferred a table format, where possible, in place of narrative descriptions, and preferred the placement of patient counseling information toward the end of labeling.

E. The Public Meeting

Based on the results of the physician survey and focus group testing, FDA developed a revised prototype (Prototype 3). This prototype differed from the two initial prototypes in that it had a shorter "Summary" section and the organization of sections was changed. The paragraph identification system was modified such that the major information headings would be assigned the same index number, regardless of product, to help familiarize prescribers more rapidly with the new indexing system and facilitate ease of access to specific types of information across products. Finally, the combined warnings and precautions section was renamed "Warnings/Precautions" and information relating to drug interactions was removed from the combined section and placed under its own separate heading.

In the **Federal Register** of October 5, 1995, FDA published a notice (60 FR 52196) announcing an informal public meeting on October 30, 1995,³ to

present background information and research concerning how approved prescription drug product labeling could be revised to communicate important information more effectively to health care practitioners, and to solicit comments on Prototype 3. Several panelists, including representatives from the American Medical Association (AMA), United States Pharmacopeial Convention, Pharmaceutical Research and Manufacturers of America, Biometric Research Institute, Inc., American Pharmaceutical Association, American Academy of Physician Assistants, and the American Academy of Nurse Practitioners presented their comments on Prototype 3 at the meeting. Many panelists supported the prototype, stating, for example, that it would "result in more useful and user-friendly professional labeling for the prescribing physician."

FDA also received 10 written comments on Prototype 3 in response to the October 5, 1995, notice. Many of these comments supported the labeling prototype, stating, for example, that "the proposed reorganization of the product labeling is a positive step that better reflects the manner in which the information is actually employed at the point of care." Another comment stated that "[t]he prototype is well organized, and the information seems to be positioned to be more accessible and, therefore, more helpful to health-care practitioners." Other comments recommended that FDA conduct additional research on the prototype and that "FDA thoroughly study any reformatting with a broad range of health care professionals who use labeling."

The written comments submitted in response to the notice are discussed below.

III. A Description of the Proposed Labeling Requirements

In its effort to develop prototypes of drug labeling and obtain feedback on those prototypes, the agency has identified certain format elements that it believes would enhance the ability of practitioners to access, read, and use prescription drug labeling. The proposed rule would revise current §§ 201.56 and 201.57 to incorporate these format elements as requirements for new and more recently approved drugs. Older drugs would remain subject to the format requirements in current § 201.57, which would be redesignated as § 201.80. Certain

requirements in current § 201.57 also would be modified to help ensure that statements appearing in the labeling of older drugs relating to effectiveness or dosage and administration are sufficiently supported. The categories of drugs that would be subject to the revised labeling format and content requirements are discussed below in conjunction with the description of proposed § 201.56. The implementation scheme for the proposed changes is discussed in detail in section IV of this document. As discussed in section IV, the agency believes that applying the revised format requirements only to more recently approved products is appropriate because, among other factors, physicians are more likely to refer to the labeling of recently approved products than the labeling of older products.

The format changes that would be required under the proposal for new and more recently approved drugs include the addition of an introductory section of prescribing information, entitled "Highlights of Prescribing Information," to the comprehensive labeling information required under current § 201.57 (the comprehensive prescribing information).⁴ The highlights section would consist of selected information that practitioners most commonly refer to and view as most important from specific sections in the comprehensive prescribing information. As discussed further in this section and in section IV of this document, sponsors would be responsible for proposing language to be used in the highlights section in their product applications (i.e., NDA's, BLA's, or efficacy supplements). As with all approved prescription drug labeling, review and approval of the language by FDA would be required. The proposal would also add an index to, reorder, and reorganize the comprehensive prescribing information to make it easier to use and read, and make minor changes to its content. The proposal would set minimum standards and requirements for certain critical graphic elements of the format of prescription drug labeling.

A detailed description of each section of the proposed rule is provided below. Comments received on those sections of Prototype 3 corresponding to the proposed requirements are also

³ A transcript of the meeting may be seen at the Dockets Management Branch (address above)

between 9 a.m. and 4 p.m., Monday through Friday (see Docket No. 95N-0314).

⁴ The highlights section ("Highlights of Prescribing Information") corresponds to the section entitled "Summary of Prescribing Information" in earlier prototypes. As discussed below, the agency has changed the title in response to industry comments that the section does not represent a true summary. To avoid confusion about which labeling section is being discussed, the term "summary" is used only in direct quotes of comments.

summarized and addressed.⁵ In addition to requesting general comments on the proposal, the agency is seeking comment on the following specific issues (presented here for the convenience of the reader):

(1) Whether, and under what circumstances, it may be inappropriate to include the proposed "Highlights of Prescribing Information" section in the labeling of a particular drug or drug class;

(2) Does the inclusion of a highlights section have a significant effect on manufacturers' product liability concerns and, if so, is this concern adequately addressed by: (a) Titling this section "highlights" rather than "summary,"; and (b) including the following statement, in bold, at the end of the highlights section: "These highlights do not include all the information needed to prescribe (name of drug) safely and effectively. See (name of drug)'s comprehensive prescribing information provided below." If these are not sufficient, could the agency take different or additional measures to alleviate product liability concerns without eliminating the highlights section altogether or lengthening it to an extent that it would no longer serve its intended purpose;

(3) Whether the full text of any boxed warnings should be included in the proposed "Highlights of Prescribing Information" section, regardless of length;

(4) What different types of icons could be used to signal a boxed warning and what are their costs and benefits;

(5) Whether there should be a time limit by which the "Recent Labeling Changes" section must be removed;

(6) Whether the information required under the "Indications and Usage" subsection in the proposed "Highlights of Prescribing Information" section should be presented verbatim from the comprehensive labeling section or summarized in a bulleted format;

(7) Whether it is necessary to include the proposed requirement for an index section given the proposed requirement for a highlights section (i.e., do the additional purposes served by the index justify its inclusion?);

(8) Whether not including standardized headings in the "Warnings/Precautions" section is appropriate. If it is believed that specific standardized headings should be included, FDA requests comment about what they should be;

(9) Whether it is necessary to include a contact number for reporting

suspected serious adverse drug reactions in the proposed "Comprehensive Prescribing Information" section as well as the proposed "Highlights of Prescribing Information" section;

(10) Whether the potential impact of the proposed rule on small entities has been accurately estimated by the agency, and whether small business concerns have been adequately addressed;

(11) Whether the proposed requirement to bold certain information in proposed § 201.57(d)(5) will serve its intended purpose of ensuring the visual prominence of the bolded information or whether different highlighting methods may be more effective;

(12) Whether the proposed one-half page limit on the "Highlights of Prescribing Information" section (not including boxed warning(s) or contraindication(s)) is adequate or whether there are alternatives that would be more appropriate and under what circumstances such alternatives should be considered;

(13) What means (other than the vertical line proposed in § 201.57(d)(9)) could be used to facilitate access to, and identification of, new labeling information in the proposed comprehensive prescribing information section;

(14) Whether the proposed minimum 8-point font size for labeling is sufficient or whether a minimum 10-point font size would be more appropriate; and

(15) Whether the revised format and content requirements should be applied to drug products with an NDA, BLA, or efficacy supplement that is pending at the effective date of the final rule, submitted on or after the effective date of the final rule, or that has been approved from 0 up to and including 5 years prior to the effective date of the final rule, or whether alternative application criteria should be used.

A. General Requirements on Content and Format of Labeling for Human Prescription Drugs (§ 201.56)

The proposal would revise current § 201.56 to set forth: (1) General labeling requirements applicable to all prescription drugs; (2) the categories of new and more recently approved prescription drugs subject to the revised content and format requirements in proposed §§ 201.56(d) and 201.57; (3) the schedule for implementing the revised content and format requirements in proposed §§ 201.56(d) and 201.57; (4) the required and optional sections and subsections associated with the revised format in proposed § 201.57; and (5) the required and optional sections and

subsections for the labeling of older prescription drugs not subject to the revised format and content requirements.

Proposed § 201.56(a) ("General Requirements") would set forth general labeling requirements applicable to all prescription drugs. These are currently set forth at § 201.56(a) through (c), and include the requirements that labeling contain a summary of the essential scientific information needed for the safe and effective use of the drug, that labeling be informative and accurate and neither promotional in tone nor false or misleading, and that labeling be based whenever possible on data derived from human experience.

Proposed § 201.56(b) sets forth the categories of new and more recently approved prescription drugs and biologics subject to the revised format and content requirements in proposed §§ 201.56(d) and 201.57. These would include prescription drug products for which an NDA, BLA, or efficacy supplement has been approved in the 5 years before the effective date of the final rule, drug products for which an NDA, BLA, or efficacy supplement is pending at the effective date of the final rule, and drug products for which an NDA, BLA, or efficacy supplement is submitted on or after the effective date of the final rule. The revised content and format requirements in the proposed rule would not apply to drug products approved more than 5 years before the effective date of the final rule (provided that an efficacy supplement was not approved for such products in the 5 years before the effective date of the final rule, or submitted after the effective date of the final rule). As mentioned above, these products would remain subject to the labeling requirements in current § 201.57, which under the proposal would be redesignated as § 201.80.

Proposed § 201.56(c) sets forth the schedule for implementing the revised format and content requirements in proposed §§ 201.56(d) and 201.57. The implementation schedule is discussed in detail in section IV of this document. The implementation schedule would require that for products with certain applications (i.e., NDA's, BLA's, and efficacy supplements) submitted on or after the effective date of the final rule, revised labeling must be submitted with the application. For drugs and biological products approved in the 5 years before the effective date of the final rule, revised labeling must be submitted on a staggered basis beginning 3 years after the effective date of the final rule. The implementation schedule would require that labeling for the most recently

⁵ As discussed above, the proposed rule is based on Prototype 4, which is very similar to Prototype 3.

approved drugs (i.e., those approved in the year immediately preceding the effective date of the final rule) be revised first.

Proposed § 201.56(d) would require that labeling for new and more recently approved prescription drugs contain the information required under proposed § 201.57 under specified headings and subheadings. This section sets forth required and optional headings for labeling under the revised format. Proposed § 201.57(d)(1) through (d)(4) is similar to current § 201.56(d), but reflects the revised headings and subheadings that are included under proposed § 201.57(a) (Highlights of Prescribing Information) and § 201.57(c) (Comprehensive Prescribing Information). The section also reflects the proposed reorganization and revisions of the comprehensive prescribing information. Proposed § 201.56(d)(5) would permit the use of additional subheadings where appropriate to emphasize specific topics within the text of required sections. For example, under the "Warnings/Precautions" section, additional subheadings could be used to set off each warning or precaution. The use of headings in this manner is consistent with current labeling formatting practice and would provide sponsors with a valuable tool in designing labeling that effectively communicates important information to prescribers.

Proposed § 201.56(e) would set forth the required section headings and subheadings for older drugs (i.e., drugs approved more than 5 years before the effective date of the final rule). The section incorporates current § 201.56(d) without change, except for the references to § 201.57, which would be changed to reflect the redesignation of current § 201.57 to § 201.80.

B. Revised Format and Content Requirements Applicable to Newer Drugs

1. Highlights of Prescribing Information

Proposed § 201.57(a) would require that the labeling of human prescription drugs, specified in § 201.56(b)(1), contain the heading "Highlights of Prescribing Information" followed by the specific information and subheadings listed in proposed § 201.57(a)(1) through (a)(17). As discussed below, information under these sections would be a concise extract of the most important information already required under current § 201.57, as well as certain additional information that the agency believes is important to prescribers (e.g., recent labeling changes). The agency is

proposing to add this highlights section to prescription drug labeling because, based on the information discussed in section II of this document, the agency believes that the usefulness of labeling can be improved by highlighting at the beginning of labeling the information that is most often used and cited as most important by health care practitioners. FDA is requesting comment, however, about whether and under what circumstances it may be inappropriate to include a highlights section for a particular drug or drug class.

Inclusion of only a limited amount of information in the highlights section would not affect any of the regulations related to prescription drug promotion. Manufacturers still would be responsible for ensuring that claims in promotional labeling and advertisements are consistent with the comprehensive prescribing information. Thus, for example, if certain limitations of use contained in the comprehensive prescribing information regarding a drug's effectiveness, contraindications, or side effects is permitted to be excluded from the highlights section, a manufacturer still would be required to include information about those limitations in its promotional labeling and advertisements in accordance with applicable regulations. It is essential that promotional labeling and advertisements be consistent with the comprehensive prescribing information because the highlights section does not include all the information needed to prescribe a drug safely and effectively, and is thus not intended to act as a substitute for the comprehensive prescribing information. This responsibility is described in the introductory paragraph of proposed § 201.57(a) which provides that, in order to comply with §§ 202.1(e) and 201.100(d)(1), statements made in promotional labeling and advertisements must be consistent with all information included in labeling under proposed § 201.57(c) (i.e., the comprehensive prescribing information).

Several comments received on Prototype 3 strongly supported inclusion of a highlights section in the labeling. One comment stated that the section "would impart key information of most common interest to prescribers" and "would be a concise and clear means of displaying information." Another comment stated that the highlights section serves "as an excellent vehicle for drawing the practitioner's attention to the most important facts and precautions associated with a product" and that "[c]ross-referencing each point in the

summary to the underlying complete prescribing information further enhanced the summary's value."

Other comments on Prototype 3 opposed inclusion of a highlights section. Several comments contended that practitioners might rely solely on this section and fail to read the comprehensive prescribing information. One comment stated that "it is difficult, if not impossible, for summary information to adequately deliver the complete message regarding complicated prescribing information" and "the mere availability of a summary, even if it is followed by the complete information, discourages a time-pressured human being from reviewing the pertinent sections of the complete prescribing information."

It is unrealistic to expect practitioners to read every word of product labeling each time they reference it, regardless of how desirable it may be for them to do so. Therefore, FDA is proposing to add the highlights section to prescription drug labeling to draw attention to those sections of the labeling that are most important, and to do so in a way that readily facilitates and encourages more detailed followup. For example, certain kinds of information that are now potentially lost in a long list of topics under "Precautions" would be identified and described at least briefly in the highlights section.

Other comments expressed concern about the inclusion of a highlights section because of its potential effect on product liability. The comments stated that including a highlights section would force manufacturers to pick and choose only certain parts of the warning information listed in the comprehensive information. One comment stated that this "would allow an expert witness testifying on behalf of a patient who suffered an adverse reaction that was listed in the full prescribing information to argue that a manufacturer's warning was inadequate or "buried" because that specific adverse reaction was not also highlighted in the Summary."

The agency recognizes that prescription drug labeling may be used as evidence in product liability cases and other types of civil actions to determine, among other things, whether a manufacturer has adequately disclosed information about risks associated with its drug. However, the agency believes that it is highly speculative to assert that, because certain risk information has been summarized in or omitted from the highlights section of prescription drug labeling (but included in its entirety in the comprehensive prescribing information), a manufacturer may be found liable in a

product liability action based on a theory that the warning is "buried."

Moreover, although the highlights section would not include all information about risks associated with a drug, the agency believes that, as described in this proposal, the highlights section would include the most important information regarding drug-related risks. As discussed below in section III.B.1.j. of this document, the "Warnings/Precautions" section of the highlights would include those ADR's that are most relevant to clinical prescribing situations. This would include both rare but life-threatening drug reactions and less serious but more common reactions that may be important from a clinical standpoint when prescribing a drug. Additionally, this section of the highlights would include, under its own subheading, the most common or frequently occurring ADR's that are reasonably associated with the use of the drug, which for most drugs would be those ADR's with an incidence of greater than 1 percent.

Nevertheless, the highlights section is not intended to act as a substitute for the comprehensive prescribing information, and it is extremely important for practitioners to be aware of this and to review all relevant sections of the comprehensive prescribing information before making prescribing decisions. Thus, in response to the comments' concerns, to generally aid in avoiding misunderstandings about the purpose of the highlights section by health care practitioners and others, and to encourage practitioners to review the relevant sections of the comprehensive prescribing information, the agency is proposing two modifications to Prototype 3. First, FDA is proposing that the introductory section be entitled "Highlights of Prescribing Information." This title more appropriately acknowledges that the section does not comprehensively summarize all sections of product labeling. Second, the following statement would be required to be presented in bold print, at the end of the highlights section: "These highlights do not include all the information needed to prescribe (*insert name of drug product*) safely and effectively. See (*insert name of drug product*)'s comprehensive prescribing information provided below." The agency is seeking comment on whether the inclusion of a highlights section would have a significant effect on manufacturers' product liability concerns and, if so, whether this concern has been adequately addressed in this proposal. If it is believed that product liability concerns have not been adequately

addressed, the agency seeks comment on whether it could take different or additional measures to alleviate product liability concerns without eliminating the highlights section altogether, or lengthening it to an extent that it would no longer serve its intended purpose.

a. *Product names and other basic information.* Proposed § 201.57(a)(1) would require that information necessary to identify a drug product—the proprietary name and the established name or, for biologics, the proper name (as defined in § 600.3 (21 CFR 600.3)) and any informative descriptors—be the first information that appears in the highlights section. This information would be followed by the product's dosage form and route of administration. For drugs that are controlled substances, the controlled substance symbol designating the schedule in which the controlled substance is listed must also be included in this section. In accordance with § 1302.04 (21 CFR 1302.4), the symbol must be clear and large enough to afford prompt identification of the controlled substance.

b. *Inverted black triangle.* Proposed § 201.57(a)(2) would require placement of the "▼" symbol if the drug has been approved in the United States for less than 3 years and contains a new molecular entity (NME) or new biological product, a new combination of active ingredients, is indicated for a new population, is administered by a new route, or uses a novel drug delivery system. It is well recognized that many important ADR's are not discovered until several years of marketing have elapsed. FDA believes that providing an easily recognizable symbol to serve as a signal for increased vigilance and reporting of suspected adverse reactions will facilitate faster recognition of rare but serious side effects that may be associated with newly marketed products and help ensure that drugs are used with particular care during their initial years of marketing. The inverted black triangle symbol is currently used in the United Kingdom to alert prescribers to the fact that a product contains a new active ingredient or is indicated for a new route of administration, among other things. FDA recognizes that U.S. prescribers' experience with the ▼ symbol is limited and that it will take time and an educational program to familiarize them with it. FDA believes that efforts to educate the public about this symbol, as well as general education concerning revisions to the labeling format, can be largely accomplished through the agency's routine outreach and education programs.

c. *Prescription drug symbol.* Proposed § 201.57(a)(3) would require placement of the "Rx" symbol to indicate that the drug is a prescription drug.

d. *Highlighted boxed warning.* Proposed § 201.57(a)(4) would require that the full text of boxed warning(s) or contraindication(s) required by proposed § 201.57(c)(1) be included in the highlights section, provided that the text does not exceed 20 lines. For boxed warnings longer than 20 lines, the proposed section would require a statement, not to exceed 20 lines, summarizing the contents of the boxed warning. The agency has tentatively concluded that the proposed limit of 20 lines of text, together with a "pointer" to the full boxed warning (discussed below) and any other pertinent information in the comprehensive prescribing information, is sufficient to disclose the most important aspects of the warning for the purposes of the highlights section. However, because of the importance of the information in the boxed warning, the agency requests comment on whether the full text of any boxed warning should be included in the highlights, regardless of the length of its text.

The agency is proposing to require that the text of all boxed warnings in the highlights section be preceded by an appropriate heading, in uppercase letters, that contains the signal word "WARNING" and describes the subject of the warning. For example, an appropriate heading for a boxed warning regarding use of the drug product during pregnancy could be entitled "WARNING REGARDING USE IN PREGNANCY" or a warning about agranulocytosis could be entitled "WARNING: AGRANULOCYTOSIS." When the agency determines that a contraindication must be placed inside a box, the heading should reflect that the information inside the box is a contraindication. For example, an appropriate heading for a contraindication against use in pregnant women could be "WARNING: DO NOT USE IN PREGNANT WOMEN." Research on the effectiveness of warning labels has consistently shown that the use of a signal word to attract attention increases the effectiveness of warnings (Ref. 3). Both the text of the summary statement and the heading would be required to be contained within a box and bolded. The signal word and title would be required to be in uppercase letters to provide for additional prominence.

In addition to the requirements discussed above, proposed § 201.57(a)(4) would require that, for boxed warning(s) or contraindication(s)

that must be summarized because it exceeds 20 lines of text, a statement be placed immediately under the heading that states: "See for full boxed warning." This statement would alert practitioners to the fact that the boxed warning statement appearing in the "Highlights" section does not constitute the full boxed warning.

e. *Recent labeling changes.* Proposed § 201.57(a)(5) would require the subheading title "Recent Labeling Changes" (instead of the title "New Information" in Prototype 3) to indicate that this section of the labeling includes recent FDA approved or authorized substantive labeling changes, not other kinds of new information, such as information that is in the scientific literature, but not approved or authorized by FDA for inclusion in labeling. Minor or nonsubstantive changes, such as changes in an address, correction of typographical errors, or grammatical changes, would not be required to be included under this section. The agency is proposing to require that the "Recent Labeling Changes" section remain for at least 1 year after the date of the labeling change. In response to the comments, the section would be permitted to be retained, after the expiration of the 1-year period, until the next labeling revision. FDA is requesting comments, however, concerning whether there should be a time limit by which the section must be removed. To ensure that practitioners are aware of the date of the most recent labeling revision, FDA is proposing, under § 201.57(a)(16), that the highlights section prominently include the date of the most recent labeling revision.

f. *Indications and usage.* Proposed § 201.57(a)(6) would require the heading "Indications and Usage," followed by a concise statement of each of the product's indications, as specified in proposed § 201.57(c)(2), with any appropriate subheadings. This information must include major limitations of use (e.g., particular subsets of the population, second line therapy status, antimicrobials limited to certain microorganisms). At the public meeting, the agency requested public comment about whether the information required under this heading should be presented verbatim from the comprehensive labeling section or summarized in a bulleted format. Although FDA received strong support for the latter, it remains interested in receiving further comment on this subject.

g. *Dosage and administration.* Proposed § 201.57(a)(7) would require the heading "Dosage and

Administration," followed by highlights of the comprehensive prescribing information proposed under § 201.57(c)(3), with any appropriate subheadings. Information under this heading would consist of the most common dosage regimen(s) and the most important moderating information, such as different doses for population subsets, critical monitoring requirements, and other therapeutically important information. If different dosage regimens are associated with different indications or patient populations, this information should be summarized as succinctly as possible. As discussed above, many physicians in the initial focus groups stated that tabular presentation of dosage and administration information is useful. The agency encourages development of such a format and provides in Prototype 4 one example of a tabular presentation of different dosage regimens for different indications.

h. *How supplied.* Proposed § 201.57(a)(8) would require the heading "How Supplied," followed by a concise summary of information concerning the product's dosage form(s) under proposed § 201.57(c)(4). This would ordinarily include the metric strength or strengths of the dosage form and whether the tablets are scored. If appropriate, the information in this section heading could include subheadings to specify different dosage forms (e.g., tablets, capsules, suspension).

i. *Contraindications.* Proposed § 201.57(a)(9) would require the heading "Contraindications," followed by a concise summary of the comprehensive prescribing information in proposed § 201.57(c)(5), and any appropriate subheadings.

j. *Warnings/precautions.* Proposed § 201.57(a)(10) would require the heading "Warnings/Precautions," followed by a concise summary of the most clinically significant aspects of the comprehensive prescribing information in proposed § 201.57(c)(6), with any appropriate subheadings. The cautionary information chosen from the comprehensive prescribing information for inclusion in this section should be that which is most relevant to clinical prescribing situations. Rare but life-threatening drug reactions must be included, especially when the likelihood of occurrence can be reduced by taking recommended steps (e.g., by monitoring, by checking the patient's history or current medication use, or through informing patients which symptoms to look for and report immediately). However, seriousness of reaction should not be the only

criterion. It may be just as, if not more, important from a clinical standpoint for a prescriber to know about a less serious, but common and irritating adverse reaction likely to reduce compliance with drug therapy in many patients. Thus, in determining whether specific cautionary information should be included in the highlights section, consideration should be given to a combination of factors, including the seriousness of an adverse reaction and its frequency of occurrence, whether steps can be taken to avoid the adverse reaction or identify and treat it at an early stage, and the likelihood that the reaction could affect patient compliance or continuation of therapy. These factors should be assessed in light of how they would affect a health care practitioner's decision to prescribe the particular drug in a clinical setting and how the practitioner would use and monitor the drug.

The agency is also proposing that the "Warnings/Precautions" heading in the highlights section include the subheading "Most Common Adverse Reactions ($\geq n/100$)."

This subheading would typically list the most common or frequently occurring ADR's that are reasonably associated with the use of the drug from the adverse reactions section under proposed § 201.57(c)(9). As stated in the report of the Council for International Organizations of Medical Sciences (CIOMS) Working Group III report entitled "Guidelines for Preparing Core Clinical-Safety Information on Drugs" (Ref. 4), common ADR's include those with an incidence of greater than 1 in 100 (i.e., 1 percent). Therefore, the agency believes that, for most drugs, it would be appropriate to report ADR's with an incidence of greater than 1 percent. However, for those drugs that are associated with a very large number of ADR's, and/or for which many of the ADR's occur at an incidence rate of more than 1 percent, it may be appropriate to report in the highlights section only those ADR's associated with incidences of 2, 3, 4, or 5 percent, or more. The incidence rate that is used to determine inclusion in this subsection would be required to be disclosed in parentheses together with this subheading.

k. *Contacts for ADR reporting.* Proposed § 201.57(a)(11) would require, for drug products other than vaccines, the following statement be placed in the highlights section following "Warnings/Precautions": "To report SUSPECTED SERIOUS ADR's, call (insert name of manufacturer) at (insert manufacturer's phone number) or FDA's MedWatch at (insert the current FDA MedWatch number)." For vaccines, the following

statement would be required: "To report SUSPECTED SERIOUS ADR's, call (*insert name of manufacturer*) at (*insert manufacturer's phone number*) or VAERS at (*insert the current VAERS number*)."

In partnership with many professional associations and private sector groups, FDA has consistently encouraged the reporting of suspected serious adverse drug reactions. The proposed section would alert practitioners to the importance of reporting suspected serious ADR's and provide convenient reporting contacts.

l. *Drug interactions.* Proposed § 201.57(a)(12) would require the heading "Drug Interactions," followed by a concise summary from the comprehensive prescribing information in proposed § 201.57(c)(7) of other prescription or over-the-counter drugs or foods that interact in clinically significant ways with the product, with any appropriate subheadings.

m. *Use in specific populations.* Proposed § 201.57(a)(13) would require the heading "Use in Specific Populations," followed by a concise listing of any clinically important differences in response to or use of the drug in specific populations from the comprehensive prescribing information in proposed § 201.57(c)(8), with any appropriate subheadings. With respect to pregnancy categories, the agency does not believe that prescribers would find it helpful to include in the highlights section the category for the drug or selected animal data related to use of the drug during pregnancy. Thus, manufacturers should include under this heading only that information concerning use of the drug during pregnancy that is provided under the "Contraindications" or "Warnings/Precautions" sections of the highlights. In the absence of such information, the availability of human data regarding use during pregnancy should be briefly noted.

n. *Referral to patient counseling information.* Proposed § 201.57(a)(14) would require, where applicable, the verbatim statement "See P for Patient Counseling Information." This statement would inform practitioners of the existence of patient counseling information and allow them to easily access the information. As discussed below in the description of § 201.57(c)(17), patient counseling information is intended to help practitioners communicate important drug information to patients. For drugs that have approved patient labeling or Medication Guides, the following statement would be required: "See P for Patient Counseling Information, followed by (*insert name of drug*)'s

(*insert either approved patient labeling or Medication Guide*)."

o. *Highlights reminder.* Proposed § 201.57(a)(15) would require that the labeling include the statement: "These highlights do not include all the information needed to prescribe (*insert name of drug product*) safely and effectively. See (*insert name of drug product*)'s comprehensive prescribing information provided below." As discussed previously, this statement would be a prominent reminder to practitioners that the highlights section is not intended to be an all-inclusive source of drug prescribing information.

p. *Labeling revision date.* As discussed previously, proposed § 201.57(a)(16) would require that the highlights section include the date of the most recent labeling revision, identified as such. The inclusion of this date in the highlights section would indicate to practitioners precisely when the "recent labeling changes" identified under § 201.57(a)(5) were incorporated into the labeling.

q. *Index numbers in the highlights section.* Proposed § 201.57(a)(17) would require that any subheadings required by paragraphs (a)(4) through (a)(10), (a)(12), and (a)(13), as well as additional subheadings included in the highlights under § 201.56(d)(5), be followed in parentheses by their corresponding index number (i.e., the number appearing before required subheadings under § 201.56(d)(1) or assigned to optional subheadings in accordance with § 201.56(d)(5)). The agency is proposing the use of a numbering system to facilitate the cross-referencing of specific topics between the highlights section, the index, and the comprehensive prescribing information. As discussed in the following section III.B.2, several comments supported this numbering system.

2. Comprehensive Prescribing Information: Index

Proposed § 201.57(b) would require the heading "Comprehensive Prescribing Information: Index" followed by a list that contains each subheading required under § 201.56(d)(1), if not omitted under § 201.56(d)(3), and each optional subheading included in the comprehensive prescribing information under § 201.56(d)(5). Each subheading would be required to be preceded by its corresponding index number or identifier. The agency is proposing to require this indexing system to make it easier for practitioners to access specific topics included in the comprehensive prescribing information and to facilitate

hypertext links in electronic labeling that will be available in the near future.

In general, the comments on Prototype 3 supported the indexing system. For example, one comment stated that when standardized across all approved drug product labeling, this system will provide a useful mechanism for facilitating electronic retrieval of information by subject area and will enable practitioners to more quickly and easily locate needed data. Some comments stated that the index should be used in place of the highlights section because the index alone is sufficient to direct the reader to the appropriate information. In contrast, one comment asserted that the use of index numbers in the highlights section that cross-reference the comprehensive prescribing information would be sufficient without inclusion of an index.

As discussed above, the purpose of the highlights section is to highlight only the labeling information that practitioners considered to be most important. The index, in contrast, is intended to make it easier for the practitioner to access any details in the comprehensive prescribing information, regardless of the perceived importance of the information. Although both sections contribute to enabling practitioners to more easily access, read, and use prescription drug labeling information, the highlights section and the index serve separate and distinct purposes. Therefore, FDA is proposing to include both sections in prescription drug labeling. However, FDA requests comment on whether the additional purposes served by the index are sufficient to justify its inclusion in labeling.

3. Comprehensive Prescribing Information

The agency is proposing to revise the content and format of the comprehensive prescribing information contained in current § 201.57 to make it easier for health care practitioners to access, read, and use the labeling information. The proposal would reorder the information to place more prominently those sections that the agency found, based on the physician surveys, focus groups, public comments, and its own experience, to be most important and most commonly referenced by practitioners. In most cases, this would require moving the information closer to the beginning of the comprehensive section. The agency is also proposing to reorganize certain sections of the labeling, to require standardized index numbers for each subheading, and certain other format and content changes.

a. *Proposed § 201.57(c)(1)—boxed warning.* Under the current “Warnings” section (§ 201.57(e)), labeling must describe serious adverse reactions and potential safety hazards, limitations in use imposed by them, and steps that should be taken if they occur. The section provides that, “Special problems, particularly those that may lead to death or serious injury, may be required by the Food and Drug Administration to be placed in a prominently displayed box.” If a boxed warning is required, “its location will be specified by the Food and Drug Administration.” Under the current regulation, boxed warnings have frequently been placed at or near the beginning of labeling to increase their prominence and accessibility. However, this has not always been the case.

The proposal would move the language describing when boxed warnings may be required from § 201.57(e) to § 201.57(c)(1). The agency is proposing to move this requirement out of the “Warnings” section because, in the past, information required to be placed within a box has consisted of contraindications information as well as warnings information. Proposed § 201.57(c)(1) would revise the language in current § 201.57(e) to specify that a box is appropriate for contraindications information as well as warnings information. Additionally, because of the importance of the information contained in boxed warnings, the agency believes that boxed warnings should always be placed before other labeling information. Accordingly, proposed § 201.57(c)(1) would require that any boxed warning(s) be the first substantive information to appear in the comprehensive prescribing information section of prescription drug labeling. As with the boxed warning in the highlights section, the agency is proposing to require that the boxed warning in the comprehensive labeling section be preceded by an appropriately descriptive heading, placed within the box, that contains the signal word “WARNING,” and a brief descriptive title in uppercase letters. The heading may be general (e.g., “WARNING: USE IN PREGNANCY”) or specific (e.g., “WARNING: INTERACTION WITH CYP3A4 INHIBITORS”).

The agency is proposing to require that, for indexing purposes, the boxed warning be preceded by an exclamation point “!” instead of the number “1.” This is appropriate because index numbers will be standardized across all products, yet many products do not have a boxed warning. Therefore, if the number “1” were to be used in conjunction with boxed warnings for

the relatively few products that have a boxed warning, the highlights and comprehensive prescribing information for the many products without a boxed warning would begin with the index number “2,” which might be confusing. In addition, the agency believes that the exclamation point is an appropriate icon to help alert prescribers to the importance of the information contained in the boxed warning. However, other icons could be considered, such as an open hand that signals “stop” or, if labeling is in color, a red octagon that signals “stop.” The agency requests comments on the relative benefits and costs of different icons that could be associated with a boxed warning.

b. *Proposed § 201.57(c)(2)—indications and usage.* Under current § 201.57(c), a drug product’s indications must be included after the “Description” and “Clinical Pharmacology” sections of labeling. The section requires, among other things, that indications be supported by substantial evidence of effectiveness based on adequate and well-controlled studies, unless the requirement is waived under § 201.58 (21 CFR 201.58) or § 314.126(c) (21 CFR 314.126(c)).⁶

Under proposed § 201.57(c)(2), the “Indications and Usage” section would be placed more prominently toward the beginning of the comprehensive prescribing section than it is currently. Proposed § 201.57(c)(2)(i) would modify current § 201.57(c)(1) to remove certain examples of indications that have become outdated. Section 201.57(c)(2)(ii) would modify current § 201.57(c)(2) to clarify that indications or uses not included in the “Indications and Usage” section may not be implied or suggested in other sections of labeling.

Proposed § 201.57(c)(2)(iii) would be added to address biological drug products subject to licensing under section 351 of the Public Health Service Act (the PHS Act) (42 U.S.C. 262). The proposed section would make clear that substantial evidence of effectiveness must support indications for biological drug products. Under section 351 of the PHS Act, FDA approves BLA’s on, among other things, a demonstration that the biological product that is the subject of the application is safe, pure, and potent. Potency has long been interpreted to include effectiveness (§ 600.3(s)).

In 1972, FDA initiated a review of the safety and effectiveness of all previously

licensed biologics. The agency stated then that proof of effectiveness would consist of controlled clinical investigations as defined in the provision for “adequate and well controlled studies” for new drugs, § 314.126, unless waived as not applicable to the biological product or essential to the validity of the study when an alternative method is adequate to substantiate effectiveness (§ 601.25(d)(2) (21 CFR 601.25(d)(2) (the biologics efficacy review)). One example of such an adequate alternative was identified to be serological response data where a previously accepted correlation with clinical effectiveness exists.

Although the biologics efficacy review regulation, § 601.25, references § 314.126, and the Food and Drug Administration Modernization Act of 1997 (the Modernization Act) directs FDA to take measures to minimize differences between the review and approval of BLA’s and NDA’s, § 314.126 does not expressly apply to BLA’s. However, FDA believes that it is appropriate to take the characteristics of an adequate and well-controlled clinical investigation, as described in § 314.126, into account in evaluating the sufficiency of evidence of effectiveness that sponsors submit in BLA’s to satisfy the licensure standards in section 351 of the PHS Act. (See FDA’s guidance for industry entitled “Providing Clinical Evidence of Effectiveness for Human Drugs and Biological Products,” May 1998.)

Proposed § 201.57(c)(2)(iv)(A) would modify current § 201.57(c)(3) to specify that if evidence is available to support the safety and effectiveness of the drug or biologic only in selected subgroups of the larger population with the disease or condition, or if evidence to support the indication is based on surrogate endpoints, the limitations in the usefulness of the drug (or, in the case of surrogate endpoints, the limitations of the supporting efficacy data) must be described succinctly. Reference should be made to the “Clinical Studies” section (proposed § 201.57(c)(15)) for a detailed discussion of the specific methodology and clinical data relevant to the limitation. The agency anticipates that this change would facilitate a more focused “Indications and Usage” section for the practitioner seeking basic information. For those practitioners seeking more detailed information, the reference to the “Clinical Studies” section should be sufficient to signal that additional information is available.

Current § 201.57(c)(3)(iv) permits the agency to require a statement that there is a lack of evidence supporting a drug’s

⁶ Current §§ 201.57(c) and 201.58 inadvertently refer to waiver under § 314.126(b) instead of (c). The agency is proposing to correct these references in the current rulemaking.

effectiveness for a use or condition if there is a common belief that a drug may be effective for a certain use, or if there is a common use of the drug for a condition, but the preponderance of evidence shows that the drug is ineffective. Proposed

§ 201.57(c)(2)(iv)(D) would modify the current section to permit the agency to require a statement that there is a lack of evidence that a drug is *safe* for a use or condition when the preponderance of the evidence shows that the therapeutic benefits of the product do not generally outweigh its risks. The agency believes that the current language is too limiting in that it only addresses products that are shown to be ineffective for a particular use or condition. This fails to address products that may be effective, but pose an unacceptable safety risk for the condition or use.

c. *Proposed § 201.57(c)(3)—dosage and administration; proposed § 201.57(c)(4)—how supplied/storage and handling.* Under current § 201.57, the “Dosage and Administration” and “How Supplied” headings appear toward the end of prescription drug labeling. Under “Dosage and Administration,” labeling must state the usual dose and dosage range, the recommended intervals between doses, duration of treatment, and any modification of doses needed in special patient populations, among other information. Under “How Supplied,” labeling must include the strength of the dosage form, units in which the dosage form is ordinarily available, information appropriate to the identification of the dosage form, and special handling and storage conditions.

Based on the DPI survey and focus groups conducted by FDA, the agency has determined that the information contained in these sections is important to practitioners and frequently referenced by them. Accordingly, the agency is proposing to move both sections closer to the beginning of the comprehensive prescribing section to facilitate access to them. In addition, the agency is proposing that the current heading “How Supplied” be changed to “How Supplied/Storage and Handling” to emphasize the placement of storage and handling information in the section, which may otherwise be overlooked by practitioners. The proposal would add a provision to the current dosage and administration section stating that, where established and when clinically important, efficacious and/or toxic drug and/or metabolite concentration ranges and therapeutic concentration windows for drug and/or metabolite(s) must be stated in this section. The proposed section would also require information

on therapeutic drug concentration monitoring (TDM) when TDM is clinically necessary. Finally, the current dosage and administration section would be revised to specify that dosing regimens must not be implied or suggested in other sections of labeling if not included in this section.

d. *Proposed § 201.57(c)(5)—contraindications.* Current § 201.57(d) requires contraindications to be placed immediately following indications. The section requires labeling to describe those situations in which a drug should not be used because the risk of use clearly outweighs any possible benefit. Proposed § 201.57(c)(5) would incorporate the current section without substantive change.

e. *Proposed § 201.57(c)(6)—warnings/precautions.* Warning and precautionary information currently appears under two separate headings in accordance with § 201.57(e) and (f), respectively. Under “Warnings,” labeling must describe serious adverse reactions and potential safety hazards, limitations in use imposed by them, and steps that should be taken if they occur. Under the heading “Precautions,” labeling must contain, among other things, information regarding any special care to be exercised by the practitioner for safe and effective use of the drug (current § 201.57(f)(1)) and information on laboratory tests that may be helpful in following a patient’s response or in identifying possible adverse reactions (current § 201.57(f)(3)).

To make this information easier to use, the agency is proposing to combine the “Warnings” information required by current § 201.57(e) with the “Precautions” information required by current § 201.57(f)(1) and (f)(3) into one heading entitled “Warnings/Precautions.” As discussed below, the remaining information covered in current § 201.57(f) would be presented under new proposed section headings.

Observations and suggestions from the physician focus groups discussed in section II of this document, combined with FDA’s experience, have convinced the agency that the distinction between warnings and precautions is perceived by prescribers as being relatively arbitrary and frequently not clinically meaningful. FDA first attempted to address these concerns by combining the Warnings and Precautions sections in the labeling prototype presented at the public hearing (i.e., Prototype 3). That prototype, however, continued to account for differences in the types of information required in the current Warnings and Precautions sections by creating subsections that distinguished more specifically between

“Hypersensitivity Reactions,” “Major Toxicities,” and “General Precautions.”

After further consideration, FDA believes that the clinical relevance of an adverse reaction is not always related to the seriousness of the reaction. For example, if a drug is associated with two adverse reactions (one serious, but very rare, and another less serious, but extremely common), it may be as important from a clinical standpoint, if not more so, for a prescriber to know about the less serious reaction as it is to know about the serious reaction. This is especially true where the less serious reaction may affect compliance with drug therapy for many patients. In addition, for certain products, a warning about a serious but nonpredictable ADR may be less clinically meaningful than the recommendation for routine monitoring to detect a relatively less serious but predictable ADR. Accordingly, the proposed “Warnings/Precautions” section would substitute the terminology “clinically significant adverse reaction” for the terminology “serious adverse reactions” in the current “Warnings” section to clarify that clinically significant adverse reactions must be included under the section. In addition, the proposed rule would not require adverse reactions selected for inclusion in the “Warnings/Precautions” section to be distinguished by specific standardized headings on the basis of seriousness or other criteria. However, certain adverse reactions (including those that result in contraindications) may be serious enough to warrant being placed inside a box under proposed § 201.57(c)(1). FDA requests comment about whether the lack of standardized headings in the “Warnings/Precautions” section is appropriate. If it is believed that specific standardized headings are appropriate, FDA requests comment about what they should be.

Proposed § 201.57(c)(6)(iv) would require, where applicable, a brief notation of the information that is currently required under § 201.57(f)(4)(ii) (i.e., information on known interference of a drug with laboratory tests) and a reference to the detailed labeling information. As discussed below, under the proposal the detailed labeling information would be moved from its present location under “Precautions” to a separate “Drug Interactions” section. The agency is proposing this requirement to alert practitioners to the existence of important laboratory test interference information without making the “Warnings/Precautions” section unnecessarily lengthy.

Proposed § 201.57(c)(6)(v) would require, for drug products other than vaccines, the inclusion of the statement "To report SUSPECTED SERIOUS ADR's, call (insert name of manufacturer) at (insert manufacturer's phone number) or FDA's MedWatch at (insert the current FDA MedWatch number)." For vaccines, the following statement would be required: "To report SUSPECTED SERIOUS ADR's, call (insert name of manufacturer) at (insert manufacturer's phone number) or VAERS at (insert the current VAERS number)." As discussed above, inclusion of these statements would also be required in the highlights section. The agency believes that inclusion of these statements in both places would contribute to the communication of this important information. FDA is requesting comments, however, concerning whether this additional requirement constitutes unnecessary repetition.

As discussed in further detail below, the remaining information currently required to appear under the "Precautions" section would be reorganized into new section headings. The agency believes that this is appropriate because some of the information currently included under "Precautions" is in fact not cautionary (e.g., a negative carcinogenicity study or lack of drug interactions). Other information currently included may be cautionary, but was deemed to be sufficiently important to be included under its own section heading to provide greater emphasis and ease of access. The proposal would move the information required by current § 201.57(f)(2) ("Information for patients") to proposed § 201.57(c)(17); move the information required by current § 201.57(f)(4) ("Drug interactions") to proposed § 201.57(c)(7); move the information required by current § 201.57(f)(5) ("Carcinogenesis, mutagenesis, impairment of fertility") to proposed § 201.57(c)(14); and move the information required by current § 201.57(f)(6) through (f)(10) ("Pregnancy," "Labor and delivery," "Nursing mothers," "Pediatric use," and "Geriatric use") to proposed § 201.57(c)(8).

f. *Proposed § 201.57(c)(7)—drug interactions.* Under current § 201.57(f)(4), "Drug interactions" is a subsection under "Precautions." The subsection requires the inclusion of practical guidance for the practitioner on preventing clinically significant drug/drug and drug/food interactions that may occur in patients taking the drug. Specific drugs with which the

labeled drug interacts in vivo must be identified, and the mechanisms of action briefly noted.

Proposed § 201.57(c)(7) would move "Drug interactions" from current § 201.57(f)(4) to create a separate section with the same heading. The agency believes that placing this information in a separate section under its own heading would draw attention to this area of increasingly recognized importance. This change was supported both by focus group participants and by comments received on the prototype.

g. *Proposed § 201.57(c)(8)—use in specific populations.* Under current § 201.57(f)(6) through (f)(10), information on specific populations (i.e., "Pregnancy," "Labor and Delivery," "Nursing mothers," "Pediatric use," and "Geriatric use") is placed under "Precautions." The agency is proposing to move this information to its own section entitled "Use in Specific Populations." FDA believes that by establishing a more descriptive heading for this information, and separating the information from other types of information currently required to appear under the precautions section, the information would be easier to find and use.

Current § 201.57(f)(6)(i)(d) and (f)(6)(i)(e) require the labeling of drug products in Pregnancy Categories D and X to contain the statement "* * * If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to the fetus." Proposed § 201.57(c)(8)(i)(A)(4) and (c)(8)(i)(A)(5) would modify this statement to read: "If this drug is administered to a woman with reproductive potential, the patient should be apprised of the potential hazard to a fetus." The agency is proposing this revision to alert practitioners to the risk of prescribing the drug to any woman of child bearing age, since such a woman can be in the first trimester of pregnancy and be unaware that she is pregnant. This caution would highlight to prescribers the importance of considering the pregnancy-related effects of drugs, especially those used on a chronic basis, for women who may become pregnant as well as those who are already pregnant. The agency is also currently considering other initiatives to revise pregnancy labeling that may be proposed in the future. However, because of the importance of the current revision, the agency believes that it is appropriate to propose it immediately.

Proposed § 201.57(c)(8)(iii) would change the subheading "Nursing mothers" to "Lactating Women" to

recognize the role of women who may nurse an infant but are not the mother, as well as women who produce breast milk for others' use. Proposed § 201.57(c)(8)(iii)(B) and (c)(8)(iii)(C) would substitute the terminology "clinically significant adverse reactions" for the "serious adverse reaction" terminology in current § 201.57(f)(8)(i) and (f)(8)(ii) to clarify that all clinically significant adverse reactions, not just those that are classified as serious, must be taken into consideration when placing the required precautionary statements in labeling. Minor conforming changes would also be made to the section.

Under proposed § 201.57(c)(8)(vi), the agency would permit additional subsections representing other types of patient subpopulations to be included under the "Use in Specific Populations" section if sufficient data are available concerning the use of the drug in the subpopulations (e.g., hepatically or renally impaired or immunocompromised populations).

h. *Proposed § 201.57(c)(9)—adverse reactions.* Current § 201.57(g) defines adverse reaction as an "undesirable effect, reasonably associated with the use of the drug, that may occur as part of the pharmacological action of the drug or may be unpredictable in its occurrence." Proposed § 201.57(c)(9) would revise the definition of adverse drug reaction to read: "An adverse reaction is a noxious and unintended response to any dose of a drug product for which there is a reasonable possibility that the product caused the response."

The revised definition of "adverse reaction" in proposed § 201.57(c)(9) is consistent with the definition of "adverse drug reaction" developed by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) in a final ICH guideline entitled "Clinical Safety Data Management: Definitions and Standards for Expedited Reporting" (60 FR 11284, March 1, 1995) (the ICH E2A guideline). The ICH E2A guideline defines an adverse drug reaction as follows:

All noxious and unintended responses to a medicinal product related to any dose should be considered adverse drug reactions. The phrase 'response to medicinal products' means that a causal relationship between a medicinal product and an adverse event is at least a reasonable possibility, i.e., the relationship cannot be ruled out.

ICH was formed to facilitate international consideration of issues, particularly safety issues, concerning the use of global data in the

development and use of drugs and biological products. ICH has worked to promote the harmonization of technical requirements for products among three regions: The European Union (EU), Japan, and the United States. As discussed in further detail below, FDA believes that adoption of the proposed definition of "adverse reaction" will result in a more focused "Adverse Reactions" section and will promote consistency in labeling worldwide. Moreover, the agency is currently in the process of developing a proposed rule revising its adverse event reporting regulations for drugs and biological products, and the revised definition of "adverse reaction" in proposed § 201.57(c)(9) is consistent with definitions being considered by the agency for inclusion in that rulemaking. FDA will ensure that the term is consistently defined in both regulations.

The definition of "adverse reaction" in proposed § 201.57 would change the current definition in two respects. It would substitute the terminology "a noxious and unintended response to any dose of a drug product" for "an undesirable effect." This change in terminology would clarify that only those responses that are noxious (i.e., injurious to health) and unintended, rather than all effects that are undesirable (which does not necessarily imply either that the effect is injurious or unintended) may be included in the "Adverse Reaction" section of labeling. In addition, the proposed definition would substitute the terminology "for which there is a reasonable possibility that the product caused the response" for "reasonably associated with the use of the drug, that may occur as part of the pharmacological action of the drug or may be unpredictable in its occurrence." The agency is proposing this change in terminology because the "reasonably associated" language in the current definition can be and in many cases has been interpreted as meaning that a reaction should be included merely if there is a temporal association, rather than a reasonable causal association, between a response and a drug. This has resulted in the inclusion of information in the "Adverse Reactions" section of labeling that is not meaningful to prescribers and which dilutes the usefulness of the clinically meaningful information. The revised definition would clarify that at least a reasonably plausible causal relationship must exist between a drug and a noxious and unintended response for the response to be included as an adverse reaction in the "Adverse Reactions" section of labeling.

i. *Proposed § 201.57(c)(10)—drug abuse and dependence; proposed § 201.57(c)(11)—overdosage.* Labeling sections "Drug Abuse and Dependence" and "Overdosage" are currently required to appear in labeling under § 201.57(h) and (i), respectively. Proposed § 201.57(c)(10) and (c)(11) would incorporate the current sections without change.

j. *Proposed § 201.57(c)(12)—description.* Under current § 201.57(a), the "Description" section appears at the beginning of prescription drug labeling and requires certain basic information about the drug such as the proprietary and established name of the drug and its dosage form and route of administration.

Under proposed § 201.57(c)(12), the information would be moved toward the end of product labeling, but retain its current placement in relation to the "Clinical Pharmacology" section. Movement of the description section reflects the findings of the focus group studies and physician surveys that the information in the section is less important than other labeling information that would be required under proposed § 201.57(c)(1) through (c)(11). In addition, the most important information prescribers need from the description section, the proprietary or established name of the drug (or, for biologics, the proper name), is required to appear at the beginning of the highlights section under proposed § 201.57(a)(1).

k. *Proposed § 201.57(c)(13)—clinical pharmacology.* Under current § 201.57(b), the "Clinical Pharmacology" section appears near the beginning of prescription drug labeling, immediately following the "Description" section. The section requires a concise factual summary of the product's clinical pharmacology and actions. The section includes absorption, distribution, metabolism, excretion, elimination, pharmacokinetic, and pharmacodynamic (i.e., concentration in body fluids associated with therapeutic and/or toxic effects) information important for safe and effective use of the drug, if known. The section may include information based on in vitro or animal data if the information is essential to a description of the biochemical and/or physiological mode of action of the drug or is otherwise pertinent to human therapeutics. Under current § 201.57(b)(2), in vitro or animal data related to the activity or efficacy of a drug that have not been shown to be pertinent to clinical use by adequate and well-controlled clinical studies are generally prohibited except in two

specific circumstances: (1) In vitro data for anti-infective drugs may be included if the data are immediately preceded by the statement: "The following in vitro data are available but their clinical significance is unknown"; and (2) in vitro and animal data for classes of drugs other than anti-infectives may be included if a waiver is granted under § 201.58 or § 314.126(c).

Under proposed § 201.57(c)(13), the section would be moved toward the end of product labeling. Movement of the section reflects prescribing physicians' reports, as demonstrated in the physician surveys, that the clinical pharmacology information appearing in this section is used less often than other labeling information. In addition, the current positioning of this sometimes lengthy section, just before the "Indications and Usage" section, may make it more difficult and time consuming to find the latter section, which is more commonly referred to by practitioners. This revised placement of the clinical pharmacology section would also be consistent with the practice of the EU, which requires this information be placed toward the end of its Summary of Product Characteristics (the EU's equivalent of approved product labeling). Clinical pharmacology information that is relevant to other labeling sections and affects practitioners' prescribing concerns may be placed in other sections of the comprehensive prescribing information and/or highlights. For example, clinically important information related to special populations or drug interactions may appear under "Special Populations" or "Drug Interactions." Similarly, clinically important information related to efficacious and/or toxic drug concentration ranges may appear under "Dosage and Administration." Therefore, the agency does not believe that the placement toward the end of product labeling of clinical pharmacology information that is less likely to be used is objectionable to the majority of prescribers.

The proposal would revise current § 201.57(b)(1) to require that the information currently required under that section be presented under three separate subsections entitled "Mechanism of action," "Pharmacodynamics," and "Pharmacokinetics." Where a category of information is not available for a specific drug, the labeling would be required to contain a statement about the lack of information. The information required under these subsections is substantially similar to currently required information. The changes are

intended primarily to enhance the clinical pharmacology section's organization and clarity. In addition, an optional subsection entitled "Other clinical pharmacology information" has been added to permit the presentation of information that is not covered by the three required subsections but is helpful to optimal use and understanding of the clinical pharmacology of the drug or biological product. Information within this section could include information related to the clinical pharmacology of drug/drug interactions or use in specific populations. The agency also is proposing that, if specific data on alternative dosing regimens (e.g., for hepatically or renally impaired patients) appears in the "Clinical Pharmacology" section, it must also appear in the "Dosage and Administration" section.

The proposal also would revise current § 201.57(b)(2) such that in vitro data related to the activity or efficacy for all drugs, including anti-infective drugs, could be included only if a waiver is granted under § 201.58 or 314.126(c). Since issuing the current regulations, extensive in vitro data has been included for nearly all anti-infective drugs. The agency believes that, despite the disclaimer concerning their lack of clinical relevance, inclusion of these data in approved product labeling creates the misleading impression that a product's in vitro action represents sufficient information to treat infections with the listed pathogens in humans. In vitro data alone do not provide information about factors critical to effective therapy, including tissue levels of the product necessary to cure the treated infection, and appropriate length of treatment. Such information is often essential to help ensure safe and effective use and avoid the development of antimicrobial resistance. More specifically, using anti-infectives at subtherapeutic levels for the wrong time period facilitates the development of antimicrobial resistance. Consequently, FDA believes that "in vitro only" labeling information, in contributing to the inappropriate prescribing of anti-infectives, may also be contributing to the further development of antimicrobial resistance for many drugs. Therefore, the proposal would treat the inclusion of in vitro data for anti-infective drugs in labeling the same as other data that have not been shown by adequate and well-controlled clinical studies to be pertinent to clinical use (i.e., such data may be included only if a waiver is granted under § 201.58 or § 314.126(c)).

1. *Proposed § 201.57(c)(14)—nonclinical toxicology.* Current § 201.57(f)(5) requires a subsection

entitled "Carcinogenesis, mutagenesis, impairment of fertility" to appear in the labeling under "Precautions." The subsection must state whether long-term studies in animals have been performed to evaluate carcinogenic potential and, if so, the species and results of the studies. The section also requires a description of reproduction studies or other animal data, if any, revealing a problem or potential problem concerning mutagenesis or impairment of fertility. Under current § 201.57(l), a section entitled "Animal Pharmacology and/or Animal Toxicology" may be placed near the end of labeling to include animal data related to the safety or efficacy of a drug, if the data cannot be appropriately incorporated into other labeling sections.

Proposed § 201.57(c)(14) would move current § 201.57(f)(5) and (l) under a new section heading entitled "Nonclinical Toxicology." The agency believes that the proposed title for the section accurately describes the nature and purpose of the animal data commonly included under both of these sections. Movement of the information under current § 201.57(f)(5) toward the end of the comprehensive labeling section reflects the agency's findings that this section is less important than other labeling information that would be required before it.

m. *Proposed § 201.57(c)(15)—clinical studies.* Current § 201.57(m) permits, but does not require, that a "Clinical Studies" section appear near the end of prescription labeling in the place of a detailed discussion of a subject that is of limited interest but nonetheless important. The section also permits a reference to be made to a clinical study in any labeling section if the study is essential to understanding the available information.

Proposed § 201.57(c)(15) would revise current § 201.57(m) to require a separate heading entitled "Clinical Studies." The section would be required to contain a discussion of clinical study results that are important to a prescriber's understanding of the basis for approval of the drug product, including the extent of the product's benefits, how the drug was used in clinical trials, who was studied, and critical parameters that were monitored. The agency is proposing to require inclusion of this information to provide practitioners with more accurate and specific information about a drug's efficacy that could help them to make informed prescribing decisions. The proposed section would revise current § 201.57(m) to specify that a *brief* reference to a specific important clinical study or studies may be placed in any

labeling section, but any detailed discussion of the study's methodology and results must be included in the "Clinical Studies" section, to which the reader would be directed. This change is being proposed to make it easier for practitioners to find clinical studies information, which has typically (although not invariably) been included in either the "Indications and Usage" or "Clinical Pharmacology" sections. Language has also been added to this section to reinforce the prohibition in proposed § 201.57(c)(2) against implying or suggesting uses or dosing regimens for a product that are not included in its "Indications and Usage" or "Dosing and Administration" sections.

n. *Proposed § 201.57(c)(16)—references.* Proposed § 201.57(c)(16)(i) would state that if the reference is cited in labeling in the place of a detailed discussion of data and information concerning an indication for or use of a drug or biological product, the reference must be based upon an adequate and well-controlled clinical investigation under § 314.126(b) or, for a biological product, upon substantial evidence of effectiveness. This section incorporates current § 201.57(m), as it relates to the use of references, without substantive change except for the addition of the language for biologics. The section would be assigned the letter "R" as an identifier for indexing purposes instead of the index number "15." This would permit, where appropriate, the insertion of nonstandardized headings between the "Nonclinical Toxicology" and "References" sections without affecting the standard index numbering system (i.e., additional nonstandardized headings would be assigned the index number "15," "16," and so on).

o. *Proposed § 201.57(c)(17)—patient counseling information.* Current § 201.57(f)(2) requires a subsection entitled "Information for Patients" to appear in labeling under "Precautions." The subsection requires labeling to include information to be given to patients for the safe and effective use of a drug. In addition, the subsection requires that any printed patient information required to be distributed to a patient be referenced under the "Precautions" section and its full text printed at the end of labeling.

Based on the results of the physician survey and the comments received on Prototype 3, proposed § 201.57(c)(17) would retitle the heading of the information required under current § 201.57(f)(2) from "Information for Patients" to "Patient Counseling Information." The proposed change would clarify that the information under this section is not intended to be

distributed to patients, but is intended to facilitate practitioner counseling of patients. To further clarify this, the phrase "to be given to patients" in current § 201.57(f)(2) would be changed to "useful for patients to know." The agency is proposing to use the letter "P" to identify the section for indexing purposes, rather than an index number, for the same reasons that the letter "R" has been used as an identifier for the references section (see the previous discussion of the "References" section). Finally, the agency is proposing that the section be moved from its current location under "Precautions" to a separate section at the end of the comprehensive prescribing information. This would ensure that patient counseling information would immediately precede any approved patient labeling or Medication Guide, which would be required to be reprinted immediately following it. Under the proposal, all approved printed patient information or Medication Guides would be required to be referenced in this section and reprinted following the "Patient Counseling Information" section, regardless of whether the information is required by regulation to be distributed to the patient.

To maintain flexibility in the application of graphical techniques, the agency would permit the horizontal line to consist of a series of horizontal icons (see, e.g., Prototype 4). The agency believes that a visual separation of each section of important information would facilitate search and readability.

Proposed § 201.57(d)(4) would require the use of bullet points to distinguish multiple subheadings listed under proposed § 201.56(d)(5) in paragraphs (a)(4) through (a)(10), (a)(12), and (a)(13) of § 201.57. For example, if there is more than one subheading listed under the "Indications and Usage" heading, these subheadings would be preceded by a bullet point. The agency is not proposing to specify a graphical icon for bulleted points.

Proposed § 201.57(d)(5) would require that the labeling information required by paragraphs (a)(1) through (a)(4), (a)(11), and (a)(15) of § 201.57 be highlighted by bold print. The agency requests comment on whether the proposed use of bolding in all of these sections will serve its intended purpose of ensuring visual prominence, or if different highlighting methods, such as

4. Format Requirements

Although current §§ 201.56 and 201.57 set forth required headings and a required order for prescription drug labeling information, they do not contain requirements for a minimum type size or other graphical elements.

FDA has determined, based on the focus group and survey results described in section II of this document, that the typically lengthy and undifferentiated format of prescription drug labeling makes it difficult to locate and read specific information. Proposed § 201.57(d) would set forth new minimum standards and requirements for the format of prescription drug labeling to improve its legibility, readability, and usability.

The agency believes that optimum labeling formats can be created only by permitting the flexible application of graphical techniques. However, the agency has also determined that it is necessary to establish minimum standards and requirements for certain key graphic elements to ensure an acceptable base level of readability for prescription drug labeling. Type size, letter and line spacing, contrast, print and background color, and type style are all factors that may affect the readability of labeling information (Ref. 5). Accordingly, the proposal would

“——Recent Labeling Changes——”

the use of different colors, may be equally or more effective.

Proposed § 201.57(d)(6) would require that the letter height or type size for all labeling information, headings, and subheadings set forth in paragraphs (a), (b), and (c) of this section be a minimum of 8 points. FDA believes that this minimum type size would make it easier for practitioners to read labeling information and thus help to ensure the safe and effective use of prescription drug products. The rationale for the use of 8-point type size is discussed below.

There are no clear recommendations in the literature with regard to minimum type size for medical practitioners or other "experts" in a field. Type size can affect visibility and reading speed (Ref. 6). Early studies of how type size affects the speed of reading suggest that 8-point type is read significantly more slowly than 10-point type (Ref. 7). Newspapers, which are targeted to the general public, are usually printed in 8-point type (Ref. 8). However, the smallest recommended font size for the general public typically is 10-point, while larger font sizes are recommended for populations where

establish minimum standards and requirements for many of these key graphic elements while leaving manufacturers extensive flexibility to implement their own ideas in labeling design.

Proposed § 201.57(d)(1) would require that all headings and subheadings be highlighted by bold type that prominently distinguishes the headings and subheadings from other information.

Proposed § 201.57(d)(2) would require that a horizontal line separate the three major sections of information proposed in § 201.57(a), (b), and (c). The agency believes that horizontal lines will distinctively separate each section of important information to make it more conspicuous and easier to read.

The agency is proposing to require in § 201.57(d)(3) that the headings specified in paragraphs (a)(4) through (a)(10), (a)(12), (a)(13), and (a)(14) of § 201.57 be highlighted in two ways. First, these headings must be presented in bold type. Second, these headings must be presented in the center of a horizontal line that provides a visual demarcation from the preceding section. For example, the heading "Recent Labeling Changes" could be presented as follows:

low-literacy, age, or impaired vision are significant factors (Refs. 9, 10, and 11). A recent guidance document issued by a national collaborative group recommending format parameters for written patient prescription medicine materials recommended that 10- or 12-point type be used for this information, also noting that 12-point type is generally recommended for older persons. Because many prescribers are older and subject to the same limitations as others in reading print materials, this would suggest the use of a minimum of 10- or perhaps even 12-point type for prescription drug labeling. FDA performed a cost analysis, discussed in section X of this document, comparing the cost of requiring 10- versus 8-point type in prescription drug labeling. The analysis shows that there would be significant additional costs associated with producing and packaging 10-point type size labeling versus 8-point. Thus, although 10-point type size would clearly be better than 8-point with regard to its legibility, FDA is proposing to require the use of 8-point type to minimize the economic impacts on industry. However, the agency solicits

comments on minimum type size requirements, and in particular on whether the benefits of 10-point type justify its additional costs and should therefore be required.

Proposed § 201.57(d)(7) would require that the index numbers required by paragraphs (c)(1) through (c)(17) of § 201.57 be presented in bold print and precede the heading or subheading by at least two square em's (i.e., two squares of the size of the letter "m" in 8-point type).

Proposed § 201.57(d)(8) would limit the length of the highlights section by requiring that the information under proposed § 201.57(a), except for any boxed warning information required under § 201.57(a)(4), be limited in length to an amount that, if printed in 2 columns on one side of a standard size piece of typing paper (8½ by 11 inches), single spaced, in 8-point type with ½-inch margins on all sides and between columns, would fit on one-half of the page. The length restriction is being proposed in response to certain comments and the agency's concerns that, without setting a definitive limit on the amount of information that may be included in the highlights section, there will not be sufficient incentive to make the difficult, but necessary decisions about inclusion of specific information. As discussed above, the purpose of the highlights section is to provide a concise extract of the most important information from the comprehensive prescribing information. If too much information is included, the section would no longer serve its intended purpose. However, the agency recognizes that there may be circumstances under which this limited amount of information may be inadequate to communicate appropriately even the highlights of a product's labeling. Therefore, the agency requests comments on whether the proposed space limitation is adequate or whether there are alternatives that would be more appropriate and under what circumstances such alternatives should be considered.

Proposed § 201.57(d)(9) would require that labeling sections in the comprehensive prescribing information containing recent changes identified in § 201.57(a)(5) be highlighted by a vertical line on the left edge of the new or modified text. Given the extensive amount of information in the comprehensive prescribing information section, this additional graphic emphasis should make it easier for practitioners to identify modified labeling information. In addition, this graphic device will allow those

practitioners who are reading the comprehensive information thoroughly to identify new labeling information without referring back to the highlights section. Nonetheless, FDA invites comments on other means that could be used to facilitate access to, and identification of, new labeling information for both casual and in-depth readings.

C. Revisions to Labeling for Older Drugs

As discussed in sections II and IV of this document, older drugs not subject to the revised labeling content and format requirements would remain subject to the requirements in current § 201.57. Under the proposed rule, current § 201.57 would be redesignated as § 201.80 to permit the revised content and format requirements for new drugs to be designated as § 201.57. In addition to the redesignation of the current section, the proposed rule would make certain revisions to the content of current § 201.57. The content revisions being proposed in redesignated § 201.80 are consistent with certain revisions in proposed § 201.57 for newer drugs and would help to ensure that statements currently appearing in the labeling of older drugs relating to effectiveness or dosage and administration are sufficiently supported. As discussed in section IV of this document, these content changes would be required to be made within 1 year of the effective date of the final rule.

Proposed § 201.80(b)(2) would replace current § 201.57(b)(2). Under the proposed section, in vitro or animal data related to the activity or efficacy for all drugs, including anti-infective drugs, that have not been shown by adequate and well-controlled studies to be pertinent to clinical use, could be included in the labeling only if a waiver is granted under § 201.58 or § 314.126(c). The agency is proposing this limitation because the inclusion of data showing that a drug product is effective against certain pathogens in vitro may lead practitioners to believe that the drug product is effective for treatment of infections or other illnesses in humans involving those pathogens. However, in vitro action alone is generally not sufficient to demonstrate effectiveness in humans. Therefore, under the proposal, in vitro data that does not meet the revised requirements would be required to be removed from the "Clinical Pharmacology" labeling section of older approved drug products.

Proposed § 201.80(c)(2)(i) and (c)(2)(ii) would replace current § 201.57(c)(2). Proposed § 201.80(c)(2)(i) would incorporate current § 201.57(c)(2)

and modify it to include the requirement that indications or uses must not be implied or suggested in sections of labeling other than "Indications and Usage" if not included in that section. This change is consistent with the change in proposed § 201.57(c)(2)(ii). Proposed § 201.80(c)(2)(ii) is the same as proposed § 201.57(c)(2)(iii), and would be added to address biological drug products subject to licensing under section 351 of the PHS Act. As discussed in section III of this document, the proposed section would make clear that substantial evidence of effectiveness must support indications for biological drug products.

Proposed § 201.80(f)(2) would replace the current "Information for Patients" section. The proposed section would modify the current section to require that any approved patient information or Medication Guide, not just those that are required by regulation to be distributed to patients, be referenced in the "Precautions" section and reprinted immediately following the last section of labeling. The agency believes that including this information in professional labeling will facilitate practitioner access to the information and improve their ability to communicate to patients information that the agency and sponsor believe is important.

Proposed § 201.80(j) would modify current § 201.57(j) ("Dosage and Administration") to clarify that dosing regimens must not be implied or suggested in other sections of labeling if not included in this section.

Proposed § 201.80(m)(1) would modify current § 201.57(m)(1) to state that, for biological products, references do not have to be based upon, and clinical studies do not have to constitute, adequate and well-controlled studies. This change is being made to address biological products subject to licensing under section 351 of the PHS Act. In addition, the section would be modified to clarify that clinical studies and references must not imply or suggest indications, uses, or dosing regimens not stated in the "Indications and Usage" or "Dosage and Administration" sections.

IV. Proposed Implementation Plan

A. General Implementation Scheme for the Revised Format and Content Requirements

The proposed implementation plan for the revised labeling format and content requirements in proposed §§ 201.56(d) and 201.57 is summarized in table 1.

TABLE 1.—IMPLEMENTATION PLAN

Applications (NDA's, BLA's, and Efficacy Supplements) Required to Conform to New Labeling Requirements	Time by Which Conforming Labeling Must Be Submitted to the Agency for Approval
Applications submitted on or after the effective date of the final rule	Time of submission
Applications pending at the time of the effective date of the final rule and applications approved 0 to 1 year before the effective date of the final rule.	3 years after the effective date of the final rule.
Applications approved 1 to 2 years before the effective date of the final rule	4 years after the effective date of the final rule.
Applications approved 2 to 3 years before the effective date of the final rule	5 years after the effective date of the final rule.
Applications approved 3 to 4 years before the effective date of the final rule	6 years after the effective date of the final rule.
Applications approved 4 to 5 years before the effective date of the final rule	7 years after the effective date of the final rule.

As discussed in section III of this document, the agency is proposing that, with the exception of the requirements discussed in section IV.C and IV.D of this document, the content and format revisions apply only to products with applications (i.e., NDA's, BLA's, and efficacy supplements) pending at the time of the effective date of the final rule, products for which such applications are submitted on or after the effective date of the final rule, and products with such applications that were approved up to and including 5 years before the effective date of the final rule. Thus, the proposed content and format requirements would not apply to products with applications that were approved more than 5 years before the effective date of the final rule, unless an efficacy supplement was approved for such products in the 5 years before the effective date of the final rule or is submitted after the effective date of the final rule. As discussed in section III of this document, these older products would remain subject to the labeling requirements in current § 201.57, which under the proposal would be redesignated as § 201.80.

The agency believes that applying the requirements only to more recently approved products is appropriate because, as discussed previously in section II of this document, physicians are more likely to refer to the labeling of recently approved products than the labeling of older products. Additionally, the labeling of recently approved products is likely to be longer and more complex than that of older products and thus more in need of the proposed format revisions. Finally, even though certain older products will remain subject to the current format and content requirements (as revised by the proposal), many products not initially covered by the revised format and content requirements will at some point submit efficacy supplements, and thus will be required to revise their labeling to conform to the revised format and content requirements.

The agency intends to make the final rule based on this proposal effective 120 days after the date of its publication in the **Federal Register**. As indicated in table 1, the time by which revised labeling for products with applications would be required to be submitted would depend on when the application was approved. Applications (NDA's, BLA's, and efficacy supplements) submitted for review on or after the effective date of the final rule would be required to include labeling in the new format as part of the application. Sponsors of products with applications pending at the time the final rule becomes effective and applications approved before the effective date of the final rule would be required to submit labeling supplements for approval on a staggered basis beginning 3 years after the effective date of the final rule. The proposed implementation scheme would require revised labeling to be submitted for newer products first, followed by older products. This plan is intended to minimize the rule's economic impact by providing manufacturers with sufficient time to design and print new labeling and deplete existing stocks of products with old labeling. At the same time, newer products for which revised labeling is most essential will either have revised labeling or will revise labeling at the earliest possible date.

B. Implementation of Proposed Content and Format Revisions to Products Approved or Submitted for Approval Under an ANDA

Under section 505(j)(2) of the act (21 U.S.C. 355(j)(2)) and §§ 314.94(a)(8) and 314.127(a)(7) (21 CFR 314.94(a)(8) and 314.127(a)(7)) of the agency's regulations, the labeling of a drug product submitted for approval under an ANDA must be the same as the labeling of the listed drug referenced in the ANDA, except for changes required because of differences approved under a suitability petition (see 21 CFR 314.93) or because the generic and innovator products are manufactured by different manufacturers. Thus, whether a

prescription drug product that was approved under an ANDA before the effective date of the final rule, or that is submitted for approval under an ANDA after the effective date of the final rule, will be required to have labeling that complies with the final rule will depend on the status of the labeling of the listed drug referenced in the ANDA. Where a reference listed product's labeling conforms to the requirements of the final rule (i.e., where the NDA for the product was submitted after the effective date of the final rule, the NDA for the product was pending on or submitted within 5 years before the effective date of the final rule and the labeling has been required to be revised under the implementation scheme, or the labeling for the product was revised by the sponsor to comply with the final rule voluntarily), the generic product that references the listed drug in its ANDA would be required to have labeling that is the same as the listed product and would therefore be required to comply with the final rule. On the other hand, where a reference listed product's labeling does not conform to the requirements of the final rule (i.e., the product was approved more than 5 years before the effective date of the final rule, or the final rule applies to the product but the product's labeling is not yet required to be revised under the implementation scheme), a generic product that references the product in its ANDA would not be required to have labeling that complies with the final rule.

C. Implementation of Proposed Content Requirements Applicable to Newer and Older Drugs

The agency is proposing that the revised content requirements for newer drugs in proposed § 201.57(c)(2)(ii), (c)(2)(iii), (c)(3), (c)(13)(ii), and (c)(15)(i), and the revised content requirements for older drugs at proposed § 201.80(b)(2), (c)(2)(i) and (c)(2)(ii), (j), and (m)(1), be implemented no later than 1 year after the effective date of the final rule. The agency believes that the changes necessary for existing product labeling

to comply with these sections could be made without prior FDA approval, that is, with a supplement explaining the changes at the time the applicant makes them under § 314.70(c) (21 CFR 314.70(c)) or § 601.12(f) (21 CFR 601.12(f)) (i.e., a “Changes Being Effected” supplement). FDA is proposing a broad and prompt implementation of these sections because the agency believes that the requirements proposed in the sections are necessary to help ensure that the information in labeling regarding a drug product’s indications or uses is not misleading, and to help ensure that the staggered implementation scheme does not give a marketing advantage to certain products.

In accordance with the discussion above, the proposed sections would be implemented as follows. Proposed § 201.57(c)(2)(ii) and (c)(2)(iii) and proposed § 201.80(c)(2)(i) and (c)(2)(ii) would require that indications or uses not included in the “Indications and Usage” section not be implied or suggested in other sections of labeling. Thus, any implied or suggested indication or use for a drug not included in the “Indications and Usage” section would have to be removed from the labeling by 1 year after the effective date of the final rule. Similarly, proposed § 201.57(c)(3) and proposed § 201.80(j) would require that dosing regimens not included in the “Dosage and Administration” section be removed from other sections of labeling. Proposed § 201.57(c)(15)(i) and proposed § 201.80(m)(1) would require that any clinical study that is discussed that relates to an indication for or use of a drug be adequate and well-controlled as described in § 314.126(b), except for biological products, and relate only to indications, uses, or dosing regimens stated in the “Indications and Usage” or “Dosage and Administration” sections. Thus, any discussion of a clinical study or studies related to indications, uses, or dosing regimens not included in the “Indications and Usage” or “Dosage and Administration” sections would have to be removed. Finally, under proposed § 201.57(c)(13)(ii) and proposed § 201.80(b)(2), in vitro or animal data related to the activity or efficacy of a drug that have not been shown by adequate and well controlled studies to be pertinent to clinical use would be required to be removed by 1 year after the effective date of the final rule unless a waiver is granted to permit inclusion of the data.

D. Implementation of Proposed § 201.57(c)(17) and Proposed § 201.80(f)(2)

Proposed § 201.57(c)(17) would require that any approved printed patient information or Medication Guide be reprinted immediately following “Patient Counseling Information.” Proposed § 201.80(f)(2) would require that any approved printed patient information or Medication Guide be reprinted immediately following the last section of labeling. The agency is proposing that these requirements be implemented by 1 year after the effective date of the final rule. Sponsors of newer products subject to the revised format and content requirements in proposed § 201.57 would have to comply with the requirement in proposed § 201.57(c)(17) before revising other sections of labeling. These sponsors would be required to reprint the approved patient labeling or Medication Guide following the last section of labeling (e.g., generally after “How Supplied” or “References”). The agency is proposing this broad and prompt implementation to help ensure that practitioners have access to printed patient information or Medication Guides.

E. Voluntary Submission of Labeling Conforming to Proposed Content and Format Requirements

Sponsors of drug products that are not required under the proposed rule to comply with the revised format and content requirements may voluntarily submit revised labeling for approval by the agency.

F. Relationship of Proposed Requirements to Other Prescription Drug Labeling Initiatives

The format and content revisions discussed in this proposal are the most extensive of many prescription drug labeling revision initiatives that are being considered by the agency. The agency will provide information on additional labeling initiatives, and how the agency intends to coordinate their implementation, at a later date.

V. Revisions to Prescription Drug Labels⁷

In addition to revising its regulations governing the format and content of

⁷ The proposed changes would not affect the label requirements, set forth in parts 600 through 680 (21 CFR parts 600 through 680), for most biological products. As specified in § 601.2(c)(3), the label requirements described in § 610.62 do not apply to those biological products listed in § 601.2(c)(1). However, CBER is currently evaluating how it can best address the concerns regarding drug product labels discussed under section V of this document.

labeling for prescription drugs, the agency is proposing minor revisions to the information required to appear on prescription drug product labels.⁸ The proposed changes are intended to lessen overcrowding of prescription drug product labels by eliminating unnecessary statements and moving to the package insert less critical information that is currently required to appear on the product label. The agency believes that overcrowding of drug product labels makes reading critical information on these labels more difficult and may be one possible cause of medication errors by health care practitioners.⁹ Thus, the agency hopes that by reducing the amount of required information on product labels and simplifying them, the number of medication errors will be reduced. It is estimated that at least one death every day is attributable to a medication error (Ref. 12). From January 1992 to May 1997, FDA’s Center for Drug Evaluation and Research (CDER) has received approximately 6,000 reports of errors (actual or potential). Approximately 50 percent or 3,000 of these reports were attributable to the labeling, packaging, and/or design of the drug product.

The proposed changes are consistent with the recommendations of the joint United States Pharmacopeia (USP)–FDA Advisory Panel on Simplification and Improvement of Injection Labeling, which was formed to explore ways to avoid medication errors associated with overcrowded product labels.¹⁰ The proposed changes are also consistent with the recommendations of an independent task force, the Committee to Reduce Medication Errors, which studied ways to reduce medication errors by improving label legibility.¹¹ Although the recommendations of the joint USP–FDA advisory panel and the committee were targeted primarily at labels for injection products, the agency believes that they will help to reduce medication errors for all dosage forms. Thus, the proposed changes would apply to all types of drug products. A

⁸ Under section 201(k) of the act, the term label means a display of written, printed, or graphic matter upon the immediate container of an article.

⁹ The term “medication error” is a general term used to refer to many types of errors associated with medication use including improper dosage, wrong strength or concentration, wrong drug or dosage form, use of the drug for an improper duration, or use on the wrong patient.

¹⁰ The recommendations were published in the *Pharmacopeial Forum* (Ref. 13).

¹¹ The Committee to Reduce Medication Errors was assembled by the State of Washington and included individuals from pharmaceutical associations, industry, and health care practitioners.

detailed description of the proposed changes follows.

Current § 201.100(b)(2) requires that the label of a prescription drug bear a statement of the recommended or usual dosage. Current § 201.55 explains that, because the dosage may vary widely for treatment of different conditions, it may not be possible to present an informative or useful statement of the recommended or usual dosage in the space available on the label. Section 201.55 states that, in this case, the requirements of § 201.100(b)(2) may be met by including on the label a statement such as "See package insert for dosage information," provided that detailed dosage information is contained in the package insert. The proposal would revise §§ 201.55 and 201.100(b)(2) such that, if it is not possible to place an informative and useful statement of the recommended or usual dosage on the label, the statement on the label would not be required. In these cases, the dosage information would appear in the comprehensive prescribing information section of the labeling without a statement on the label referencing the information.

Current § 201.100(b)(5) states that the label of a prescription drug for other than oral use must bear the names of all inactive ingredients, with some exceptions. Under current § 201.57(a)(iii), this information must also appear under the "Description" section in the package insert. The proposal would eliminate current § 201.100(b)(5) so that inactive ingredient information would not have to appear on the label. Instead, proposed § 201.57(c)(12)(i)(D) would require the information to appear in the package insert under the section entitled "Description."

Current § 201.100(b)(7) requires that the label of a prescription drug bear a statement directed to the pharmacist specifying the type of container to be used in dispensing the drug product to maintain its identity, strength, quality, and purity. The proposal would eliminate the requirement that this information appear on the label and instead under proposed § 201.57(c)(4)(v) require the information to appear in the package insert under the section entitled "How Supplied/Storage and Handling."

In addition to these changes to drug product labels, the agency recently proposed a change to § 201.100(b)(1) to require that the label of prescription drugs bear the "Rx only" symbol, rather than the statement: "Caution, Federal law prohibits dispensing without prescription." (See 65 FR 18934, April 10, 2000.) This change was proposed in accordance with section 126 of the

Modernization Act, which required that the "Rx only" symbol replace the longer statement. The change, when finalized in the other rulemaking, will eliminate unnecessary verbiage in the drug product label and thus should also contribute to the reduction of medication errors.

The proposed changes described in this section V, if finalized, would be implemented for all new NDA's as soon as the final rule takes effect. For products with approved or pending NDA's at the time the final rule takes effect, the changes would be implemented as follows. Changes affecting the labeling of a prescription drug product (i.e., changes made to the package insert in accordance with proposed § 201.57(c)(12)(i)(D) and (c)(4)(v)) would not be required to be made until the first time that labeling is revised for reasons other than to comply with the proposed requirements or 7 years after the final rule takes effect, whichever occurs first. The proposed changes to the container label (i.e., changes made to remove currently required statements from the container label) should not be made until the changes to the package insert are made. This would ensure that the information that currently is required to appear on the container label appears on the package insert before it is removed from the label. Once changes to the package insert are made, the changes to the container label would not be required until the first time the label is revised for reasons other than to comply with the proposed requirements. Thus, no additional printing costs would be associated with the proposed changes and, as discussed in section X of this document, economic impacts associated with the proposed changes would be minimal.

VI. Revisions to §§ 201.58 and 201.100(d)(3), Rescission of § 201.59 (21 CFR 201.59)

The agency is proposing to revise §§ 201.58 and 201.100(d)(3) to be consistent with revisions to proposed § 201.57 and the addition of proposed § 201.80 (proposed redesignated § 201.57).

The agency is also proposing to rescind § 201.59. Section 201.59(a) sets forth the effective date, December 26, 1979, for current §§ 201.56, 201.57, and 201.100(d)(3). Section 201.59(b) sets forth the effective date, April 10, 1981, for § 201.100(e). Section 201.59(a)(1), (a)(2), and (a)(3) set forth exceptions to the December 26, 1979, effective date for current §§ 201.56, 201.57, and 201.100(d)(3) for certain categories of drugs. Section 201.59(a)(1) sets forth an

effective date of April 10, 1981, for prescription drugs that are not biologics and not subject to section 505 of the act and that were not subject to former section 507 of the act (21 U.S.C. 357, repealed 1997). Section 201.59(a)(2) sets forth different effective dates, and a schedule for submitting revised labeling, for certain classes of prescription drugs (e.g., anticonvulsants and progestins) that as of December 26, 1979, were: (1) A licensed biologic, (2) a new drug subject to an approved NDA or ANDA, or (3) an antibiotic drug subject to an approved antibiotic form. Section 201.59(a)(3) applies the same effective dates and schedule for submitting revised labeling in § 201.59(a)(2) to drugs that are approved after December 26, 1979, that are duplicates of drugs approved on or before December 26, 1979. Because all of the effective dates and dates for submission of revised labeling set forth in § 201.59 have passed and current §§ 201.56, 201.57, 201.100(d)(3), and 201.100(e) have been implemented for all categories of drugs and drug classes identified in § 201.59, § 201.59 is no longer necessary and the agency is proposing that it be removed from the regulations.

VII. Paperwork Reduction Act of 1995

This proposed rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). A description of these provisions is given below with an estimate of the annual reporting burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

FDA invites comments on: (1) Whether the proposed collection of information is necessary for proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Requirements on Content and Format of Labeling for Human Prescription Drugs and Biologics;

Requirements for Prescription Drug Product Labels.

Description: FDA is proposing to amend its regulations governing the format and content of labeling for human prescription drug and biologic products. The proposal would revise current regulations to require that the labeling of new and recently approved products include a section containing highlights of prescribing information and a section containing an index to prescribing information, reorder currently required information and make minor changes to its content, and establish minimum graphical requirements. These revisions would make it easier for health care practitioners to access, read, and use information in prescription drug labeling and would enhance the safe and effective use of prescription drug products. The proposal would also amend prescription drug labeling requirements for older drugs to require that certain types of labeling statements currently appearing in labeling be removed if they are not sufficiently supported. Finally, the proposal would eliminate certain unnecessary statements that are currently required to appear on prescription drug product labels and move other, less important information to labeling. These changes would simplify drug product labels and reduce the possibility of medication errors.

FDA's legal authority to amend its regulations governing the content and format of labeling for human prescription drug and biologic products and to amend its regulations governing the requirements for prescription drug product labels derives from sections 201, 301, 501, 502, 503, 505, and 701 of the act (21 U.S.C. 321, 331, 351, 352, 353, 355, and 371) and section 351 of the PHS Act (42 U.S.C. 262).

A. Summary of Provisions in Proposed Rule That Contain Collections of Information

1. Requirements on Content and Format of Labeling for Human Prescription Drugs and Biologics (Proposed § 201.56)

Current FDA regulations at § 201.56 require that prescription drug labeling contain certain information in the format specified in current § 201.57. Current § 201.56 also sets forth general requirements for prescription drug labeling, including the requirement that labeling contain a summary of the essential scientific information needed for the safe and effective use of the drug, that it be informative and accurate without being promotional in tone or false or misleading, and that labeling be

based whenever possible on data derived from human experience. In addition, current § 201.56 sets forth required and optional section headings for prescription drug labeling and specifies the order in which those headings must appear.

The proposal would revise current § 201.56 to set forth: (1) General labeling requirements applicable to all prescription drugs; (2) the categories of new and more recently approved prescription drugs subject to the revised content and format requirements in proposed §§ 201.56(d) and 201.57; (3) the schedule for implementing the revised content and format requirements in proposed §§ 201.56(d) and 201.57; (4) the required and optional sections and subsections associated with the revised format in proposed § 201.57; and (5) the required and optional sections and subsections for the labeling of older prescription drugs not subject to the revised format and content requirements.

2. Specific Requirements on Content and Format (Proposed § 201.57)

Current § 201.57 specifies the kind of information that is required to appear under each of the section headings set forth in § 201.56. This information is intended to help ensure that health care practitioners are provided with a complete and accurate explanation of prescription drugs to facilitate safe and effective prescribing. Thus, current FDA regulations already require prescription drug labeling to contain detailed information on various topics that may be important to practitioners.

The proposed regulations would require that prescription drug labeling for newer products include a new section entitled "Highlights of Prescribing Information" (proposed § 201.57(a)) and a new section containing an index to prescribing information (entitled "Comprehensive Prescribing Information: Index"; proposed § 201.57(b)). The proposal would also reorder currently required information (current § 201.57, proposed as § 201.57(c) "Comprehensive Prescribing Information"), make minor content changes, and establish minimum graphical requirements.

Proposed § 201.57(a) would require that the labeling of newer human prescription drugs contain a new section entitled "Highlights of Prescribing Information." Information under this section would be a concise extract of the most important information already required under current § 201.57, as well as certain additional information that the agency believes is important to prescribers.

Proposed § 201.57(b) would require that the labeling of newer human prescription drugs contain a new section entitled "Comprehensive Prescribing Information: Index" and would consist of a list of all the sections of the labeling required in the Comprehensive Prescribing Information (proposed § 201.57(c); current § 201.57), preceded by a corresponding index number or identifier.

Proposed § 201.57(c) would require that the labeling of newer human prescription drugs contain a section entitled "Comprehensive Prescribing Information" and would revise the content and format of the labeling requirements contained in current § 201.57 to make it easier for health care practitioners to access, read, and use the labeling information. The proposal would reorder the information to place more prominently those sections found to be most important and most commonly referenced by practitioners. In most cases, this would require moving the information closer to the beginning of the comprehensive section. The proposal would also reorganize sections of the labeling, require standardized index numbers for each subheading, and make certain other format and content changes.

Although current §§ 201.56 and 201.57 set forth required headings and a required order for prescription drug labeling information, they do not contain requirements for a minimum type size or other graphical elements. Proposed § 201.57(d) would set forth new minimum requirements for the format of prescription drug labeling to improve its legibility, readability, and usability. The proposal would establish minimum requirements for key graphic elements such as bold type, bullet points, type size, spacing, and other highlighting techniques.

Older drugs not subject to the revised labeling content and format requirements in proposed § 201.57 would remain subject to the requirements in current § 201.57 which would be redesignated as § 201.80. In addition to the redesignation of current § 201.57, the proposed rule would make certain revisions to its content. The content revisions being proposed are consistent with certain revisions for newer drugs in proposed § 201.57. These revisions are designed to help ensure that labeling statements related to effectiveness or dosage and administration are sufficiently supported.

In addition to revising the regulations governing the format and content of labeling for prescription drugs, proposed § 201.100(b) would make

minor revisions to the information required to appear on prescription drug product labels. The proposed changes are intended to lessen overcrowding of drug product labels by eliminating unnecessary statements and moving to the package insert less critical information that currently must appear on the product label.

B. Estimates of Reporting Burden

1. Labeling Design, Testing, and Submission to FDA for New Applications (§§ 201.56 and 201.57)

Current § 201.56 requires that prescription drug labeling contain certain information in the format specified in current § 201.57, and also sets forth general requirements for prescription drug labeling. Current § 201.57 specifies the kind of information that is required to appear under each of the section headings set forth in § 201.56. As a result of these regulations, applicants must design drug product labeling, test the designed labeling, and prepare and submit the labeling to FDA for approval. Based on information received from the pharmaceutical industry, FDA estimates that it takes applicants approximately 3,200 hours to design, test (e.g., to ensure that the redesigned labeling will still fit into carton-enclosed products), and submit prescription drug product labeling to FDA as part of a new drug application. Annually, FDA receives (on average) 137 new applications containing such labeling from approximately 101 applicants.

2. The Reporting Burdens for the General Requirements (Proposed § 201.56)

The reporting burdens for the general requirements in proposed § 201.56(a) are the same as those for current § 201.56(a) through (c), and are estimated in table 2 under current §§ 201.56 and 201.57. Proposed § 201.56(b) and (c) set forth the categories of new and more recently approved prescription drugs subject to the revised content and format requirements in proposed §§ 201.56(d) and 201.57 and the schedule for implementing the revised content and format requirements. No reporting burdens are directly associated with these requirements. Proposed § 201.56(d) sets forth the required and optional sections and subsections associated with the revised format in proposed § 201.57. The reporting burdens for this paragraph are estimated in table 2 under the requirements for proposed § 201.57.

Proposed §§ 201.56(e) and 201.80 set forth the labeling requirements for older prescription drugs. These are the same as the requirements in current §§ 201.56 and 201.57, with one exception. The exception is that provisions have been added in proposed § 201.80(b), (c), (f), (j), and (m) that would require certain statements to be removed from labeling or modified within 1 year of the effective date of the final rule. Therefore, the reporting burden associated with proposed §§ 201.56(e) and 201.80 will generally be the same as that for current §§ 201.56 and 201.57, which has been estimated in table 2. The reporting burden for proposed § 201.80(b), (c), (f), (j), and (m) is estimated in table 2 under proposed § 201.80, and has been combined with the reporting burden for the corresponding requirements for newer drugs in proposed § 201.57(c).

3. Labeling Redesign, Testing, and Submission to FDA for Approved Applications (Proposed § 201.57(a), (b), (c), and (d))

Proposed § 201.57(a) would require a new section in prescription drug product labeling entitled "Highlights of Prescribing Information"; proposed § 201.57(b) would require a new section in the labeling entitled "Comprehensive Prescribing Information: Index"; proposed § 201.57(c) would require a revision of the content and format requirements in current § 201.57 and a new title "Comprehensive Prescribing Information"; and proposed § 201.57(d) would establish new requirements for type size and other graphical elements. For applications approved during the 5 years before the effective date of these new prescription drug labeling requirements, and for applications pending on the effective date, applicants must redesign drug product labeling, test the redesigned labeling (e.g., to ensure that the larger labeling will still fit in carton-enclosed products), and prepare and submit that labeling to FDA for approval. Based on the data and information provided in the "Analysis of Economic Impacts" (section X of this document), approximately 366 labeling supplements would be submitted to FDA during the period 3 to 7 years after the effective date. Approximately 145 applicants would submit these labeling supplements, and the time required for redesigning, testing, and submitting the labeling to FDA would be approximately 190 hours.

4. Labeling Revision and Submission to FDA Within 1 Year for Approved Applications (Proposed § 201.57(c) and Proposed § 201.80(b), (c), (f), (j), and (m))

Under the "Proposed Implementation Plan" (see section IV of this document), certain provisions under proposed § 201.57(c) and proposed § 201.80 would be implemented within 1 year after the effective date. Based on the data and information provided in the analysis of economic impacts, approximately 1,888 labeling supplements would be submitted to FDA during the first year after the effective date. Approximately 145 applicants would submit these labeling supplements, and the time required for revising and submitting the labeling for these supplements would be approximately 38 hours.

5. Labeling Design and Testing for New Applications (Proposed § 201.57(a), (b), (c), and (d))

Under the proposed implementation plan, prescription drug labeling in new applications submitted after the effective date must include new sections entitled "Highlights of Prescribing Information" and "Comprehensive Prescribing Information: Index," as well as other new information and features not currently required in prescription drug labeling. Based on the data and information provided in the economic analysis, approximately 1,421 new applications would be submitted to FDA over a 10-year period after the effective date. Approximately 145 applicants would submit these applications, and the time required for the new labeling design and testing for each application would be approximately 149 hours.

6. Label Revisions (Proposed § 201.100(b))

In addition to revising the regulations governing the format and content of labeling for prescription drugs, the proposal, as explained above, would make minor revisions to the information required to appear on prescription drug product container labels. Neither the economic analysis nor this Paper Reduction Act analysis include burden estimates for these label revisions because, under the proposed rule, these changes do not have to be made until the next label revision. Thus, no new burdens would result from these proposed label revisions.

C. Capital Costs

A small number of carton-enclosed products may require new packaging to accommodate the longer insert. The economic analysis estimates that 1

percent of both the products with new efficacy supplement changes and the products approved in the 5 years before the effective date of the rule would incur costs of \$200,000 each for needed

packaging changes. Products approved after the effective date of the final rule would not incur added equipment costs because their labeling and packaging are not yet established. The estimated

present costs for equipment changes over 10 years totals \$1 million.

Description of Respondents: Persons and businesses, including small businesses and manufacturers.

TABLE 2.—ESTIMATED REPORTING BURDEN ¹

21 CFR section	Number of respondents	Number of responses per respondent	Total responses	Hours per response	Total hours
<i>Current 201.56 and 201.57:</i> Labeling design, testing, and submission to FDA for new applications	101	1.36	137	3,200	438,400
<i>Proposed 201.57(a),(b),(c), (d):</i> Labeling redesign, testing, and submission to FDA for approved applications	145	2.52	366	190	69,540
<i>Proposed 201.57(c) and 201.80:</i> Labeling revision and submission to FDA within 1 year for approved applications	145	13.02	1,888	38	71,744
<i>Proposed 201.57(a),(b),(c), (d):</i> Labeling design and testing for new applications	145	9.80	1,421	149	211,729
Total					791,413

¹ There is no capital costs or operating and maintenance costs associated with this collection of information.

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507)(d), the agency has submitted the information collection provisions of this proposed rule to OMB for review. Interested persons are requested to send comments regarding collection of information by January 22, 2001, to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Wendy Taylor.

VIII. Environmental Impact

The agency has determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IX. Executive Order 13132: Federalism

FDA has analyzed this proposed rule in accordance with Executive Order 13132: Federalism. The Order requires Federal agencies to carefully examine actions to determine if they contain policies that have federalism implications or that preempt State law. As defined in the Order, "policies that have federalism implications" refers to regulations, legislative comments or proposed legislation, and other policy statements or actions that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government.

FDA is publishing this proposed rule to revise its regulations governing the format and content of labeling for human prescription drug products. The proposal would revise current regulations to require that labeling include a section containing highlights of prescribing information and a section containing an index to prescribing information. The proposal would also reorder currently required labeling information and make minor changes to its content. Finally, the proposal would establish minimum graphical requirements for labeling. This proposal would also eliminate certain unnecessary statements on prescription drug product labels and move other, less important information to labeling. Because enforcement of these labeling provisions is a Federal responsibility, there should be little, if any, impact from this rule, if finalized, 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. In addition, this proposed rule does not preempt State law.

Accordingly, FDA has determined that this proposed rule does not contain policies that have federalism implications or that preempt State law.

X. Analysis of Economic Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and,

when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Under the Regulatory Flexibility Act, if a rule may have a significant economic impact on a substantial number of small entities, an agency must consider alternatives that would minimize the economic impact of the rule on small entities. Section 202(a) of the Unfunded Mandates Reform Act of 1995 (Public Law 104–4) requires that agencies prepare a written assessment of anticipated costs and benefits before proposing any rule that may result in an expenditure by State, local, and tribal governments, in the aggregate, or by the private sector of \$100 million in any one year (adjusted annually for inflation).

The agency believes that this proposed rule is consistent with the regulatory philosophy and principles identified in Executive Order 12866 and in these two statutes. The proposed rule would amend current requirements for the format and content of labeling for human prescription drug and biologic products.

Based on the analysis following, as summarized in table 3, FDA projects that the present value of the quantifiable benefits of the proposed rule could exceed \$296 million over 10 years. Direct costs resulting from the proposed changes are projected to range from approximately \$8 million to \$16.9 million in any one year, for a total present value of approximately \$94.5 million over 10 years at 7 percent. The agency thus concludes that the benefits of this proposal substantially outweigh

the costs. Furthermore, the agency has determined that the proposed rule is not an economically significant rule as described in the Executive Order, because annual impacts on the economy are substantially below \$100 million.

The Unfunded Mandates Reform Act does not require FDA to prepare a statement of costs and benefits for the proposed rule because the proposed rule is not expected to result in any one-year

expenditure that would exceed \$100 million adjusted annually for inflation. The current inflation-adjusted statutory threshold is \$110 million.

This rule may affect a substantial number of small entities, as defined by the Regulatory Flexibility Act. About half of the costs associated with relabeling are directly proportional to sales volume; thus, products with fewer sales would be associated with

relatively lower relabeling costs. Nonetheless, it is possible that some small firms that produce small amounts of affected drugs, or small firms that might be required to undertake packaging modifications, may be significantly affected by this proposed rule. The following analysis constitutes the agency's initial regulatory flexibility analysis as required by the Regulatory Flexibility Act.

TABLE 3.—SUMMARY OF PROJECTED QUANTIFIABLE BENEFITS AND COSTS OVER 10 YEARS

Benefits and costs	Total (\$ million)	Present value (\$ million)
Benefits:		
Physician time saved	102.09	62.76
Adverse drug events avoided	345.58	233.80
Total benefits	447.67	296.56
Costs:		
Reformatting, revising, and FDA approval	14.68	11.62
Producing prescription drug labeling	81.43	54.37
PDR costs	43.96	28.54
Total costs	140.07	94.53

A. Purpose

The objective of the proposed rule is to make it easier for health care practitioners to find, read, and use information important to the safe and effective prescribing of prescription pharmaceuticals (drugs and biologics) for patient treatment. The agency has found that the current format, while effective, can be improved to more optimally communicate important drug information. The proposed rule is designed to achieve this objective by amending the current format for the labeling of human prescription drug and biological products to, among other things, highlight frequently accessed and new information, include an indexing system, and reorder certain information.

B. Benefits of Regulation

The expected economic benefits of this proposed rule are the sum of the present values of: (1) The reduced time needed by health professionals to read or review prescription drug labeling for desired information; (2) the increased effectiveness of treatment; and (3) the decreased number of adverse events resulting from avoidable drug-related errors.

1. Decreased Health Professional Time

The proposed new format for prescription drug labeling (*i.e.*, package inserts or professional labeling) would reduce the time physicians,

pharmacists, and other health professionals must spend reading prescription drug labeling by highlighting frequently used information, by including an indexing system to direct readers to more detailed material in other sections of the labeling, and by reordering and reorganizing the detailed material to facilitate access to information deemed to be most important to prescribers. Although FDA is unaware of any data estimating the total time health professionals spend reading the labeling of prescription drugs, a 1994 FDA survey of physicians found that 42 percent referred to labeling at least once a day, 33 percent less often than once a day but more often than once a week, and 25 percent once a week or less. Even if physicians spend, on average, only 30 seconds referring to labeling (once the labeling is at hand), these findings imply that the cumulative amount of time spent referring to labeling by the nation's approximately 599,000 physicians active in patient care equals about 1.1 million hours per year (Ref. 14). If the new format reduced by 15 seconds the amount of time physicians needed to find information on prescription drug labeling, implementing that format for all prescription drug products would save approximately 525,000 hours per year.

Although the proposed rule initially applies to only a small percentage of all prescription drug labeling, its focus on

the most recently approved products includes the labeling that health professionals are most likely to consult frequently. In FDA's survey of physicians, newness of the product was the factor most often rated by physicians as "very likely" to trigger referral to prescription drug labeling. This analysis assumes that the rule will begin affecting labeling consultations in the second year of implementation and that it will affect 5 percent of all consultations in that year. The percentage of reformatted labeling consulted by physicians is assumed to increase to 10, 15, and 25 percent in years 3, 4, and 5 respectively. Thereafter, it is assumed to increase an additional 5 percent each year, until reaching 50 percent in year 10. Thus, in year 10, the time savings for physicians is projected to equal about 264,000 hours per year. FDA has not attempted to project impacts beyond 10 years, due to the uncertainty of the longer term technological changes that would affect these estimates. Table 4 shows the annual value of physician time saved and indicates that the present value over 10 years equals approximately \$62.8 million.¹² Savings in pharmacist time

¹² Hourly income for physicians was calculated using AMA data for the 1996 average net income of all non-Federal physicians (excluding residents) and average weekly workload (Jacob, J., 1998, "Income Data Spark Debate Among Delegates," *American Medical News*, July 13, 1998, http://www.ama-assn.org/sci-pubs/amnews/pick_98/anna0713.htm.) FDA's analysis assumes, on

could also be substantial, although they were not estimated.

TABLE 4.—ANNUAL BENEFITS OF REGULATION

Year	Physician time Saved (\$ million)		Adverse Drug Events Avoided (\$ million)		Total Benefits (\$ million)	
	Current value	Present value	Current value	Present value	Current value	Present value
1	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00
2	2.00	1.75	38.40	33.54	40.40	35.29
3	4.00	3.27	38.40	31.34	42.40	34.61
4	6.01	4.58	38.40	29.29	44.40	33.87
5	10.01	7.14	38.40	27.38	48.41	34.51
6	12.01	8.00	38.40	25.59	50.41	33.59
7	14.01	8.73	38.40	23.91	52.41	32.64
8	16.01	9.32	38.40	22.35	54.41	31.67
9	18.02	9.80	38.40	20.89	56.41	30.69
10	20.02	10.18	38.40	19.52	58.41	29.70
Total	\$102.09	\$62.76	\$345.60	\$233.81	\$447.66	\$296.57

2. Improved Effectiveness of Treatment

Under the proposed rule, the highlights section would emphasize the drug information that physicians report is the most important for decisionmaking. In addition, any patient information or Medication Guide approved by FDA would be printed at the end of the labeling regardless of when the product was approved. Moreover, certain information will be removed from existing professional labeling because the rule only allows inclusion of data that are pertinent to the clinical uses specified in the indications section. Consequently, this proposed rule would improve the ability of physicians to select the most safe and effective pharmaceutical treatments for their patients and to administer those treatments in the most safe and effective manner. In addition, the proposal may enhance the likelihood that physicians will communicate important information to patients, which could improve patient understanding and compliance with treatment. FDA is unable to quantify the magnitude of these expected improvements in treatment effectiveness and health outcomes, but the agency believes they could be significant.

3. Decrease in Avoidable Adverse Events

Because it will highlight important information about dosage, side effects, and contraindications, the proposed

new prescription drug labeling format would decrease the number of adverse drug events (ADE's) caused by incorrect product use. Many ADE's result from poor or incorrectly applied information (e.g., prescribing too high a dose for a patient with poor kidney function, or prescribing a drug to a patient with known contraindications) and are potentially preventable. Studies of hospitalized patients in the early 1990's suggest that the rate of preventable ADE's that occur during hospitalization is approximately 1.2 to 1.8 ADE's per 100 patients admitted (Refs. 15 and 16). Moreover, the latter study found that a majority of preventable ADE's (about 1 ADE per 100 hospital admissions) were related to errors or miscalculations in physician ordering, the stage most likely to be affected by improved prescription drug labeling information. Given the approximately 35 million hospitalizations annually in the United States,¹³ these data suggest that about 350,000 ADE's among hospitalized patients are potentially preventable with better labeling for health professionals. Studies show that the occurrence of an ADE in a hospitalized patient increased the costs of caring for the patient by an average of \$2,262 to \$2,595 (Refs. 15 and 17). Costs associated with preventable ADE's were even higher, averaging about \$4,685 per patient (Ref. 17). If other hospitals incur similar costs for preventable ADE's, the potentially preventable annual costs from this

source could total \$1.6 billion nationally.

In addition, many outpatients are hospitalized as a result of preventable adverse events associated with outpatient drugs. FDA previously estimated that the costs associated with these hospitalizations total \$4.4 billion per year¹⁴ (60 FR 44232, August 24, 1995). If half of these adverse events also are related to physician ordering errors, about \$2.2 billion per year additional hospital costs result from this source of error. Thus, combining both inpatient and outpatient adverse drug events, about \$3.8 billion per year in hospital costs may be potentially preventable through better prescription drug labeling.

The actual proportion of the ADE costs that would be prevented under the proposed rule cannot be predicted with certainty. If these costs were reduced by even 1 percent, however, the proposed rule would reduce hospitalization costs by \$38.4 million per year. Over 10 years, the present value of these benefits would total \$233.8 million (table 4). Furthermore, if additional averted costs (e.g., physician visits, additional outpatient costs, patient time, lost productivity) were included, the savings from the ADE's avoided would be substantially higher.

C. Costs of Regulation

The proposed rule mandates two broad types of changes to the labeling of

average, that physicians work 56 hours per week for 47 weeks per year and that physician employee benefits are 20 percent of annual income. Thus, the hourly income of about \$75 was calculated as follows: $(\$166,000 \times 1.2) / (47 \times 56)$. A 7 percent discount rate was used to derive the present value of the benefit stream.

¹³ 1997 hospital discharges, Healthcare Cost and Utilization Project (HCUP) Nationwide Inpatient Sample, 1997, Agency for Healthcare Research and Quality (AHRQ), April 2000. <http://www.ahrq.gov/data/hcupnet.htm>.

¹⁴ 60 FR 44232, August 24, 1995. An estimated 498,750 patients are hospitalized annually for a preventable adverse drug reaction to a prescription

drug product, costing \$4.4 billion in hospital charges. $(\$4.4 \text{ billion} = 498,750 \text{ patients} \times \$8,890 \text{ average hospital charges per patient}; 498,740 \text{ patients} = 35 \text{ million discharges} \times 3\% \text{ treated for adverse drug events} \times 95\% \text{ of adverse drug events from prescription drug products} \times 50\% \text{ of adverse drug events that are preventable.})$

prescription drug products. First, the professional labeling of recently approved and future products must follow format and content requirements proposed in the rule. Second, some labeling of products already approved for marketing must be revised to: (1) Delete information not pertinent to the approved indication, and (2) add previously approved printed patient information or a Medication Guide. Therefore, direct costs incurred to change professional labeling include the costs of: (1) Designing or revising prescription drug labeling and submitting the new labeling to FDA for approval, (2) the costs of producing

longer labeling, and (3) printing a longer PDR.

1. Labeling Changes for Recently Approved and Future Prescription Drug Products

a. *Affected products.* The proposed rule would require that prescription drug labeling conform to format and content requirements for two categories of products: (1) All NDA's, BLA's, and efficacy supplements submitted to FDA on or after the effective date of the final rule; and (2) all NDA's, BLA's, and efficacy supplements pending at the time of the effective date of the final rule or approved over the 5 years preceding the effective date of the final

rule. For the first category of products, the labeling requirements would apply when a sponsor files an NDA or BLA (new applications) or efficacy supplement. Products in the second category must file supplemental applications within 3 to 7 years after the effective date of the final rule according to the implementation plan provided in table 1. Labeling for nonprescription products (including nonprescription products approved under NDA's) is not covered by this rule.

Estimates of the number of new applications that would be affected by the rule over a 10-year period are shown in table 5 and are based on the number of application approvals since 1990.

TABLE 5.—NUMBER OF AFFECTED NEW DRUG AND BIOLOGICAL APPLICATIONS AND ESTIMATED LABELING DESIGN COSTS

Year	Number of affected applications by type				Cost for prescription drug labeling design (\$ mil)				
	New NDA's/BLA's	ES's*	Before—5**	Total	New NDA's/BLA's	ES's*	Before—5**	Total	Present value
1	85	59	0	144	\$0.43	\$0.30	\$0.00	\$0.72	\$0.67
2	134	73	0	207	0.67	0.37	0.00	1.04	0.90
3	121	57	74	252	0.61	0.29	0.56	1.45	1.18
4	113	38	74	225	0.57	0.19	0.56	1.31	1.00
5	113	20	73	206	0.57	0.10	0.55	1.21	0.86
6	113	14	73	200	0.57	0.07	0.55	1.18	0.79
7	113	10	72	195	0.57	0.05	0.54	1.16	0.72
8	113	8	0	121	0.57	0.04	0.00	0.61	0.35
9	113	6	0	119	0.57	0.03	0.00	0.60	0.32
10	113	5	0	118	0.57	0.03	0.00	0.59	0.30
Total	1,131	290	366	1,787	\$5.66	1.47	2.76	9.87	7.09

* Efficacy supplements

** Approvals 5 years before effective date.

For this analysis, January 1, 1995, was used as a proxy for the effective date of the proposed rule. The number of covered application approvals for the 3 consecutive years beginning in 1995 were 85, 134, and 121, an average of 113 each year. FDA assumes that this average rate will continue. During this same 3-year period, 59, 73, and 57 efficacy supplements were approved for applications that initially had been approved prior to 1995. FDA estimates, therefore, that if this rule had become effective on January 1, 1995, as many as 144 products (*i.e.*, 85 covered applications and 59 efficacy supplements) would have incurred design costs in the first year. Most efficacy supplements are filed and approved within 5 years of the approval date of their original application. Therefore, beginning in 1997, an increasing number of efficacy supplements would not have required changes to the labeling format because these changes would have been made in the original application. As the annual number of affected efficacy supplements

declined over time, the annual number of affected total applications would likewise diminish, as projected in table 5. Furthermore, between 1990 and 1994 (*i.e.*, the 5-year period before the proxy effective date), an additional 366 applications were approved. Thus, an average of 73 additional applications would have been received annually in years 3 through 7.

b. *Prescription drug labeling design costs.* The cost of designing prescription drug labeling that conforms to the proposed format and content requirements will depend heavily on when, during a product's life cycle, labeling design occurs. Costs will be highest for products already marketed with approved labeling that would otherwise not be changed. Conversely, design costs will be lowest for products that are closely related to a prior product application that has already had its labeling changed to the new format. Costs for currently marketed products undergoing relabeling for other reasons (*e.g.*, related to an efficacy supplement)

will be intermediate between these extremes.

FDA has estimated the cost of designing novel patient labeling (for the first prescription drug in a therapeutic class) at about \$12,000.¹⁵ The estimated costs of redesigning patient labeling for products that could use previously developed prototypes (*i.e.*, generic drugs or innovator drugs in the same therapeutic class for which patient labeling was already developed) ranged from \$500 to \$1,500 per product. Although the design of prescription drug labeling under the proposed rule will primarily follow a format specified by FDA, detailed discussion and drug-specific decisions (*e.g.*, regarding exactly which adverse reactions should be listed in the highlights section) will be necessary. Consequently, this analysis estimates \$7,500 as the average cost to a firm that needs to redesign the labeling of an existing innovator drug, to

¹⁵ 60 FR 44232. \$11,667 for 2 months full-time effort of professional/technical employees with annual compensation, including 40 percent benefits of \$70,000 (\$11,667 = \$50,000 × 1.4 × 2/12).

test the redesigned labeling (e.g., to ensure that the larger labeling will still fit in carton-enclosed products), and to prepare and submit that labeling to FDA for approval. Additional costs for the latter task, however, would be incurred only for those drugs approved in the 5 years before the effective date of the rule. Although sponsors of new applications and efficacy supplements would incur many of the same design costs, they would experience no additional testing and application costs. Thus, the design of labels for new applications and efficacy supplements is estimated to cost \$5,000 on average.

In the first year after the final rule becomes effective, an estimated 144 affected products would incur an additional cost per drug of \$5,000 to comply with the proposed rule. As shown in table 5, the total first-year costs would amount to \$720,000, increasing in the second year to \$1.04 million. Costs increase in year 3 to a high of \$1.45 million as sponsors of recently approved products begin submitting FDA supplemental applications, at \$7,500 per application, to comply with the new labeling format and content. After the seventh year, when all products approved within 5 years before the rule's effective date or pending approval at that time have redesigned labeling, the costs decline to about \$0.6 million per year. As a result, the estimated present value of the costs of redesigning prescription drug labeling over 10 years is about \$7.1 million.

c. *Costs associated with producing labeling.* Under the proposed rule, labeling for each affected product would be expanded to include a highlights

section, an index, and additional formatting and font size requirements (if the labeling does not already meet these requirements). Consequently, all affected labeling will be longer than at present, with current shorter labeling affected proportionately more than current longer labeling (due to the fact that the highlights section will add nearly the same amount of absolute length to every affected product with prescription drug labeling). Longer labeling increases the cost of paper, ink, and other ongoing incremental printing costs. These costs apply both to the labeling that physically accompanies the product and to the labeling that accompanies promotional materials. Also, some products packaged in cartons containing package inserts will require a product-by-product review to assess whether the carton can still accommodate the longer labeling. It is possible that a few products would require equipment changes (e.g., different insert-folding machinery).

i. *Incremental printing costs.* Based on quotes from industry consultants, FDA estimates that the cost of printing larger prescription drug labeling is approximately \$0.0086 for each additional 100 square inches. The agency estimates that the proposed rule would increase the average size of labeling by about 93 square inches¹⁶ adding \$.008 to the per label printing cost, or \$7,960 per million package inserts printed. The new highlights and index sections account for about 37 percent of the additional printing cost, whereas the larger font size imposes the remaining 63 percent of the incremental printing cost.

U.S. retail pharmacies dispense about 2.3 billion prescriptions per year, of which an estimated 560 million are for unit-of-use products, which often include labeling within the package.¹⁷ If the remaining 1.7 billion pharmacy-prepared prescriptions average one insert per 3.33 prescriptions (assumes an average of 100 units per container and 30 units dispensed per prescription), the total number of inserts accompanying retail products equals roughly 1.1 billion. Adding hospital pharmaceutical volume, estimated at approximately 38 percent of retail volume, yields an annual total of 1.5 billion package inserts accompanying prescribed products. Allowing 10 percent for wastage indicates that pharmaceutical companies distribute roughly 1.65 billion package inserts with prescribed products each year. Over time, an increasing number of these inserts would have to be revised. Because the rule initially affects only innovator products and about 60 percent of all prescriptions are for branded products, FDA calculated that about 1 billion of these inserts are currently provided with about 2,287 branded products.¹⁸ Thus, on average, about 435,000 inserts (1 billion ÷ 2,287) may be shipped annually for each affected product. Table 6 shows the estimated number of revised inserts that would accompany the prescribed products. Multiplying these numbers by the estimated incremental printing cost of \$.008 per label indicates that the annual costs for package inserts would rise to about \$6.2 million by the 10th year.

TABLE 6.—INCREMENTAL PRINTING COSTS FOR REFORMATTED PROFESSIONAL LABELING YEAR

Year	Number of approvals	Number printed per year (million)		Incremental printing costs (\$ million)			
		Package inserts	Promotional labeling	Package inserts	Promotional labeling	Total	Present value
1	144	62.6	250.5	\$0.50	\$1.99	\$2.49	\$2.33
2	207	152.7	416.1	1.22	3.31	4.53	3.95
3	252	262.3	616.0	2.09	4.90	6.99	5.71
4	225	360.2	677.8	2.87	5.40	8.26	6.30
5	206	449.8	675.9	3.58	5.38	8.96	6.39
6	200	536.8	634.9	4.27	5.05	9.33	6.21

¹⁶ The length of professional labeling from a random sample of approximately 5 percent of the listings printed in the PDR averaged 2.67 pages with a font size of 6.5 point. Twenty-four percent of the sample had at least one boxed warning with an average length of about 5.6 square inches in 6.5-point font or 6.25 square inches in 8-point font. Increasing the font size from 6.5 point to 8 point (i.e., the minimum font size specified in the proposed rule) would increase the average length by an estimated 59 percent, or approximately 1.6 pages. Moreover, the agency estimates that the new

highlights section, including any boxed warnings, and indexing system may add up to 90 percent of a page to professional labeling. Therefore, the proposed rule would increase the length of the average professional labeling by about 2.5 pages. Because package inserts are printed on both sides, the average package insert would increase in size by 92.6 square inches.

¹⁷ Unpublished FDA analysis based on survey results from nine pharmacists and applied to IMS data.

¹⁸ Derived from the 1998 *Approved Drug Products With Therapeutic Equivalence Evaluations* (Orange Book), CDER, FDA. The estimate is a count of all branded products marketed under an NDA and differentiated by active ingredient, dosage form, or manufacturer, not including multiple dosage strengths. Although biologics were not counted, adding biologics would not significantly alter results.

TABLE 6.—INCREMENTAL PRINTING COSTS FOR REFORMATTED PROFESSIONAL LABELING YEAR—Continued

Year	Number of approvals	Number printed per year (million)		Incremental printing costs (\$ million)			
		Package inserts	Pro-motional labeling	Package inserts	Pro-motional labeling	Total	Present value
7	195	621.6	611.1	4.95	4.86	9.81	6.11
8	121	674.3	540.3	5.37	4.30	9.67	5.63
9	119	726.0	476.8	5.78	3.80	9.57	5.21
10	118	777.3	416.4	6.19	3.31	9.50	4.83
Total	1,787	4,623.6	5,315.8	\$36.82	\$42.30	\$79.11	\$52.67

To calculate the amount of labeling printed for promotional purposes, FDA assumed that the 23.7 million office and hospital calls per year made by pharmaceutical representatives¹⁹ involved an average of 2 printed pieces of labeling per visit, or a total of 47.4 million per year. In addition, sales representatives made 8.2 million sample calls, distributing an estimated 82 million package inserts per year, or an average of 10 samples per call. Since most promotional visits involve relatively new products—the products most affected by this rule—FDA assumed that all of this labeling would incur additional printing costs, amounting to about \$1.0 million annually.

Finally, FDA estimated that about 800,000 pieces of labeling per approval would be distributed each year by mail or at conferences to physicians, other health care professionals, consumers, retail pharmacy outlets and hospital pharmacies for 3 years following approval of a new drug.²⁰ As shown in table 6, annual total promotional labeling costs peak at \$5.4 million in year 4. Over 10 years, the present value of the incremental printing costs for all types of longer prescription drug labeling would be about \$52.7 million.

Some companies may incur additional costs associated with maintaining the labeling posted on their

web sites. The agency did not estimate these related costs but believes they would be minimal and a routine cost of doing business. Nonetheless, the agency requests comment.

ii. *Equipment costs.* Agency consultants with expertise in pharmaceutical labeling operations estimate that only a small number of carton-enclosed products may require new packaging to accommodate the longer insert. This analysis assumes that 1 percent of both the products with new efficacy supplement changes and the products approved in the 5 years before the effective date of the rule would incur costs of \$200,000 each for needed packaging changes. Products approved subsequent to the effective date of the final rule would not incur added equipment costs because their labeling and packaging are not yet established. The estimated present value of equipment changes totals \$1.0 million over 10 years.

d. *PDR costs.* FDA estimates that the new highlights section, including any boxed warnings, and index would add about one-half pages to each affected labeling printed in the PDR.²¹

Conversations with Medical Economics (the publisher of the PDR) on the cost per printed page imply that the annual publishing costs of the extra space required for printing the expanded labeling would be about

\$4,300 for each affected product, plus an additional cost if the product was included in one of two annual supplements. FDA assumed that these costs would be incurred by the pharmaceutical industry via publishing fees paid to Medical Economics. The agency assumed that 75 percent of the new drugs and efficacy supplements would be published in the PDR (some smaller firms decline to publish labeling in the PDR). It was further assumed that 90 percent of the new drugs published would be included in the PDR supplements and 33 percent of the published efficacy supplements would be included in the PDR supplements (about half are actually included, but only two-thirds of these include full prescription drug labeling—the remainder include only the added indication). FDA also assumed that the labeling changes made as a result of the 5-year rule (applications approved in the 5 years preceding the effective date of the final rule) would not be included in the PDR supplements. Based on these assumptions, the estimated cost of publishing the extended labeling in the PDR would be about \$0.75 million for year 1. These costs would continue to increase over time as all drug approvals after the effective date of the rule would have longer PDR listings. The estimated annual and total cost of printing longer PDR listings are shown in table 7.

¹⁹ Data from IMS, 1997, as presented at FDA on June 3, 1998. Data include an estimated 17.8 million office calls, 8.2 million sample calls, and 5.9 million hospital calls made in 1997.

²⁰ For each approval, it was assumed that all physicians involved in primary care and 25 percent of physicians practicing a medical specialty would receive 2 mailings per year, or an estimated 711,535 pieces (*i.e.*, = (274,726 × 2) + (0.25 × 324,198 × 2)), for 3 years following product launch. An additional 10 percent or 71,153 pieces are estimated to be distributed annually for 3 years to other health professionals or consumers. Furthermore, FDA

assumes that 50,829 retail pharmacy outlets and 7,120 hospital pharmacies would receive one mailing to announce the launch of a new product in the year of approval.

²¹ The new highlights section could add up to one-half page when printed in 8-point size. Because the PDR is printed in a 6.5-point New Century Schoolbook Roman font, the highlights section would require less than one-half page in the PDR. The agency estimates 37 percent less space is required to print information in the smaller PDR font, reducing the size required for the new highlights section to 0.3 pages (*i.e.*, 0.5 × (1—

0.37) = 0.315 pages). A sample of labeling printed in the PDR found that about 24 percent of the products may be required to print a boxed warning averaging 5.6 square inches. Therefore, the agency estimates an additional 0.02 pages for these warnings (*i.e.*, 23.9 percent × 5.6 square inches / 75 square inches per page = 0.02 pages). Furthermore, the new indexing system is estimated to add approximately 60 column lines to a PDR listing, equaling approximately 0.2 pages (*i.e.*, (60 lines / 96 lines per column) / 3 columns per page = .21 pages). In total, up to .54 pages may be added to the professional labeling printed in the PDR.

TABLE 7.—COST FOR LONGER LISTINGS IN THE PDR

Year	PDR printing costs (\$ million)			
	PDR bound	Supplement	Total	Present value
1	\$0.47	\$0.31	\$0.78	\$0.73
2	1.13	0.47	1.60	1.40
3	1.95	0.41	2.36	1.93
4	2.68	0.37	3.05	2.32
5	3.34	0.35	3.69	2.63
6	3.99	0.34	4.33	2.89
7	4.62	0.34	4.96	3.09
8	5.01	0.34	5.35	3.11
9	5.39	0.34	5.73	3.12
10	5.78	0.33	6.11	3.11
Total	\$34.36	\$3.60	\$37.96	\$24.33

2. Labeling Changes for All Approved Prescription Drug Products

The agency is also proposing several new restrictions for the labeling of all prescription drug products. These changes can be made, without prior FDA approval, upon submission of a "changes being effected" supplement. Labeling for all prescription drug products must comply with the proposed content requirements within 1 year after the effective date of the final rule.

a. *Affected products.* The proposed rule will no longer allow certain information that is sometimes now included in professional labeling (*e.g.*, discussion of studies not supporting approved indications, suggestion of uses or indications not included in the "Indications and Uses" section, or discussion of in vitro and animal studies on drug action or efficacy that have not been shown to be pertinent to clinical use by adequate and well-controlled studies). FDA does not know how much product labeling would be affected, but because labeling of most antibiotics currently contains data from in vitro studies, the agency estimates that the proposed rule could affect 90 percent of all antibiotics. Of the approximately 5,300 marketed products in the United States, there are an estimated 789 antibiotics products.²² Moreover, up to 25 percent of all other marketed products could have labeling

containing information that would be prohibited. In the first year, therefore, as many as 1,838 products might have to delete some material from their professional labeling.

In addition, any existing prescription drug product with approved printed patient information or Medication Guide must reprint this information following the last section of the professional labeling. The agency estimates that about 50 approved products, or approximately 1 percent of the existing products, could be affected by this requirement.

b. *Professional labeling design costs.* Industry consultants estimate that, on average, prescription drug manufacturers would incur about \$2,000 per product in design and implementation costs for a major revision in the content of professional labeling. Industry consultants with expertise in pharmaceutical labeling estimate that professional labeling inventories represent approximately 3 months worth of production. If given an adequate lead time, companies should be able to minimize inventory losses. This proposed rule would require changes within 1 year of the effective date. Assuming that not all affected firms would have sufficient time to deplete their inventories, consultants estimate the per product professional labeling inventory losses are \$570 for a 12 month lead time. Thus, including

excess inventory losses, the cost to change professional labeling is estimated at \$2,600 per product. In the first year, therefore, firms may incur one-time costs of \$4.7 million and \$0.1 million, respectively, to remove prohibited material from labeling and to add printed patient information to labeling for all affected products (table 8).

c. *Incremental printing costs for professional labeling.* FDA estimates that an average of 310,000 package inserts may be printed annually for each prescription drug product marketed in the United States.²³ The removal of prohibited information from professional labeling may reduce the size of current package inserts by about 3 percent or 3 square inches. With such a small change in the length of professional labeling, it is unlikely that the package insert would actually change size. Therefore, the agency assumed no cost savings for shorter professional labeling.

In contrast, printed patient information would add an estimated 2 pages or about 75 square inches to the length of professional labeling. For each of the affected products, manufacturers would incur additional incremental printing costs of about \$2,000 for longer labeling.²⁴ For all 50 affected products, annual incremental printing costs would increase by \$0.1 million (table 8).

²² Derived from the 1998 *Approved Drug Products With Therapeutic Equivalence Evaluation* (Orange Book), CDER, FDA. Products with NDA numbers in the 50,000 or 60,000 series (*i.e.*, antibiotics), with a distinct dosage form or manufacturer were

counted. This number, however, probably overestimates the number of antibiotic products with distinct labeling.

²³ 310,000 inserts per product = 1.65 billion inserts printed annually/5,300 products.

²⁴ \$2,000 per product = 75 square inches/insert × 0.000086 square inches × 310,000 inserts per product.

TABLE 8.—COSTS TO REVISE PROFESSIONAL LABELING OF EXISTING PRESCRIPTION PRODUCT

Changes to Labeling	Number of affected products	One-Time labeling revision costs (\$ million)	Annual incremental printing costs (\$ million)	Annual PDR costs (\$ million)
Removal of prohibited material	1,838	\$4.70	\$0.00	\$0.00
Addition of approved printed patient information or Medication Guide	50	0.13	0.10	0.60
Total	1,888	4.83	0.10	0.60

d. *PDR costs.* The agency assumes that 75 percent of prescription drug products have labeling already printed in the PDR. In accord with the rationale described above, the annual printing costs for the PDR are estimated to be unchanged for products that remove information and to increase for products that add patient information. The per product annual cost to print two

additional pages in the PDR is about \$16,000.²⁵ For all affected products, the annual PDR costs would increase by \$0.6 million (table 8).

3. Changes to Drug Product Labels

The proposed rule also specifies minor changes to prescription drug product labels to remove excess information from the label to help

reduce medication errors. To reduce the burden on industry, changes to labels are not required until the first time labeling is revised after the effective date of the final rule. Therefore, no additional compliance costs are estimated for these changes.

Table 9 displays the estimated compliance costs for the three major cost categories over a 10-year period.

TABLE 9.—COMPLIANCE COST OVER 10-YEAR PERIOD

Year	Cost Category (\$ million)			
	Labeling design and FDA approval	Producing professional labeling (including equipment costs)	Printing PDR	Total costs (\$ million)
1	\$5.55	\$2.71	\$1.38	\$9.64
2	1.04	4.77	2.20	8.01
3	1.45	7.35	2.96	11.76
4	1.31	8.59	3.65	13.54
5	1.21	9.25	4.29	14.75
6	1.18	9.60	4.93	15.72
7	1.16	10.08	5.56	16.79
8	0.61	9.78	5.95	16.34
9	0.60	9.69	6.33	16.61
10	0.59	9.61	6.71	16.91
Total current value	14.68	81.43	43.96	140.07
Total present value	11.62	54.37	28.54	94.52

D. Impacts on Small Entities

1. The Need for and the Objectives of the Rule

As discussed in detail in section II of this document, various developments in recent years have contributed to an increase in the length and complexity of prescription drug product labeling, and made it more difficult for health care practitioners to find specific information and discern the most critical information in labeling. The objective of the proposed requirements is to enhance the safe and effective use of prescription drug products by making it easier for health care practitioners to access, read, and use information in prescription drug product labeling.

As previously stated, FDA's legal authority to amend its regulations governing the content and format of labeling for human prescription drug and biologic products and to amend its regulations governing the requirements for prescription drug product labels derives from sections 201, 301, 501, 502, 503, 505, and 701 of the act (21 U.S.C. 321, 331, 351, 352, 353, 355, and 371) and section 351 of the PHS Act (42 U.S.C. 262).

2. Description and Estimate of the Number of Small Entities Affected

This proposed rule would affect all small entities required to design their prescription drug labeling to comply with this rule. The Small Business Administration (SBA) considers firms in

Standardized Industrial Classification Code 2834, Pharmaceutical Preparations, with fewer than 750 employees to be small entities. Although U.S. Census size categories do not correspond to SBA size categories, of the approximately 600 firms identified, over 90 percent have fewer than 500 employees.²⁶ Thus, most of the firms in the pharmaceutical industry are considered small entities for Regulatory Flexibility Act purposes. In contrast, an agency review of NDA's received in FY 97, 98, and 99 found that about 19 small entities submit NDA's each year. In addition, an equal number of small firms that submit BLA's, ES's and/or reformatted professional labeling for approval would also be affected, for a total of about 38.

²⁵ \$16,000 per product = \$8,000/page × 2 pages.

²⁶ U.S. Department of Commerce, Bureau of the Census, *1992 Census of Manufacturers, Industry Series, Drugs, MC92-1-28C*.

Census of Manufactures data on revenues per firm apply to all establishments classified in 2834, Pharmaceutical Preparations. As noted above, only a subset of this industry is affected by this rule. The agency does not know the average revenues for the affected sectors.

3. Description of the Compliance Requirements

The compliance requirements for small entities under this proposed rule are the same as those described above for other affected entities. Compliance primarily involves: (1) Designing labeling that conforms to the format requirements as illustrated in the FDA-designed prototype; and (2) once the labeling is approved by FDA, ensuring that all future printed labeling

(including labeling used for promotional purposes) is in the new format. Because sponsors already submit labeling with NDA's and supplements to FDA, no additional skills will be required to comply with the proposed rule.

The group of small entities likely to bear the highest total costs under this proposed rule are those firms that have: (1) Existing products with labeling that must be revised in the first year; or (2) more than one affected high-volume product per year, such as a small firm with two or three recently approved, high-volume products that must undergo labeling reformatting simultaneously in the same year. However, the high-cost small entities are also the small firms with the highest sales of affected product; thus, their

incremental cost per unit sold is likely to be relatively low. In contrast, small firms with a single, low-volume product would have lower total costs of compliance, but the incremental cost per unit sold would be higher.

To illustrate the impact on small entities with different production volumes, the following examples estimate the professional labeling costs for a small firm with a single carton-enclosed product (marketed under an NDA) that must: (1) Have its labeling reformatted in year 3 of the rule, and (2) add patient information in year 1. Table 10 outlines the projected per-unit and total costs to the firm under three different levels of production: 1,000, 10,000, and 100,000 units produced per year.

TABLE 10.—ESTIMATED COSTS FOR HYPOTHETICAL SMALL FIRM WITH A SINGLE PRODUCT, UNDER THREE ALTERNATIVE LEVELS OF PRODUCTION

Cost category	Number of units produced and sold each year		
	100,000	10,000	1,000
Example 1—Change labeling approved less than 1 year before effective date:			
Professional labeling redesign/application	\$7,500	\$7,500	\$7,500
Printing package inserts ¹	87	88	9
Printing professional labeling used for promotional purposes ²	1,611	161	16
Total	9,987	7,749	7,525
Additional cost per unit sold	0.10	0.77	7.53
Example 2—Add patient information to labeling of an existing product:			
Professional labeling redesign	2,600	2,600	2,600
Printing package inserts ³	710	71	7
Printing longer PDR ⁴	16,000	16,000	16,000
Total	19,310	18,671	18,607
Additional cost per unit sold	0.87	1.87	18.61

¹ Number of package inserts printed is calculated as units produced/year plus 10 percent wastage factor, at an incremental printing cost of \$.00796 per label.

² Incremental costs associated with printing labeling used for promotional purposes are assumed to be 184% of the costs of printing package inserts, based on the ratio of the average number of pieces printed for mailings to the average number printed as package inserts.

³ Number of package inserts printed is calculated as units produced/year plus 10 percent wastage factor, at an incremental printing cost of \$.00645 per package insert.

⁴ Assume that professional labeling is already being printed in the PDR.

In addition to the costs identified in table 10, a very small number of small firms might incur equipment costs to include longer prescription drug labeling in carton-enclosed products. It is likely, however, that this one-time capital cost (estimated at \$200,000) will affect a total of no more than two or three small firms in the 10 years following implementation of the rule. Based on this analysis, FDA finds that the impact of this proposed rule would not be significant for most small entities in this industry, but it is possible that more than a few small firms may incur significant costs. The agency solicits public comment on the potential impact of the proposed rule on small entities.

4. Alternatives Considered

a. *Formatting alternatives.* FDA has considered numerous alternative formats, including a longer highlights section. The highlights section was limited to about one-half page to respond to health professionals' concerns about length as well as to reduce the incremental printing costs to sponsors.

The agency also considered increasing the minimum required font size from 8 point to 10 point. The larger font size would increase labeling by approximately 196 square inches, whereas labeling printed in 8-point font size is estimated to increase by only 93 square inches. Furthermore, the

incremental costs for labeling printed in 10 point font size would be approximately \$16,850 per million inserts, more than double the incremental costs of labeling printed in 8-point font size. Over 10 years, the total present value of producing longer labeling would increase by \$111.5 million with the larger font size, compared to \$52.7 million for the 8-point font size. Although the agency has tentatively rejected the minimum 10-point font size requirement because of the additional burden on industry, FDA solicits comment on minimum font size requirements.

b. *Alternative categories of affected products.* Three alternative categories of products to be covered by the

rulemaking were considered: (1) All drugs, (2) a proposed set of innovator and generic drugs on a "top 200 most prescribed" list, and (3) the "top 100" or "top 200" drugs with the most adverse drug reactions. The agency has tentatively rejected these three alternatives because it was uncertain whether the benefits would exceed the costs, especially in the case of older drugs and generic drugs for which physicians infrequently consult labeling. In addition, the "top 200" lists were excluded because the agency believed that the most important subset of these products would be covered by the currently proposed rule. However, FDA solicits comment on these alternative criteria for selecting drugs to be affected by the rulemaking.

c. *Alternative implementation schedule.* FDA considered a shorter implementation schedule, requiring that the labeling for all applications and efficacy supplements approved 5 years prior to the implementation date be revised 3 years after the effective date. The more gradual implementation schedule has been proposed primarily to reduce the impact of the rule on small entities as well as the immediate impact of the rulemaking on the industry as a whole.

XI. Request for Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this proposal by March 22, 2001. 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.

XII. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Littlejohn, J.K., "Package Insert: View of a Rural Town Practitioner," *Drug Information Journal*, vol. 21, pp. 63–65, 1987.
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3. Wogalter, M.S., "Factors Influencing the Effectiveness of Warnings," in *Visual Information for Everyday Use: Design and Research Perspectives*, edited by H.J.G. Zwaga, T. Boersema, and H.C.M. Hoonhout, Taylor & Francis, 1999.
4. Council for International Organization of Medical Sciences, "Guidelines for Preparing

Core Clinical-Safety Information on Drugs: Report of CIOMS Working Group III," 1995.

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8. Steering Committee for the Collaborative Development of a Long-Range Action Plan for the Provision of Useful Prescription Medicine Information, "Action Plan for the Provision of Useful Prescription Medicine Information," Washington, DC, 1996.
9. Kripalani, S., "The Write Stuff: Simple Guidelines Can Help You Write and Design Effective Patient Education Materials," *Texas Medicine*, vol. 91, pp. 40–45, 1995.
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11. Mettger, W., and J. Mara, "Clear & Simple: Developing Effective Print Materials for Low-Literate Readers," Bethesda, MD, National Cancer Institute, Publication No. NIH 95–3594, 1994.
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14. Randolph, L., Physician Characteristics and Distribution in the United States, 1997/1998 ed., Chicago, IL, American Medical Association, 1998.
15. Classen, D.C. *et al.*, "Adverse Drug Events in Hospitalized Patients: Excess Length of Stay, Extra Costs, and Attributable Mortality," *Journal of the American Medical Association*, vol. 277, pp. 301–306, 1997.
16. Bates, D.W. *et al.*, "Incidence of Adverse Drug Events and Potential Adverse Drug Events," *Journal of the American Medical Association*, vol. 274, pp. 29–34, 1995.
17. Bates, D.W. *et al.*, "The Costs of Adverse Drug Events in Hospitalized Patients," *Journal of the American Medical Association*, vol. 277, pp. 307–311, 1997.

List of Subjects in 21 CFR Part 201

Drugs, Labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 201 be amended as follows:

PART 201—LABELING

1. The authority citation for 21 CFR part 201 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 358, 360, 360b, 360gg–360ss, 371, 374, 379e; 42 U.S.C. 216, 241, 262, 264.

§ 201.55 [Amended]

2. Section 201.55 *Statement of dosage* is amended by revising the third sentence to read as follows: "When this occurs, a statement of the recommended or usual dosage is not required on the label or carton."

3. Section 201.56 is revised to read as follows:

§ 201.56 Requirements on content and format of labeling for human prescription drugs and biologics.

(a) *General requirements.* Prescription drug labeling described in § 201.100(d) must meet the following general requirements:

(1) The labeling must contain a summary of the essential scientific information needed for the safe and effective use of the drug.

(2) The labeling must be informative and accurate and neither promotional in tone nor false or misleading in any particular.

(3) The labeling must be based whenever possible on data derived from human experience. No implied claims or suggestions of drug use may be made if there is inadequate evidence of safety or a lack of substantial evidence of effectiveness. Conclusions based on animal data but necessary for safe and effective use of the drug in humans shall be identified as such and included with human data in the appropriate section of the labeling.

(b) *Categories of prescription drugs subject to the labeling content and format requirements in §§ 201.56(d) and 201.57.* (1) The following categories of prescription drug products are subject to the labeling requirements in paragraph (d) of this section and § 201.57 in accordance with the implementation schedule in paragraph (c) of this section:

(i) Prescription drug products for which a new drug application (NDA), biological license application (BLA), or efficacy supplement has been approved by the Food and Drug Administration (FDA) anytime from 0 up to and including 5 years before [effective date of final rule];

(ii) Prescription drug products for which an NDA, BLA, or efficacy supplement is pending on [effective date of final rule]; or

(iii) Prescription drug products for which an NDA, BLA, or efficacy supplement is submitted anytime on or after [insert effective date of final rule].

(2) Prescription drug products not described in paragraph (b)(1) of this section are subject to the labeling requirements in paragraph (e) of this section and § 201.80.

(c) *Schedule for implementing the labeling content and format*

requirements in §§ 201.56(d) and 201.57. For products described in paragraph (b)(1) of this section, labeling conforming to the requirements in paragraph (d) of this section and § 201.57 must be submitted according to the following schedule:

(1) For products for which an NDA, BLA, or efficacy supplement is submitted for approval on or after [effective date of the final rule], proposed conforming labeling must be submitted as part of the application.

(2) For products for which an NDA, BLA, or efficacy supplement is pending at [effective date of final rule], or that has been approved any time from [effective date of final rule] up to and including 1 year before [effective date of final rule], a supplement with proposed conforming labeling must be submitted no later than 3 years after [effective date of the final rule].

(3) For products for which an NDA, BLA, or efficacy supplement has been approved from 1 year up to and including 2 years before [effective date of final rule], a supplement with proposed conforming labeling must be submitted no later than 4 years after [effective date of the final rule].

(4) For products for which an NDA, BLA, or efficacy supplement has been approved from 2 years up to and including 3 years before [effective date of final rule], a supplement with proposed conforming labeling must be submitted no later than 5 years after [effective date of the final rule].

(5) For products for which an NDA, BLA, or efficacy supplement has been approved from 3 years up to and including 4 years before [effective date of final rule], a supplement with proposed conforming labeling must be submitted no later than 6 years after [effective date of the final rule].

(6) For products for which an NDA, BLA, or efficacy supplement has been approved from 4 years up to and including 5 years before [effective date of the final rule], a supplement with proposed conforming labeling must be submitted no later than 7 years after [effective date of the final rule].

(d) *Labeling requirements for newly and more recently approved prescription drug products.* This paragraph applies only to prescription drug products described in paragraph (b)(1) of this section and must be implemented according to the schedule specified in paragraph (c) of this section.

(1) Prescription drug labeling described in § 201.100(d) must contain the specific information required under § 201.57(a), (b), and (c) under the

following section headings and subheadings and in the following order:

- Highlights of Prescribing Information
 - Product Names, Other Required and Optional Information
 - Boxed Warning
 - Recent Labeling Changes
 - Indications and Usage
 - Dosage and Administration
 - How Supplied
 - Contraindications
 - Warnings/Precautions
 - Drug Interactions
 - Use in Specific Populations
- Comprehensive Prescribing Information:
 - Index
- Comprehensive Prescribing Information
 - Boxed Warning
 - 1 Indications and Usage
 - 2 Dosage and Administration
 - 3 How Supplied/Storage and Handling
 - 4 Contraindications
 - 5 Warnings/Precautions
 - 6 Drug Interactions
 - 7 Use in Specific Populations
 - 7.1 Pregnancy
 - 7.2 Labor and delivery
 - 7.3 Lactating women
 - 7.4 Pediatric use
 - 7.5 Geriatric use
 - 8 Adverse Reactions
 - 9 Drug Abuse and Dependence
 - 10 Overdosage
 - 11 Description
 - 12 Clinical Pharmacology
 - 12.1 Mechanism of action
 - 12.2 Pharmacodynamics
 - 12.3 Pharmacokinetics
 - 12.4 Other clinical pharmacology information
 - 13 Nonclinical Toxicology
 - 13.1 Carcinogenesis, mutagenesis, impairment of fertility
 - 13.2 Animal toxicology and/or pharmacology
 - 14 Clinical Studies
- P Patient Counseling Information
 - (2) The labeling may contain an additional section entitled "References" if appropriate and if in compliance with § 201.57(c)(16).
 - (3) Sections or subsections of the labeling required under § 201.57(a), (b), or (c) may be omitted if clearly inapplicable.
 - (4) The labeling required under § 201.57(c) may contain a "Product Title" section preceding any boxed warning as required in § 201.57(c)(1) or, in the absence of such warning, preceding the "Indications and Usage" section, and containing only the information required by §§ 201.57(c)(12)(i)(A) through (c)(12)(i)(D) and 201.100(e). The information required by § 201.57(c)(12)(i)(A) through (c)(12)(i)(D) must appear in the "Description" section of the labeling, whether or not

it also appears in a "Product Title" section.

(5) The labeling required under § 201.57(c) may include additional nonstandardized subheadings under the standardized subheadings listed in paragraphs (d)(1) and (d)(2) of this section to emphasize specific topics within the text of the required sections where the use of additional subheadings will enhance labeling organization, presentation, or ease of use (e.g., subheadings may be used to set off individual warnings or precautions, or for each drug interaction). If additional subheadings are used, they must be assigned a decimal index number that corresponds to their placement in labeling and is consistent with the standardized index numbers and identifiers listed in paragraphs (d)(1) and (d)(2) of this section (e.g., subheadings added to the "Warnings/Precautions" subsection could be numbered 5.1, 5.2, and so on; subheadings in the "Patient Counseling Information" subsection could be numbered P.1, P.2, and so on).

(e) *Labeling requirements for older prescription drug products.* This paragraph applies only to approved prescription drug products not described in paragraph (b)(1) of this section.

(1) Prescription drug labeling described in § 201.100(d) must contain the specific information required under § 201.80 under the following section headings and in the following order:

- Description
- Clinical Pharmacology
- Indications and Usage
- Contraindications
- Warnings
- Precautions
- Adverse Reactions
- Drug Abuse and Dependence
- Overdosage
- Dosage and Administration
- How Supplied

(2) The labeling may contain the following additional section headings if appropriate and if in compliance with § 201.80(l) and (m):

- Animal Pharmacology and/or Animal Toxicology
- Clinical Studies
- References

(3) The labeling may omit any section or subsection of the labeling format if clearly inapplicable.

(4) The labeling may contain a "Product Title" section preceding the "Description" section and containing only the information required by § 201.80(a)(1)(i), (a)(1)(ii), (a)(1)(iii), and (a)(1)(iv) and § 201.100(e). The information required by § 201.80(a)(1)(i) through (a)(1)(iv) shall appear in the

"Description" section of the labeling, whether or not it also appears in a "Product Title."

(5) The labeling must contain the date of the most recent revision of the labeling, identified as such, placed prominently after the last section of the labeling.

4. Section 201.57 is redesignated as § 201.80 and new § 201.57 is added to read as follows:

§ 201.57 Specific requirements on content and format of labeling for human prescription drugs and biologic products described in § 201.56(b)(1).

The requirements in this section apply only to prescription drug products described in § 201.56(b)(1) and must be implemented according to the schedule specified in § 201.56(c), except for the requirements in paragraphs (c)(2)(ii), (c)(2)(iii), (c)(3), (c)(13)(ii), (c)(15)(i), and (c)(17) of this section, which must be implemented no later than 1 year after [effective date of the final rule].

(a) *Highlights of prescribing information.* This section must appear in all prescription drug labeling. Statements made in promotional labeling and advertisements must be consistent with all information included in labeling under paragraph (c) of this section in order to comply with § 202.1(e) and § 201.100(d)(1) of this chapter. The section must include the following information under the identified subheading, if any, in the following order:

(1) *Drug names, dosage form, route of administration and controlled substance symbol.* The proprietary name and the established name of the drug, if any, as defined in section 502(e)(3) of the Federal Food, Drug, and Cosmetic Act (the act) or, for biological products, the proper name (as defined in § 600.3 of this chapter) including any appropriate descriptors. This information must be followed by the drug's dosage form and route of administration. For controlled substances, the controlled substance symbol designating the schedule in which the controlled substance is listed.

(2) *Inverted black triangle symbol.* The "▼" symbol if the drug product has been approved for less than 3 years in the United States and contains a new molecular entity or new biological product, a new combination of active ingredients, is indicated for a new population, is administered by a new route, or uses a novel drug delivery system. This symbol must be placed on the same line as the proprietary name of the product, or the established or proper name if there is no proprietary name.

(3) *Prescription drug symbol.* The R symbol to indicate that the drug is a prescription drug. This symbol must be placed on the same line as the proprietary name of the product, or the established or proper name if there is no proprietary name, immediately following any "▼" symbol.

(4) *Boxed warnings or contraindications.* The full text of any boxed warning or contraindication required by paragraph (c)(1) of this section, provided that the text does not exceed a length of 20 lines. Where the text exceeds 20 lines, a statement summarizing the contents of the boxed warning(s) or contraindication(s) must be included, also not to exceed a length of 20 lines. The boxed warning or summary statement of the boxed warning must be preceded by a heading, in upper-case letters, containing the word "WARNING(S)" and other words that are appropriate to identify the subject of the warning. Both the text of the boxed warning or summary statement of the boxed warning and heading must be contained within a box and bolded. For summary statements of a boxed warning, the following statement shall be placed immediately following the heading of the boxed warning: "See ! for full boxed warning."

(5) *Recent labeling changes.* A listing of the section(s) of the comprehensive prescribing information in paragraph (c) of this section that contain(s) substantive labeling changes that have been approved by FDA or authorized under § 314.70(c)(2) or (d)(2) of this chapter, or § 601.12(f)(1) through (f)(3) of this chapter. The heading(s) and, if appropriate, the subheading(s) of the labeling section(s) affected by the change must be listed together with each section's index number or identifier. This section must be retained in the labeling for at least 1 year after the date of the labeling change, and may be retained until such time that the labeling is reprinted for the first time following the change.

(6) *Indications and usage.* A concise statement of each of the product's indications as required under paragraph (c)(2) of this section, with any appropriate subheadings. Major limitations of use (e.g., particular subsets of the population, second line therapy status, or antimicrobials limited to certain microorganisms) must be briefly noted.

(7) *Dosage and administration.* The most important aspects of the comprehensive prescribing information required under paragraph (c)(3) of this section, with any appropriate subheadings. This would include the most common dosage regimen(s) and

critical differences among population subsets, monitoring requirements, and other therapeutically important clinical pharmacologic information. The use of tables is encouraged, where appropriate (e.g., when there are different dosage regimens for different indications).

(8) *How supplied.* A concise summary of information concerning the product's dosage form(s) that is required under paragraph (c)(4) of this section. This would ordinarily include the metric strength or strengths of the dosage form and whether the product is scored. If appropriate, the information in this section of the labeling should include subheadings to specify different dosage forms (e.g., tablets, capsules, injectables, suspension).

(9) *Contraindications.* A concise summary of the comprehensive prescribing information required under paragraph (c)(5) of this section, with any appropriate subheadings.

(10) *Warnings/precautions.* A concise summary of the most clinically significant aspects of the comprehensive prescribing information required under paragraph (c)(6) of this section, with any appropriate subheadings. Clinically significant warnings and precautions include those that affect prescribing because of their severity and consequent influence on the decision to use the drug, because it is critical to safe use of the drug to monitor patients for them, or because measures can be taken to prevent or mitigate harm. This section of the the labeling must also include the subheading "Most Common Adverse Reactions (≥ n/100)." Under this subheading, the most frequently occurring adverse reactions (i.e., noxious and unintended responses for which there is a reasonable causal association with the use of the drug), as described in paragraph (c)(9) of this section, must be listed along with the incidence rate used to determine inclusion. Typically, the incidence rate for inclusion would be expected to be ≥ 1/100. When appropriate, adverse reactions important for other reasons (e.g., because they lead to discontinuation or dosage adjustment) may be included.

(11) *ADR reporting contacts.* For drug products other than vaccines, the verbatim statement "To report SUSPECTED SERIOUS ADR's, call (insert name of manufacturer) at (insert manufacturer's phone number) or FDA's MedWatch at (insert current FDA MedWatch number)." For vaccines, the verbatim statement "To report SUSPECTED SERIOUS ADR's, call (insert name of manufacturer) at (insert manufacturer's phone number) or

VAERS at (*insert the current VAERS number*)."

(12) *Drug interactions*. A concise summary of other prescription and over-the-counter drugs or foods that interact in clinically significant ways with the product, from the comprehensive prescribing information required under paragraph (c)(7) of this section, with any appropriate subheadings.

(13) *Use in specific populations*. A concise summary of any clinically important differences in response or use of the drug in specific populations, from the comprehensive prescribing information required under paragraph (c)(8) of this section, with any appropriate subheadings.

(14) *Patient counseling information statement*. When applicable, the verbatim statement "See P for Patient Counseling Information." If the product has approved patient labeling or a Medication Guide, the verbatim statement "See P for Patient Counseling Information, followed by (*insert name of drug*)'s (*insert either approved patient labeling or Medication Guide*)."

(15) *Highlights limitation statement*. The verbatim statement "These highlights do not include all the information needed to prescribe (*insert name of drug product*) safely and effectively. See (*insert name of drug product*)'s comprehensive prescribing information provided below."

(16) *Revision date*. The date of the most recent revision of the labeling, identified as such, placed at the end of the highlights section.

(17) *Index number placement*. Any subheadings required by paragraphs (a)(4) through (a)(10), (a)(12), and (a)(13) of this section, as well as additional subheadings included in the highlights section of the labeling under § 201.56(d)(5), must be followed by their index number in parentheses.

(b) *Comprehensive prescribing information: Index*. This section must appear in all prescription drug labeling immediately following the information required under paragraph (a) of this section and must contain a list of each subheading required under § 201.56(d)(1), if not omitted under § 201.56(d)(3), preceded by the index number or identifier required under § 201.56(d)(1) or (d)(2). The section must also contain additional subheading(s) included in the comprehensive prescribing information section of labeling under § 201.56(d)(5), preceded by the index number or identifier assigned under that section of the labeling.

(c) *Comprehensive prescribing information*. This section must appear in prescription drug labeling

immediately following the information required under paragraph (b) of this section. The section of the labeling must contain the information in the order required under paragraphs (c)(1) through (c)(17) of this section, together with the subheadings and index numbers or identifiers required under § 201.56(d)(1), unless omitted under § 201.56(d)(3). If additional subheadings are used within a labeling subsection in accordance with § 201.56(d)(5), they must be preceded by the index number assigned under that section.

(1) *Boxed warnings and contraindications*. Special problems, particularly those that may lead to death or serious injury, may be required by FDA to be placed in a prominently displayed box. The boxed warning(s) or contraindication(s) ordinarily must be based on clinical data, but serious animal toxicity may also be the basis of boxed information in the absence of clinical data. If a box containing warning(s) or contraindication(s) is required, it must be located preceding the "Indications and Usage" section of the labeling. The box must be preceded by an exclamation point (!) and must contain, in uppercase letters, a heading inside the box that includes the word "WARNING(S)" and is appropriate to communicate the general focus of the boxed information. If the information related to the boxed risk is extensive, the detailed information must be included under a bolded subheading in the appropriate section of the labeling (either "Contraindications" or "Warnings/Precautions"). The brief explanation of the risk(s) in the box must be followed by a reference (*i.e.*, the appropriate index number) to this more detailed information.

(2) 1 *Indications and usage*. (i) This section of the labeling must state that:

(A) The drug is indicated in the treatment, prevention, mitigation, cure, or diagnosis of a recognized disease or condition; and/or

(B) The drug is indicated for the treatment, prevention, mitigation, cure, or diagnosis of an important manifestation of a recognized disease or condition; and/or

(C) The drug is indicated for the relief of symptoms associated with a recognized disease or syndrome; and/or

(D) The drug, if used for a particular indication only in conjunction with a primary mode of therapy (*e.g.*, diet, surgery, behavior changes, or some other drug), is an adjunct to the mode of therapy.

(ii) For drug products other than biologics, all indications listed in this section of the labeling must be supported by substantial evidence of

effectiveness based on adequate and well-controlled studies as defined in § 314.126(b) of this chapter unless the requirement is waived under § 201.58 or § 314.126(c) of this chapter. Indications or uses must not be implied or suggested in other sections of labeling if not included in this section.

(iii) For biologics, all indications listed in this section of the labeling must be supported by substantial evidence of effectiveness. Indications or uses must not be implied or suggested in other sections of labeling if not included in this section of the labeling.

(iv) This section of the labeling must also contain the following additional information:

(A) If evidence is available to support the safety and effectiveness of the drug or biologic only in selected subgroups of the larger population with a disease, syndrome, manifestation, or symptom under consideration (*e.g.*, patients with mild disease or patients in a special age group), or if evidence to support the indication is based on surrogate endpoints (*e.g.*, CD4 cell counts or viral load), this section of the labeling must succinctly describe the available evidence and state the limitations of usefulness of the drug. In such cases, reference should be made to the "Clinical Studies" section of the labeling for a detailed discussion of the methodology and results of clinical studies relevant to such limitation(s). The labeling must also identify specific tests needed for selection or monitoring of the patients who need the drug (*e.g.*, microbe susceptibility tests). Information on the approximate kind, degree, and duration of improvement to be anticipated must be stated if available and for all drugs except biological products must be based on substantial evidence derived from adequate and well-controlled studies as defined in § 314.126(b) of this chapter unless the requirement is waived under § 201.58 or § 314.126(c) of this chapter. For biological products, such information must be based upon substantial evidence. If the information is relevant to the recommended intervals between doses, the usual duration of treatment, or any modification of dosage, it must be stated in the "Dosage and Administration" section of the labeling and referenced in this section of the labeling.

(B) If safety considerations are such that the drug should be reserved for certain situations (*e.g.*, cases refractory to other drugs), this information must be stated in this section of the labeling.

(C) If there are specific conditions that should be met before the drug is used on a long-term basis (*e.g.*, demonstration

of responsiveness to the drug in a short-term trial in a given patient), the labeling must identify the conditions; or, if the indications for long-term use are different from those for short-term use, the labeling must identify the specific indications for each use.

(D) If there is a common belief that the drug may be effective for a certain use or if there is a common use of the drug for a condition, but the preponderance of evidence related to the use or condition shows that the drug is ineffective or that the therapeutic benefits of the product do not generally outweigh its risks, FDA may require that the labeling state that there is a lack of evidence that the drug is effective or safe for that use or condition.

(E) Any statements comparing the safety or effectiveness, either greater or less, of the drug with other agents for the same indication must, except for biological products, be supported by substantial evidence derived from adequate and well-controlled studies as defined in § 314.126(b) of this chapter unless this requirement is waived under § 201.58 or § 314.126(c) of this chapter. For biological products, such statements must be supported by substantial evidence.

(3) 2 *Dosage and administration.* This section of the labeling must state the recommended usual dose, the usual dosage range, and, if appropriate, an upper limit beyond which safety and effectiveness have not been established. Dosages must be stated for each indication and subpopulation when appropriate. Dosing regimens must not be implied or suggested in other sections of labeling if not included in this section of the labeling. When established and clinically important, efficacious and/or toxic drug and/or metabolite concentration ranges and therapeutic concentration windows for drug and/or metabolites must be stated in this section of the labeling. Information on therapeutic drug concentration monitoring (TDM) must also be included in this section of the labeling when TDM is clinically necessary. This section of the labeling must also state the intervals recommended between doses, the optimal method of titrating dosage, the usual duration of treatment, and any modification of dosage needed in special patient populations (e.g., in children, in geriatric age groups, or in patients with renal or hepatic disease). Specific tables or monographs should be used when they would clarify dosage schedules. Radiation dosimetry information must be stated for both the patient receiving a radioactive drug and the person administering it. This section

of the labeling must also contain specific direction on dilution, preparation (including the strength of the final dosage solution, when prepared according to instructions, in terms of milligrams of active ingredient per milliliter of reconstituted solution, unless another measure of the strength is more appropriate), and administration of the dosage form, if needed (e.g., the rate of administration of parenteral drug in milligrams per minute; storage conditions for stability of the drug or reconstituted drug, when important; essential information on drug incompatibilities if the drug is mixed in vitro with other drugs; and the following statement for parenterals: "Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.")

(4) 3 *How supplied/storage and handling.* This section of the labeling must contain information on the available dosage forms to which the labeling applies and for which the manufacturer or distributor is responsible. The information must ordinarily include:

(i) The strength or potency of the dosage form in metric system (e.g., 10-milligram tablets), and, if the apothecary system is used, a statement of the strength must be placed in parentheses after the metric designation;

(ii) The units in which the dosage form is ordinarily available for prescribing by practitioners (e.g., bottles of 100);

(iii) Appropriate information to facilitate identification of the dosage forms, such as shape, color, coating, scoring, and National Drug Code number; and

(iv) Special handling and storage conditions.

(v) A statement directed to the pharmacist specifying the type of container to be used in dispensing the drug product to maintain its identity, strength, quality, and purity. Where there are standards and test procedures for determining that the container meets the requirements for specified types of containers as defined in an official compendium, such terms may be used. For example, "Dispense in tight, light-resistant container as defined in the National Formulary." Where standards and test procedures for determining the types of containers to be used in dispensing the drug product are not included in an official compendium, the specific container or types of containers known to be adequate to maintain the identity, strength, quality, and purity of the drug products must be described.

For example, "Dispense in containers that (*statement of specifications that clearly enable the dispensing pharmacist to select an adequate container*)."

(5) 4 *Contraindications.* This section of the labeling must describe those situations in which the drug should not be used because the risk of use clearly outweighs any possible therapeutic benefit. These situations include administration of the drug to patients known to have a severe hypersensitivity reaction to it; use of the drug in patients who, because of their particular age, sex, concomitant therapy, disease state, or other condition, have a substantial risk of being harmed by it; or continued use of the drug in the face of an unacceptably hazardous adverse reaction. Known hazards and not theoretical possibilities must be listed (e.g., if severe hypersensitivity to the drug has not been demonstrated, it should not be listed as a contraindication). If no contraindications are known, this section of the labeling must state "None known."

(6) 5 *Warnings/precautions.* (i) *General.* Under this section heading, the labeling must describe clinically significant adverse reactions and other potential safety hazards, including those resulting from drug/drug interactions; limitations in use imposed by them; and steps that should be taken if they occur. The labeling must be revised to include a warning as soon as there is reasonable evidence of an association of a clinically significant hazard with a drug; a causal relationship need not have been definitely established. A specific warning relating to a use not provided for under the "Indications and Usage" section of the labeling may be required by FDA if the drug is commonly prescribed for a disease or condition, and there is lack of substantial evidence of effectiveness for that disease or condition, and such usage is associated with clinically significant risk or hazard. The frequency of all clinically significant adverse reactions (including those that do not require a boxed warning) and, if known, the approximate mortality and morbidity rates for patients sustaining the reaction, which are important to safe and effective use of the drug, must be expressed as provided under the "Adverse Reactions" section of the labeling.

(ii) *Other special care precautions.* This section of the labeling must also contain information regarding any special care to be exercised by the practitioner for safe and effective use of the drug (e.g., precautions not required

under any other specific section or subsection of the labeling).

(iii) *Monitoring: Laboratory tests.* This subsection of the labeling must identify any laboratory tests that may be helpful in following the patient's response or in identifying possible adverse reactions. If appropriate, information must be provided on such factors as the range of normal and abnormal values expected in the particular situation and the recommended frequency with which tests should be performed before, during, and after therapy.

(iv) *Interference with laboratory tests.* If the product is known to interfere with laboratory tests, this subsection of the labeling must briefly note this interference and reference where the detailed information is discussed (typically this will be under the "Drug Interactions" section).

(v) *ADR reporting contacts.* This section of the labeling must include the statement: "To report SUSPECTED SERIOUS ADR's, call (insert name of manufacturer) at (insert manufacturer's phone number) or FDA's MedWatch at (insert current FDA MedWatch number)." For vaccines, this section of the labeling must include the statement: "To report SUSPECTED SERIOUS ADR's, call (insert name of manufacturer) at (insert manufacturer's phone number) or VAERS at (insert the current VAERS number)."

(7) 6 *Drug interactions.* (i) This section of the labeling must contain specific practical guidance for the practitioner on preventing clinically significant drug/drug interactions with other prescription or over-the-counter drugs, and drug/food interactions (for example, interactions with dietary supplements and such foods as grapefruit juice) that may occur in patients taking the drug. Specific drugs or classes of drugs with which the drug to which the labeling applies may interact in vivo must be identified, and the mechanism(s) of the interaction must be briefly described. Information in this section of the labeling must be limited to that pertaining to clinical use of the drug in patients. Drug interactions supported only by animal or in vitro experiments should not ordinarily be included, but animal or in vitro data may be used if shown to be clinically relevant. Interactions that have particularly serious consequences may be described briefly in the "Contraindications" or "Warnings/Precautions" sections of labeling, as appropriate, with a more complete description under this section of the labeling. Drug incompatibilities, i.e., drug interactions that may occur when drugs are mixed in vitro, as in a solution

for intravenous administration, must be discussed under the "Dosage and Administration" section of the labeling rather than under this section of the labeling.

(ii) This section of the labeling must also contain practical guidance on known interference of the drug with laboratory tests.

(8) 7 *Use in specific populations.* This section of the labeling must contain the following subsections:

(i) 7.1 *Pregnancy.* This subsection of the labeling may be omitted only if the drug is not absorbed systemically and the drug is not known to have a potential for indirect harm to the fetus. For all other drugs, this subsection of the labeling must contain the following information:

(A) *Teratogenic effects.* Under this subheading, the labeling must identify one of the following categories that applies to the drug, and the labeling must bear the statement required under the category:

(1) *Pregnancy category A.* If adequate and well-controlled studies in pregnant women have failed to demonstrate a risk to the fetus in the first trimester of pregnancy (and there is no evidence of a risk in later trimesters), the labeling must state: "Pregnancy Category A. Studies in pregnant women have not shown that (name of drug) increases the risk of fetal abnormalities if administered during the first (second, third, or all) trimester(s) of pregnancy. If this drug is used during pregnancy, the possibility of fetal harm appears remote. Because studies cannot rule out the possibility of harm, however, (name of drug) should be used during pregnancy only if clearly needed." The labeling must also contain a description of the human studies. If animal reproduction studies are also available and they fail to demonstrate a risk to the fetus, the labeling must also state: "Reproduction studies have been performed in (kinds of animal(s)) at doses up to (x) times the human dose and have revealed no evidence of impaired fertility or harm to the fetus due to (name of drug)." The labeling must also contain a description of available data on the effect of the drug on the later growth, development, and functional maturation of the child.

(2) *Pregnancy category B.* If animal reproduction studies have failed to demonstrate a risk to the fetus and there are no adequate and well-controlled studies in pregnant women, the labeling must state: "Pregnancy Category B. Reproduction studies have been performed in (kind(s) of animal(s)) at doses up to (x) times the human dose and have revealed no evidence of impaired fertility or harm to the fetus

due to (name of drug). There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed." If animal reproduction studies have shown an adverse effect (other than decrease in fertility), but adequate and well-controlled studies in pregnant women have failed to demonstrate a risk to the fetus during the first trimester of pregnancy (and there is no evidence of a risk in later trimesters), the labeling must state: "Pregnancy Category B. Reproduction studies in (kind(s) of animal(s)) have shown (describe findings) at (x) times the human dose. Studies in pregnant women, however, have not shown that (name of drug) increases the risk of abnormalities when administered during the first (second, third, or all) trimester(s) of pregnancy. Despite the animal findings, it would appear that the possibility of fetal harm is remote, if the drug is used during pregnancy. Nevertheless, because the studies in humans cannot rule out the possibility of harm, (name of drug) should be used during pregnancy only if clearly needed." The labeling must also contain a description of the human studies and a description of available data on the effect of the drug on the later growth, development, and functional maturation of the child.

(3) *Pregnancy category C.* If animal reproduction studies have shown an adverse effect on the fetus, if there are no adequate and well-controlled studies in humans, and if the benefits from the use of the drug in pregnant women may be acceptable despite its potential risks, the labeling must state: "Pregnancy Category C. (Name of drug) has been shown to be teratogenic (or to have an embryocidal effect or other adverse effect) in (name(s) of species) when given in doses (x) times the human dose. There are no adequate and well-controlled studies in pregnant women. (Name of drug) should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus." The labeling must contain a description of the animal studies. If there are no animal reproduction studies and no adequate and well-controlled studies in humans, the labeling must state: "Pregnancy Category C. Animal reproduction studies have not been conducted with (name of drug). It is also not known whether (name of drug) can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. (Name of drug) should be given to a pregnant woman

only if clearly needed.” The labeling must contain a description of any available data on the effect of the drug on the later growth, development, and functional maturation of the child.

(4) *Pregnancy category D.* If there is positive evidence of human fetal risk based on adverse reaction data from investigational or marketing experience or studies in humans, but the potential benefits from the use of the drug in pregnant women may be acceptable despite its potential risks (for example, if the drug is needed in a life-threatening situation or serious disease for which safer drugs cannot be used or are ineffective), the labeling must state: “Pregnancy Category D. See ‘Warnings/Precautions’ section.” Under the “Warnings/Precautions” section, the labeling must state: *(Name of drug)* can cause fetal harm when administered to a pregnant woman. *(Describe the human data and any pertinent animal data.)* If this drug is administered to a woman with reproductive potential, the patient should be apprised of the potential hazard to a fetus.”

(5) *Pregnancy category X.* If studies in animals or humans have demonstrated fetal abnormalities or if there is positive evidence of fetal risk based on adverse reaction reports from investigational or marketing experience, or both, and the risk of the use of the drug in a pregnant woman clearly outweighs any possible benefit (for example, safer drugs or other forms of therapy are available), the labeling must state: “Pregnancy Category X. See ‘Contraindications’ section.” Under “Contraindications,” the labeling must state: “*(Name of drug)* may *(can)* cause fetal harm when administered to a pregnant woman. *(Describe the human data and any pertinent animal data.) (Name of drug)* is contraindicated in women who are or may become pregnant. If this drug is administered to a woman with reproductive potential, the patient should be apprised of the potential hazard to a fetus.”

(B) *Nonteratogenic effects.* Under this subheading, the labeling must contain other information on the drug’s effects on reproduction and the drug’s use during pregnancy that is not required specifically by one of the pregnancy categories, if the information is relevant to the safe and effective use of the drug. Information required under this heading must include nonteratogenic effects in the fetus or newborn infant (for example, withdrawal symptoms or hypoglycemia) that may occur because of a pregnant woman’s chronic use of the drug for a preexisting condition or disease.

(ii) 7.2 *Labor and delivery.* If the drug has a recognized use during labor or delivery (vaginal or abdominal delivery), whether or not the use is stated in the indications section of the labeling, this subsection of the labeling must describe the available information about the effect of the drug on the mother and the fetus, on the duration of labor or delivery, on the possibility that forceps delivery or other intervention or resuscitation of the newborn will be necessary, and the effect of the drug on the later growth, development, and functional maturation of the child. If any information required under this subsection of the labeling is unknown, it must state that the information is unknown.

(iii) 7.3 *Lactating women.* (A) If a drug is absorbed systemically, this subsection of the labeling must contain, if known, information about excretion of the drug in human milk and effects on the nursing infant. Pertinent adverse effects observed in animal offspring must be described.

(B) If a drug is absorbed systemically and is known to be excreted in human milk, this subsection of the labeling must contain one of the following statements, as appropriate. If the drug is associated with clinically significant adverse reactions or if the drug has a known tumorigenic potential, the labeling must state: “Because of the potential for serious adverse reactions in nursing infants from *(name of drug)* (or, “Because of the potential for tumorigenicity shown for *(name of drug)* in *(animal or human)* studies), a decision should be made whether to discontinue producing milk for consumption or to discontinue the drug, taking into account the importance of the drug to the lactating woman.” If the drug is not associated with clinically significant adverse reactions and does not have a known tumorigenic potential, the labeling must state: “Caution should be exercised when *(name of drug)* is administered to a lactating woman.”

(C) If a drug is absorbed systemically and information on excretion in human milk is unknown, this subsection of the labeling must contain one of the following statements, as appropriate. If the drug is associated with clinically significant adverse reactions or has a known tumorigenic potential, the labeling must state: “It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk and because of the potential for clinically significant adverse reactions in nursing infants from *(name of drug)* (or, “Because of the potential for tumorigenicity shown for *(name of drug)* in *(animal or human)*

studies), a decision should be made whether to discontinue producing milk for consumption or to discontinue the drug, taking into account the importance of the drug to the lactating woman.” If the drug is not associated with clinically significant adverse reactions and does not have a known tumorigenic potential, the labeling must state: “It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when *(name of drug)* is administered to a lactating woman.”

(iv) 7.4 *Pediatric use.* (A) Pediatric population(s)/pediatric patient(s): For the purposes of paragraphs (c)(8)(iv)(B) through (c)(8)(iv)(H) of this section, the terms *pediatric population(s)* and *pediatric patient(s)* are defined as the pediatric age group, from birth to 16 years, including age groups often called neonates, infants, children, and adolescents.

(B) If there is a specific pediatric indication (i.e., an indication different from those approved for adults) that is supported by adequate and well-controlled studies in the pediatric population, it must be described under the “Indications and Usage” section of the labeling, and appropriate pediatric dosage information must be given under the “Dosage and Administration” section of the labeling. The “Pediatric use” subsection of the labeling must cite any limitations on the pediatric indication, need for specific monitoring, specific hazards associated with use of the drug in any subsets of the pediatric population (e.g., neonates), differences between pediatric and adult responses to the drug, and other information related to the safe and effective pediatric use of the drug.

Data summarized in this subsection of the labeling should be discussed in more detail, if appropriate, under the “Clinical Pharmacology” or “Clinical Studies” section. As appropriate, this information must also be contained in the “Contraindications,” and/or “Warnings/Precautions” section(s) of the labeling.

(C) If there are specific statements on pediatric use of the drug for an indication also approved for adults that are based on adequate and well-controlled studies in the pediatric population, they must be summarized in the “Pediatric use” subsection of the labeling and discussed in more detail, if appropriate, under the “Clinical Pharmacology” and “Clinical Studies” sections. Appropriate pediatric dosage must be given under the “Dosage and Administration” section of the labeling. The “Pediatric use” subsection of the

labeling must also cite any limitations on the pediatric use statement, need for specific monitoring, specific hazards associated with use of the drug in any subsets of the pediatric population (e.g., neonates), differences between pediatric and adult responses to the drug, and other information related to the safe and effective pediatric use of the drug. As appropriate, this information must also be contained in the

“Contraindications,” and/or “Warnings/Precautions” section(s) of the labeling.

(D) FDA may approve a drug for pediatric use based on adequate and well-controlled studies in adults, with other information supporting pediatric use. In such cases, the agency will have concluded that the course of the disease and the effects of the drug, both beneficial and adverse, are sufficiently similar in the pediatric and adult populations to permit extrapolation from the adult efficacy data to pediatric patients. The additional information supporting pediatric use must ordinarily include data on the pharmacokinetics of the drug in the pediatric population for determination of appropriate dosage. Other information, such as data from pharmacodynamic studies of the drug in the pediatric population, data from other studies supporting the safety or effectiveness of the drug in pediatric patients, pertinent premarketing or postmarketing studies or experience, may be necessary to show that the drug can be used safely and effectively in pediatric patients. When a drug is approved for pediatric use based on adequate and well-controlled studies in adults with other information supporting pediatric use, the “Pediatric use” subsection of the labeling must contain either the following statement, or a reasonable alternative:

The safety and effectiveness of (drug name) have been established in the age groups ____ to ____ (note any limitations, e.g., no data for pediatric patients under 2, or only applicable to certain indications approved in adults). Use of (drug name) in these age groups is supported by evidence from adequate and well-controlled studies of (drug name) in adults with additional data (insert wording that accurately describes the data submitted to support a finding of substantial evidence of effectiveness in the pediatric population).

Data summarized in the preceding prescribed statement in this subsection of the labeling must be discussed in more detail, if appropriate, under the “Clinical Pharmacology” or the “Clinical Studies” section of the labeling. For example, pediatric pharmacokinetic or pharmacodynamic studies and dose-response information should be described in the “Clinical

Pharmacology” section of the labeling. Pediatric dosing instructions must be included in the “Dosage and Administration” section of the labeling. Any differences between pediatric and adult responses, need for specific monitoring, dosing adjustments, and any other information related to safe and effective use of the drug in pediatric patients must be cited briefly in the “Pediatric use” subsection of the labeling and, as appropriate, in the “Contraindications,” “Warnings/Precautions,” and “Dosage and Administration” sections.

(E) If the requirements for a finding of substantial evidence to support a pediatric indication or a pediatric use statement have not been met for a particular pediatric population, the “Pediatric use” subsection of the labeling must contain an appropriate statement such as “Safety and effectiveness in pediatric patients below the age of (____) have not been established.” If use of the drug in this pediatric population is associated with a specific hazard, the hazard must be described in this subsection of the labeling, or, if appropriate, the hazard must be stated in the

“Contraindications” or “Warnings/Precautions” section of the labeling and this subsection must refer to it. (F) If the requirements for a finding of substantial evidence to support a pediatric indication or a pediatric use statement have not been met for any pediatric population, this subsection of the labeling must contain the following statement: “Safety and effectiveness in pediatric patients have not been established.” If use of the drug in premature or neonatal infants, or other pediatric subgroups, is associated with a specific hazard, the hazard must be described in this subsection of the labeling, or, if appropriate, the hazard must be stated in the

“Contraindications” or “Warnings/Precautions” section of the labeling and this subsection must refer to it. (G) If the sponsor believes that none of the statements described in paragraphs (c)(8)(iv)(B) through (c)(8)(iv)(F) of this section is appropriate or relevant to the labeling of a particular drug, the sponsor must provide reasons for omission of the statements and may propose alternative statement(s). FDA may permit use of an alternative statement if FDA determines that no statement described in those paragraphs is appropriate or relevant to the drug’s labeling and that the alternative statement is accurate and appropriate.

(H) If the drug product contains one or more inactive ingredients that present an increased risk of toxic effects to

neonates or other pediatric subgroups, a special note of this risk must be made, generally in the “Contraindications” or “Warnings/Precautions” section of the labeling.

(v) 7.5 *Geriatric use.* (A) A specific geriatric indication, if any, that is supported by adequate and well-controlled studies in the geriatric population must be described under the “Indications and Usage” section of the labeling, and appropriate geriatric dosage must be stated under the “Dosage and Administration” section of the labeling. The “Geriatric use” subsection of the labeling must cite any limitations on the geriatric indication, need for specific monitoring, specific hazards associated with the geriatric indication, and other information related to the safe and effective use of the drug in the geriatric population. Unless otherwise noted, information contained in the “Geriatric use” subsection of the labeling must pertain to use of the drug in persons 65 years of age and older. Data summarized in this subsection of the labeling must be discussed in more detail, if appropriate, under “Clinical Pharmacology” or the “Clinical Studies” section of the labeling. As appropriate, this information must also be contained in the “Warnings/Precautions” or “Contraindications” section of the labeling.

(B) Specific statements on geriatric use of the drug for an indication approved for adults generally, as distinguished from a specific geriatric indication, must be contained in the “Geriatric use” subsection and must reflect all information available to the sponsor that is relevant to the appropriate use of the drug in elderly patients. This information includes detailed results from controlled studies that are available to the sponsor and pertinent information from well-documented studies obtained from a literature search. Controlled studies include those that are part of the marketing application and other relevant studies available to the sponsor that have not been previously submitted in the investigational new drug application, new drug application, biologics license application, or a supplement or amendment to one of these applications (e.g., postmarketing studies or adverse drug reaction reports). The “Geriatric use” subsection of the labeling must contain the following statement(s) or reasonable alternative, as applicable, taking into account available information:

(1) If clinical studies did not include sufficient numbers of subjects aged 65 and over to determine whether elderly

subjects respond differently from younger subjects, and other reported clinical experience has not identified such differences, the "Geriatric use" subsection of the labeling must include the following statement:

Clinical studies of (name of drug) did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

(2) If clinical studies (including studies that are part of marketing applications and other relevant studies available to the sponsor that have not been submitted in the sponsor's applications) included enough elderly subjects to make it likely that differences in safety or effectiveness between elderly and younger subjects would have been detected, but no such differences (in safety or effectiveness) were observed, and other reported clinical experience has not identified such differences, the "Geriatric use" subsection of the labeling must contain the following statement:

Of the total number of subjects in clinical studies of (name of drug), _____ percent were 65 and over, while _____ percent were 75 and over. (Alternatively, the labeling may state the total number of subjects included in the studies who were 65 and over and 75 and over.) No overall differences in safety or effectiveness were observed between these subjects and younger subjects, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

(3) If evidence from clinical studies and other reported clinical experience available to the sponsor indicates that use of the drug in elderly patients is associated with differences in safety or effectiveness, or requires specific monitoring or dosage adjustment, the "Geriatric use" subsection of the labeling must contain a brief description of observed differences or specific monitoring or dosage requirements and, as appropriate, must refer to more detailed discussions in the "Contraindications," "Warnings/Precautions," "Dosage and Administration," or other sections of the labeling.

(C)(1) If specific pharmacokinetic or pharmacodynamic studies have been carried out in the elderly, they must be described briefly in the "Geriatric use"

subsection of the labeling and in detail under the "Clinical Pharmacology" section of the labeling. The "Clinical Pharmacology" and "Drug interactions" section of the labelings ordinarily contain information on drug-disease and drug-drug interactions that is particularly relevant to the elderly, who are more likely to have concomitant illness and to use concomitant drugs.

(2) If a drug is known to be substantially excreted by the kidney, the "Geriatric use" subsection of the labeling must include the statement:

This drug is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

(D) If use of the drug in the elderly appears to cause a specific hazard, the hazard must be described in the "Geriatric use" subsection of the labeling, or, if appropriate, the hazard must be stated in the "Contraindications" or "Warnings/Precautions" section of the labeling, and the "Geriatric use" subsection must refer to those sections of the labeling.

(E) Labeling under paragraphs (c)(8)(v)(A) through (c)(8)(v)(C) of this may include statements, if they would be useful in enhancing safe use of the drug, that reflect good clinical practice or past experience in a particular situation, e.g., for a sedating drug, it could be stated that: "Sedating drugs may cause confusion and over-sedation in the elderly; elderly patients generally should be started on low doses of (name of drug) and observed closely."

(F) If the sponsor believes that none of the requirements described in paragraphs (c)(8)(v)(A) through (c)(8)(v)(E) of this section is appropriate or relevant to the labeling of a particular drug, the sponsor must provide reasons for omission of the statements and may propose an alternative statement. FDA may permit omission of the statements if FDA determines that no statement described in those paragraphs is appropriate or relevant to the drug's labeling. FDA may permit use of an alternative statement if the agency determines that such statement is accurate and appropriate.

(vi) *Additional subsections of the labeling.* Additional subsections of the labeling may be included, as appropriate, if sufficient data are available concerning the use of the drug in other specified subpopulations (e.g., renal or hepatic impairment).

(9) *Adverse reactions.* An adverse reaction is a noxious and unintended

response to any dose of a drug product for which there is a reasonable possibility that the product caused the response (i.e., the relationship cannot be ruled out).

(i) *Listing of adverse reactions.* This section of the labeling must list the adverse reactions (not all the adverse events) that occur with the drug and with drugs in the same pharmacologically active and chemically related class, if applicable.

(ii) *Categorization of adverse reactions.* In this listing, adverse reactions may be categorized by organ system, by severity of the reaction, by frequency, or by toxicological mechanism, or by a combination of these, as appropriate. If frequency information from adequate clinical studies is available, the categories and the adverse reactions within each category must be listed in decreasing order of frequency. An adverse reaction that is significantly more severe than the other reactions listed in a category, however, must be listed before those reactions, regardless of its frequency. If frequency information from adequate clinical studies is not available, the categories and adverse reactions within each category must be listed in decreasing order of severity. The approximate frequency of each adverse reaction must be expressed in rough estimates or orders of magnitude essentially as follows:

The most frequent adverse reaction(s) to (name of drug) is (are) (list reactions). This (these) occur(s) in about (e.g., one-third of patients; one in 30 patients; less than one-tenth of patients). Less frequent adverse reactions are (list reactions), which occur in approximately (e.g., one in 100 patients). Other adverse reactions, which occur rarely, in approximately (e.g., one in 1,000 patients), are (list reactions).

Percent figures may not ordinarily be used unless they are documented by adequate and well-controlled studies as defined in § 314.126(b) of this chapter (except for biological products), they are shown to reflect general experience, and they do not falsely imply a greater degree of accuracy than actually exists.

(iii) *Potentially fatal adverse reactions.* The "Warnings/Precautions" section of the labeling or, if appropriate, the "Contraindications" section of the labeling must identify any potentially fatal adverse reaction.

(iv) *Comparisons of adverse reactions between drugs.* For drug products other than biologics, any claim comparing the drug to which the labeling applies with other drugs in terms of frequency, severity, or character of adverse reactions must be based on adequate and well-controlled studies as defined

in § 314.126(b) of this chapter unless this requirement is waived under § 201.58 or § 314.126(c) of this chapter. For biological products, any such claim must be based on substantial evidence.

(10) *9 Drug abuse and dependence.* This section of the labeling must contain the following subsections, as appropriate for the specific drug.

(i) *Controlled substance.* If the drug is controlled by the Drug Enforcement Administration, the schedule in which it is controlled must be stated.

(ii) *Abuse.* This subsection of the labeling must be based primarily on human data and human experience, but pertinent animal data may also be used. This subsection of the labeling must state the types of abuse that can occur with the drug and the adverse reactions pertinent to them. Particularly susceptible patient populations must be identified.

(iii) *Dependence.* This subsection of the labeling must describe characteristic effects resulting from both psychological and physical dependence that occur with the drug and must identify the quantity of the drug over a period of time that may lead to tolerance or dependence, or both. Details must be provided on the adverse effects of chronic abuse and the effects of abrupt withdrawal. Procedures necessary to diagnose the dependent state must be provided, and the principles of treating the effects of abrupt withdrawal must be described.

(11) *10 Overdosage.* This section of the labeling must describe the signs, symptoms, and laboratory findings of acute overdosage and the general principles of treatment. This section of the labeling must be based on human data, when available. If human data are unavailable, appropriate animal and in vitro data may be used. Specific information must be provided about the following:

(i) Signs, symptoms, and laboratory findings associated with an overdosage of the drug;

(ii) Complications that can occur with the drug (for example, organ toxicity or delayed acidosis);

(iii) Concentrations of the drug in biologic fluids associated with toxicity and/or death; physiologic variables influencing excretion of the drug, such as urine pH; and factors that influence the dose response relationship of the drug, such as tolerance. The pharmacokinetic data given in the "Clinical Pharmacology" section of the labeling also may be referenced here, if applicable to overdoses;

(iv) The amount of the drug in a single dose that is ordinarily associated with symptoms of overdosage and the

amount of the drug in a single dose that is likely to be life-threatening;

(v) Whether the drug is dialyzable; and

(vi) Recommended general treatment procedures and specific measures for support of vital functions, such as proven antidotes, induced emesis, gastric lavage, and forced diuresis. Unqualified recommendations for which data are lacking with the specific drug or class of drugs, especially treatment using another drug (for example, central nervous system stimulants, respiratory stimulants) may not be stated unless specific data or scientific rationale exists to support safe and effective use.

(12) *11 Description.* (i) This section of the labeling must contain:

(A) The proprietary name and the established name, if any, as defined in section 502(e)(2) of the act, of the drug or, for biologics, the proper name (as defined in § 600.3 of this chapter) and any appropriate descriptors;

(B) The type of dosage form(s) and the route(s) of administration to which the labeling applies;

(C) The same qualitative and/or quantitative ingredient information as required under § 201.100(b) for drug labels or §§ 610.60 and 610.61 of this chapter for biologic labels;

(D) If the drug is for other than oral use, the names of all inactive ingredients, except that:

(1) Flavorings and perfumes may be designated as such without naming their components.

(2) Color additives may be designated as coloring without naming specific color components unless the naming of such components is required by a color additive regulation prescribed in subchapter A of this chapter.

(3) Trace amounts of harmless substances added solely for individual product identification need not be named. If the drug is intended for administration by parenteral injection, the quantity or proportion of all inactive ingredients must be listed, except that ingredients added to adjust the pH or to make the drug isotonic may be declared by name and a statement of their effect; and if the vehicle is water for injection, it need not be named.

(E) If the product is sterile, a statement of that fact;

(F) The pharmacological or therapeutic class of the drug;

(G) For drug products other than biologics, the chemical name and structural formula of the drug; and

(H) If the product is radioactive, a statement of the important nuclear physical characteristics, such as the principal radiation emission data,

external radiation, and physical decay characteristics.

(ii) If appropriate, other important chemical or physical information, such as physical constants, or pH, must be stated.

(13) *12 Clinical pharmacology.* (i) Under this section, the labeling must contain information relating to the human clinical pharmacology and actions of the drug in humans. Information based on in vitro data using human biomaterials (e.g., human liver slices) and/or pharmacologic animal models or preparations may be included if it is essential to a description of the biochemical and/or physiological mode of action of the drug or drug/drug interactions or is otherwise pertinent to human therapeutics. The section of the labeling must include the following subheadings and information:

(A) *12.1 Mechanism of action.* This section of the labeling must summarize what is known about the established mechanism(s) of the drug's action in humans at various levels (e.g., receptor, membrane, tissue, organ, whole body). A brief description of disease pathophysiology may be included to help facilitate an understanding of the drug's action and impact on this process. If the mechanism of action is not known, the labeling must contain a statement about the lack of information.

(B) *12.2 Pharmacodynamics.* This section of the labeling must include a description of any biochemical or physiologic pharmacologic effects of the drug or active metabolites thought to be related to preventing, diagnosing, mitigating, curing, or treating disease, and/or those related to adverse effects or toxicity. Dose and/or concentration response relationship(s) and the time course of action must be included if known. Information on activity of metabolites, if available, must also be included in this section of the labeling. Recommendations based on pharmacodynamic information regarding dosage titration, monitoring of therapeutic effects, or drug concentration monitoring and dosage adjustment should appear in other sections of the labeling such as the "Warnings/Precautions" and/or "Dosage and Administration" sections. If pharmacokinetic/pharmacodynamic relationships are not demonstrated or are unknown, the labeling must contain a statement about the lack of information.

(C) *12.3 Pharmacokinetics.* This section of the labeling must include clinically relevant pharmacokinetic information. In general, the focus should be on factors that lead to and/or explain altered critical measures (e.g.,

C_{max} , AUC, half-life). Information about the pharmacokinetics of a drug or active metabolites must include pertinent absorption, distribution, metabolism (including metabolic pathways and identification of the enzyme systems involved), and excretion parameters. Information regarding bioavailability, the effect of food, minimum concentration (C_{min}), maximum concentration (C_{max}), time to maximum concentration (T_{max}), pertinent half-lives ($t_{1/2}$), time to reach steady state, accumulation route(s) of elimination, routes of clearance (e.g., CL-total, renal, hepatic), and volume of distribution (V_d) for clinical doses must be presented as appropriate. Information regarding nonlinearity in pharmacokinetic parameters, metabolic induction or inhibition, and clinically relevant binding (plasma protein, erythrocyte) parameters must also be presented as appropriate. Qualitative and quantitative assessment of metabolism must be presented in this section of the labeling. The impact of age, gender, ethnicity, disease states, and other factors on pharmacokinetic parameters must be noted and referenced to other sections of the labeling as necessary (e.g., "Use in Specific Populations," "Warnings/Precautions," "Dosage and Administration"). The clinical significance of any factors that change the product's pharmacokinetics must be noted, and recommendations based on this pharmacokinetic information must appear in other sections of the labeling, such as the "Warnings/Precautions" and/or "Dosage and Administration" sections, as necessary. If important pharmacokinetic information is unavailable, the labeling must contain a statement about the lack of information.

(D) 12.4 *Other clinical pharmacology information.* Under this heading, information may be presented that is not required under other sections of the labeling where such information is helpful to an understanding of the clinical pharmacology of the product. Information within this section of the labeling may include in vitro data related to the clinical pharmacology of drug/drug interactions or use in specific populations. If specific data on alternative dosing regimens (e.g., for hepatically or renally impaired patients) is included in this section of the labeling, it must also be included under § 201.57(c)(3) (i.e., the "Dosage and Administration" section of the comprehensive prescribing information).

(ii) In vitro or animal data related to the activity or efficacy of a drug that have not been shown by adequate and well-controlled studies to be pertinent

to clinical use may only be included in this section of the labeling if a waiver is granted under § 201.58 or § 314.126(c) of this chapter.

(14) 13 *Nonclinical toxicology.*

Under this section heading, the labeling must contain the following subsections as appropriate for the drug:

(i) 13.1 *Carcinogenesis, mutagenesis, impairment of fertility.* This subsection of the labeling must state whether long-term studies in animals have been performed to evaluate carcinogenic potential and, if so, the species and results. If reproduction studies or other data in animals reveal a problem or potential problem concerning mutagenesis or impairment of fertility in either males or females, the information must be described. Any precautionary statement on these topics must include practical, relevant advice to the prescriber on the significance of these animal findings. If there is evidence from human data that the drug may be carcinogenic or mutagenic or that it impairs fertility, this information must be included under the "Warnings/Precautions" section of the labeling.

(ii) 13.2 *Animal toxicology and/or pharmacology.* In many cases, the labeling need not include this section. Significant animal data necessary for safe and effective use of the drug in humans must ordinarily be included in one or more of the other sections of the labeling, as appropriate. Commonly for a drug that has been marketed for a long time, and in rare cases for a new drug, chronic animal toxicity studies have not been performed or completed for a drug that is administered over prolonged periods or is implanted in the body. The unavailability of such data must be stated in the appropriate section of the labeling for the drug. If the pertinent animal data cannot be appropriately incorporated into other sections of the labeling, this section may be used.

(15) 14 *Clinical studies.* This section of the labeling generally must contain a discussion of clinical study design and results that are important to a prescriber's understanding of the basis for approval of the drug. However, this section of the labeling must not include an encyclopedic listing of all, or even most, studies performed as part of the product's clinical development program. The section generally will provide more specific information than contained elsewhere in labeling on the effects of the drug in relevant clinical studies, and especially on the extent of the product's demonstrated benefits (e.g., how the drug was used in clinical trials, who was studied, and critical parameters that were monitored). Although typically not needed, a brief

reference to a specific important clinical study may be made in any section of the labeling required under §§ 201.56 and 201.57 if the study is essential to an understandable presentation of the information in that section of the labeling. Following a succinct description of the available evidence, reference must be made to "Clinical Studies" for presentation of more detailed discussion of the methodology and results of relevant studies. A clinical study (including Phase I, pharmacokinetic, etc.) may be discussed in prescription drug labeling only under the following conditions:

(i) For drug products other than biologics, any clinical study that is discussed that relates to an indication for or use of the drug must be adequate and well-controlled as described in § 314.126(b) of this chapter and must not imply or suggest indications or uses or dosing regimens not stated in the "Indications and Usage" or "Dosage and Administration" section of the labeling. For biological products, any clinical study that is discussed that relates to an indication for or use of the biologic must constitute or contribute to substantial evidence and must not imply or suggest indications or uses or dosing regimens not stated in the "Indications and Usage" or "Dosage and Administration" section of the labeling.

(ii) Any discussion of a clinical study that relates to a risk or risks from the use of the drug must also reference the other sections of the labeling for the drug where the risk or risks are identified or discussed.

(16) *R References.* This section may appear in labeling in the place of a detailed discussion of a subject that is of limited interest, but nonetheless important. References may appear in sections of the labeling format, other than the "References" section, in rare circumstances only. A reference may be cited in prescription drug labeling only under the following conditions:

(i) If the reference is cited in the labeling in the place of a detailed discussion of data and information concerning an indication for or use of a drug or biological product, the reference must be based upon an adequate and well-controlled clinical investigation under § 314.126(b) of this chapter or for a biological product, upon substantial evidence of effectiveness.

(ii) If the reference is cited in the labeling in the place of a detailed discussion of data and information concerning a risk or risks from the use of the drug, the risk or risks must also be identified or discussed in the appropriate section of the labeling for the drug.

(17) *P Patient counseling information.* This section of the labeling must contain information useful for patients to know for safe and effective use of the drug (e.g., precautions concerning driving or the concomitant use of other substances that may have harmful additive effects). This section of the labeling must appear as the last section of the comprehensive prescribing information. Any approved printed patient information or Medication Guide must be referenced in this section of the labeling and the full text of such patient information or Medication Guide must be reprinted immediately following this section of the labeling.

(d) *Format requirements.* All labeling information required under paragraphs (a), (b), and (c) of this section must be printed in accordance with the following specifications:

(1) All headings and subheadings must be highlighted by bold type that prominently distinguishes the headings and subheadings from other labeling information. Reverse type is not permitted as a form of highlighting.

(2) A horizontal line must separate the information required by paragraphs (a), (b), and (c) of this section.

(3) The headings listed in paragraphs (a)(4) through (a)(10), (a)(12), (a)(13), and (a)(14) of this section must be highlighted in bold type and must be presented in the center of a horizontal line.

(4) If there are multiple subheadings listed under paragraphs (a)(4) through (a)(10), (a)(12), or (a)(13) of this section, each subheading must be preceded by a bullet point.

(5) The labeling information required by paragraphs (a)(1) through (a)(4), (a)(11), and (a)(15) must be in bold print.

(6) The letter height or type size for all labeling information, headings, and subheadings set forth in paragraphs (a), (b), and (c) of this section must be a minimum of 8 points.

(7) The index numbers and identifiers (i.e., "P" and "R") required by § 201.56(d) and paragraphs (c)(1) through (c)(17) of this section must be presented in bold print and must precede the heading or subheading by at least two square em's (i.e., two squares of the size of the letter "m" in 8-point type).

(8) The information required by paragraph (a) of this section, not including the information required under paragraph (a)(4), must be limited in length to an amount that, if printed in 2 columns on a standard sized piece of typing paper (8½ by x 11 inches), single spaced, in 8-point type with ½-inch margins on all sides and between

columns, would fit on one-half of the page.

(9) The comprehensive labeling sections or subsections identified in paragraph (a)(5) of this section (i.e., those containing recent labeling changes) must be highlighted by the inclusion of a vertical line on the left edge of the new or modified text.

5. Section 201.58 is amended by revising the first sentence to read as follows:

§ 201.58 Requests for waiver of requirement for adequate and well-controlled studies to substantiate certain labeling statements.

A request under § 201.57(c)(2)(ii), (c)(2)(iv)(A), and (c)(9)(iv), or a request under § 201.80(b)(2), (c)(2), (c)(3)(i), (c)(3)(v), and (g)(4) for a waiver of the requirements of § 314.126(b) of this chapter must be submitted in writing as provided in § 314.126(c) of this chapter to the Director, Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or, if applicable, the Director, Center for Biologics Evaluation and Research, 8800 Rockville Pike, Bethesda, MD 20892.

§ 201.59 [Removed]

6. Section 201.59 *Effective date of §§ 201.56, 201.57, 201.100(d)(3), and 201.100(e)* is removed.

7. Newly redesignated § 201.80 is amended by revising paragraphs (b)(2), (c)(2), (f)(2), and (m)(1) and by adding a new sentence after the first sentence of paragraph (j) to read as follows:

§ 201.80 Specific requirements on content and format of labeling for human prescription drugs and biologics; older drugs not described in § 201.56(b)(1).

* * * * *

(b) * * *

(2) Data that demonstrate activity or effectiveness in in vitro or animal tests and that have not been shown by adequate and well-controlled studies to be pertinent to clinical use may be included under this section of the labeling only if a waiver is granted under § 201.58 or § 314.126(c) of this chapter.

(c) * * *

(2)(i) For drug products other than biologics, all indications listed in this section of the labeling must be supported by substantial evidence of effectiveness based on adequate and well-controlled studies as defined in § 314.126(b) of this chapter unless the requirement is waived under § 201.58 or § 314.126(c) of this chapter. Indications or uses must not be implied or suggested in other sections of labeling if

not included in this section of the labeling.

(ii) For biologics, all indications listed in this section of the labeling must be supported by substantial evidence of effectiveness. Indications or uses must not be implied or suggested in other sections of labeling if not included in this section of the labeling.

* * * * *

(f) * * *

(2) *Information for patients.* This section of the labeling must contain information useful for patients to know for safe and effective use of the drug (e.g., precautions concerning driving or the concomitant use of other substances that may have harmful additive effects). Any approved printed patient information or Medication Guide must be referenced in this section of the labeling and the full text of such patient information or Medication Guide must be reprinted immediately following the last section of labeling.

* * * * *

(j) *Dosage and administration.* * * * Dosing regimens must not be implied or suggested in other sections of labeling if not included in this section of the labeling. * * *

* * * * *

(m) * * *

(1) If the clinical study or reference is cited in the labeling in place of a detailed discussion of data and information concerning an indication for use of the drug, the reference must be based upon, or the clinical study must constitute, an adequate and well-controlled study as described in § 314.126(b) of this chapter, except for biological products, and must not imply or suggest indications or uses or dosing regimens not stated in the "Indications and Usage" or "Dosage and Administration" section of the labeling.

* * * * *

8. Section 201.100 is amended by removing paragraphs (b)(5) and (b)(7), by redesignating paragraph (b)(6) as paragraph (b)(5), by adding a new paragraph (b)(6), and by revising paragraphs (b)(2) and (d)(3) and newly redesignated paragraph (b)(5) to read as follows:

§ 201.100 Prescription drugs for human use.

* * * * *

(b) * * *

(2) The recommended or usual dosage, unless not required under § 201.55; and

* * * * *

(5) An identifying lot or control number from which it is possible to

determine the complete manufacturing history of the package of the drug.

(6) In the case of containers too small or otherwise unable to accommodate a label with sufficient space to bear all such information, but which are packaged within an outer container from which they are removed for dispensing or use, the information required by paragraphs (b)(2) and (b)(3) of this section may be contained in other labeling on or within the package from which it is to be dispensed; the

information referred to in paragraph (b)(1) of this section may be placed on such outer container only; and the information required by this paragraph (b)(6) may be on the crimp of the dispensing tube.

* * * * *

(d) * * *

(3) The information required, and in the format specified, by §§ 201.56, 201.57, and 201.80.

* * * * *

Dated: August 4, 2000.

Jane E. Henney,
Commissioner of Food and Drugs.

Donna E. Shalala,
Secretary of Health and Human Services.

Note: The following appendix will not appear in the Code of Federal Regulations.

BILLING CODE 4160-01-P

HIGHLIGHTS OF PRESCRIBING INFORMATION**CAPOTEN® TABLETS**
(captopril tablets)**WARNING: USE IN PREGNANCY**

When used in pregnancy during the second and third trimesters, ACE inhibitors can cause injury and even death to the developing fetus. When pregnancy is detected, CAPOTEN should be discontinued as soon as possible. See WARNINGS/PRECAUTIONS: Fetal/Neonatal Morbidity and Mortality (5.5).

RECENT LABELING CHANGES

Indications (1.x)
Warnings/Precautions (5.x, 5.y, 5.z)
Adverse Reactions (8.x)

INDICATIONS AND USAGE

- **Hypertension** (caution in renally-impaired patients), alone or in combination with other anti-hypertensives (1.1)
- **Congestive Heart Failure**, usually in combination with diuretics and digitalis (1.2)
- **Left Ventricular (LV) Dysfunction after Myocardial Infarction** to improve survival and reduce morbidity in clinically stable patients with LV ejection fraction $\leq 40\%$ (1.3)
- **Diabetic Nephropathy** (Type I IDD with proteinuria > 500 mg/day and retinopathy) (1.4)

DOSAGE AND ADMINISTRATION

General: Take 1 hour before meals. Individualize dosage.

Indication	Initiation of Therapy	Usual Daily Dose	Do Not Exceed
Hypertension	25 mg bid or tid	25-150 mg bid or tid*	450 mg/day
Heart Failure	25 mg tid	50-100 mg tid	450 mg/day
LV Dysfunction after MI	12.5 mg tid†	50 mg tid	
Diabetic Nephropathy		25 mg tid	

* Usual daily dosing does not exceed 50 mg BID or TID. Consider adding a thiazide-type diuretic. (2.2)

† A single dose of 6.25 mg should precede initiation of 12.5 mg therapy. (2.4)

Adjust dose in renal impairment (2.6, 5.7)

HOW SUPPLIED

Tablets: 12.5, 25, 50, 100 mg; scored (3)

CONTRAINDICATIONS

Known hypersensitivity (e.g., angioedema) to any ACE inhibitor.

WARNINGS/PRECAUTIONS

- Angioedema with possibility of airway obstruction (5.1)
- Neutropenia ($<1000/\text{mm}^3$) with myeloid hypoplasia (5.2)
- Excessive hypotension (5.4)
- Fetal/Neonatal Morbidity and Mortality (5.5)
- Hepatic failure (5.6)
- Use with caution in renal impairment. (2.6, 5.7)
- Hyperkalemia (5.8)
- Cough (5.9)

Most Common Adverse Reactions ($\geq n/100$) (8)

- rash (sometimes with arthralgia and eosinophilia), taste impairment (diminution or loss), cough, pruritus, chest pain, palpitations, tachycardia, proteinuria

To report SUSPECTED SERIOUS ADRs, call (manufacturer) at (phone #) or FDA's MedWatch at 1-800-FDA-1088

DRUG INTERACTIONS

- Diuretics (6.1)
- Other vasodilators (6.2)
- Agents Causing Renin Release (6.3)
- Beta-Blockers (6.4)
- Agents Increasing Serum Potassium (6.5)
- Lithium (6.7)

USE IN SPECIFIC POPULATIONS

- **Pregnancy:** Fetal/Neonatal Morbidity and Mortality (5.5)
- **Lactating Women:** Potential for serious adverse reactions in nursing infants. (7.3)
- **Pediatric Use:** Safety and effectiveness not established. Use only if other measures ineffective. (7.4)
- **Renal-impairment:** Use with caution. (2.6, 5.7)

See P for PATIENT COUNSELING INFORMATION

These highlights do not include all the information needed to prescribe Capoten safely and effectively. See Capoten's comprehensive prescribing information provided below.

m/yy

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- 1.2 Heart Failure
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COMPREHENSIVE PRESCRIBING INFORMATION

! WARNING: USE IN PREGNANCY
When used in pregnancy during the second and third trimesters, ACE inhibitors can cause injury and even death to the developing fetus. When pregnancy is detected, CAPOTEN should be discontinued as soon as possible. See WARNINGS/PRECAUTIONS: Fetal/Neonatal Morbidity and Mortality (5.5).

1 INDICATIONS AND USAGE**1.1 Hypertension:** CAPOTEN is indicated for the treatment of hypertension.

In using CAPOTEN, consideration should be given to the risk of neutropenia/agranulocytosis (see WARNINGS/PRECAUTIONS).

CAPOTEN (captopril) may be used as initial therapy for patients with normal renal function, in whom the risk is relatively low. In patients with impaired renal function, particularly those with collagen vascular disease, captopril should be reserved for hypertensives who have either developed unacceptable side effects on other drugs, or have failed to respond satisfactorily to drug combinations.

CAPOTEN is effective alone and in combination with other antihypertensive agents, especially thiazide-type diuretics. The blood pressure lowering effects of captopril and thiazides are approximately additive.

1.2 Heart Failure: CAPOTEN is indicated in the treatment of congestive heart failure usually in combination with diuretics and digitalis. The beneficial effect of captopril in heart failure does not require the presence of digitalis, however, most controlled clinical trial experience with captopril has been in patients receiving digitalis, as well as diuretic treatment.**1.3 Left Ventricular Dysfunction After Myocardial Infarction:** CAPOTEN is indicated to improve survival following myocardial infarction in clinically stable patients with left ventricular dysfunction manifested as an ejection fraction $\leq 40\%$ and to reduce the incidence of overt heart failure and subsequent hospitalizations for congestive heart failure in these patients.**1.4 Diabetic Nephropathy:** CAPOTEN is indicated for the treatment of diabetic nephropathy (proteinuria >500 mg/day) in patients with type I insulin-dependent diabetes mellitus and retinopathy. CAPOTEN decreases the rate of progression of renal insufficiency and development of serious adverse clinical outcomes (death or need for renal transplantation or dialysis).**2 DOSAGE AND ADMINISTRATION****2.1** CAPOTEN (captopril) should be taken one hour before meals. Dosage must be individualized.**2.2 Hypertension:** Initiation of therapy requires consideration of recent antihypertensive drug treatment, the extent of blood pressure elevation, salt restriction, and other clinical circumstances. If possible, discontinue the patient's previous antihypertensive drug regimen for one week before starting CAPOTEN.

The initial dose of CAPOTEN is 25 mg bid or tid. If satisfactory reduction of blood pressure has not been achieved after one or two weeks, the dose may be increased to 50 mg bid or tid. Concomitant sodium restriction may be beneficial when CAPOTEN (captopril) is used alone.

The dose of CAPOTEN in hypertension usually does not exceed 50 mg tid. Therefore, if the blood pressure has not been satisfactorily controlled after one to two weeks at this dose, (and the patient is not already receiving a diuretic), a modest dose of a thiazide-type diuretic (e.g., hydrochlorothiazide, 25 mg daily), should be added. The diuretic dose may be increased at one- to two-week intervals until its highest usual antihypertensive dose is reached.

If CAPOTEN is being started in a patient already receiving a diuretic, CAPOTEN therapy should be initiated under close medical supervision (see DRUG INTERACTIONS regarding hypotension (6.1)), with dosage and titration of CAPOTEN as noted above.

If further blood pressure reduction is required, the dose of

CAPOTEN may be increased to 100 mg bid or tid and then, if necessary, to 150 mg bid or tid (while continuing the diuretic).

The usual dose range is 25 to 150 mg bid or tid. A maximum daily dose of 450 mg CAPOTEN should not be exceeded.

For patients with severe hypertension (e.g., accelerated or malignant hypertension), when temporary discontinuation of current antihypertensive therapy is not practical or desirable, or when prompt titration to more normotensive blood pressure levels is indicated, diuretic should be continued but other current antihypertensive medication stopped and CAPOTEN dosage promptly initiated at 25 mg bid or tid, under close medical supervision.

When necessitated by the patient's clinical condition, the daily dose of CAPOTEN may be increased every 24 hours or less under continuous medical supervision until a satisfactory blood pressure response is obtained or the maximum dose of CAPOTEN is reached. In this regimen, addition of a more potent diuretic, e.g., furosemide, may also be indicated.

Beta-blockers may also be used in conjunction with CAPOTEN therapy (see DRUG INTERACTIONS (6.4)), but the effects of the two drugs are less than additive.

2.3 Heart Failure: Initiation of therapy requires consideration of recent diuretic therapy and the possibility of severe salt/volume depletion. In patients with either normal or low blood pressure, who have been vigorously treated with diuretics and who may be hyponatremic and/or hypovolemic, a starting dose of 6.25 or 12.5 mg tid may minimize the magnitude or duration of the hypotensive effect (see WARNINGS/PRECAUTIONS: Hypotension (5.4)); for these patients, titration to the usual daily dosage can then occur within the next several days.

For most patients the usual initial daily dosage is 25 mg tid. After a dose of 50 mg tid is reached, further increases in dosage should be delayed, where possible, for at least two weeks to determine if a satisfactory response occurs. Most patients studied have had a satisfactory clinical improvement at 50 or 100 mg tid. A maximum daily dose of 450 mg of CAPOTEN should not be exceeded.

CAPOTEN should generally be used in conjunction with a diuretic and digitalis. CAPOTEN therapy must be initiated under very close medical supervision.

2.4 Left Ventricular Dysfunction After Myocardial Infarction: The recommended dose for long-term use in patients following a myocardial infarction is a target maintenance dose of 50 mg tid.

Therapy may be initiated as early as three days following a myocardial infarction. After a single dose of 6.25 mg, CAPOTEN therapy should be initiated at 12.5 mg tid. CAPOTEN should then be increased to 25 mg tid during the next several days and to a target dose of 50 mg tid over the next several weeks as tolerated (see CLINICAL PHARMACOLOGY (12.2)).

CAPOTEN may be used in patients treated with other post-myocardial infarction therapies, e.g., thrombolytics, aspirin, beta blockers.

2.5 Diabetic Nephropathy: The recommended dose of CAPOTEN for long term use to treat diabetic nephropathy is 25 mg tid.

Other antihypertensives such as diuretics, beta blockers, centrally acting agents or vasodilators may be used in conjunction with CAPOTEN if additional therapy is required to further lower blood pressure.

2.6 Dosage Adjustment in Renal Impairment: Because CAPOTEN is excreted primarily by the kidneys, excretion rates are reduced in patients with impaired renal function. These patients will take longer to reach steady-state captopril levels and will reach higher steady-state levels for a given daily dose than patients with normal renal function. Therefore, these patients may respond to smaller or less frequent doses.

Accordingly, for patients with significant renal impairment, initial daily dosage of CAPOTEN should be reduced, and smaller increments utilized for titration, which should be quite slow (one- to two-week intervals). After the desired therapeutic effect has been achieved, the dose should be slowly back-titrated to determine the minimal effective dose. When concomitant diuretic therapy is required, a loop diuretic (e.g., furosemide), rather than a thiazide diuretic, is preferred in patients with severe renal impairment. (See also WARNINGS/PRECAUTIONS: Hemodialysis (5.12))

3 HOW SUPPLIED

12.5 mg tablets in bottles of 100 and 1000, 25 mg tablets in bottles of 100 and 1000, 50 mg tablets in bottles of 100 and 1000, and 100 mg tablets in bottles of 100. Bottles contain a desiccant-charcoal canister.

Unimatic unit-dose packs containing 100 tablets are also available for each potency: 12.5 mg, 25 mg, 50 mg, and 100 mg.

The 12.5 mg tablet is a biconvex oval with a partial bisect bar; the 25 mg tablet is a biconvex rounded square with a quadriseect bar; the 50 and 100 mg tablets are biconvex ovals with a bisect bar. All captopril tablets are white and may exhibit a slight sulfurous odor.

Storage: Do not store above 86° F. Keep bottles tightly closed (protect from moisture).

4 CONTRAINDICATIONS

CAPOTEN (captopril) is contraindicated in patients who are hypersensitive to this product or any other angiotensin-converting enzyme inhibitor (e.g., a patient who has experienced angioedema during therapy with any other ACE inhibitor).

5 WARNINGS/PRECAUTIONS

To report SUSPECTED SERIOUS ADRs, call (manufacturer) at (phone #) or FDA's MedWatch at 1-800-FDA-1088

5.1 Angioedema

Angioedema involving the extremities, face, lips, mucous membranes, tongue, glottis or larynx has been seen in patients treated with ACE inhibitors, including captopril. If angioedema involves the tongue, glottis or larynx, airway obstruction may occur and be fatal. Emergency therapy, including but not necessarily limited to, subcutaneous administration of a 1:1000 solution of epinephrine should be promptly instituted.

Swelling confined to the face, mucous membranes of the mouth, lips and extremities has usually resolved with discontinuation of captopril; some cases required medical therapy. (See PATIENT COUNSELING INFORMATION (P) and ADVERSE REACTIONS (8).)

5.2 Neutropenia/Agranulocytosis

Neutropenia ($<1000/\text{mm}^3$) with myeloid hypoplasia has resulted from use of captopril. About half of the neutropenic patients developed systemic or oral cavity infections or other features of the syndrome of agranulocytosis.

The risk of neutropenia is dependent on the clinical status of the patient:

In clinical trials in patients with hypertension who have normal renal function (serum creatinine less than 1.6 mg/dL and no collagen vascular disease), neutropenia has been seen in one patient out of over 8,600 exposed.

In patients with some degree of renal failure (serum creatinine at least 1.6 mg/dL) but no collagen vascular disease, the risk of neutropenia in clinical trials was about 1 per 500, a frequency over 15 times that for uncomplicated hypertension. Daily doses of captopril were relatively high in these patients, particularly in view of their diminished renal function. In foreign marketing experience in patients with renal failure, use of allopurinol concomitantly with captopril has been associated with neutropenia but this association has not appeared in U.S. reports.

In patients with collagen vascular diseases (e.g., systemic lupus erythematosus, scleroderma) and impaired renal function, neutropenia occurred in 3.7 percent of patients in clinical trials. While none of the over 750 patients in formal clinical trials of heart failure developed neutropenia, it has occurred during the subsequent clinical experience. About half of the reported cases had serum creatinine ≥ 1.6 mg/dL and more than 75 percent were in patients also receiving procainamide. In heart failure, it appears that the same risk factors for neutropenia are present.

The neutropenia has usually been detected within three months after captopril was started. Bone marrow examinations in patients with neutropenia consistently showed myeloid hypoplasia, frequently accompanied by erythroid hypoplasia and decreased numbers of megakaryocytes (e.g., hypoplastic bone marrow and

pancytopenia); anemia and thrombocytopenia were sometimes seen.

In general, neutrophils returned to normal in about two weeks after captopril was discontinued, and serious infections were limited to clinically complex patients. About 13 percent of the cases of neutropenia have ended fatally, but almost all fatalities were in patients with serious illness, having collagen vascular disease, renal failure, heart failure or immunosuppressant therapy, or a combination of these complicating factors.

Evaluation of the hypertensive or heart failure patient should always include assessment of renal function.

If captopril is used in patients with impaired renal function, white blood cell and differential counts should be evaluated prior to starting treatment and at approximately two-week intervals for about three months, then periodically.

In patients with collagen vascular disease or who are exposed to other drugs known to affect the white cells or immune response, particularly when there is impaired renal function, captopril should be used only after an assessment of benefit and risk, and then with caution.

All patients treated with captopril should be told to report any signs of infection (e.g., sore throat, fever). If infection is suspected, white cell counts should be performed without delay.

Since discontinuation of captopril and other drugs has generally led to prompt return of the white count to normal, upon confirmation of neutropenia (neutrophil count $<1000/\text{mm}^3$) the physician should withdraw captopril and closely follow the patient's course.

5.3 Proteinuria

Total urinary proteins greater than 1 g per day were seen in about 0.7 percent of patients receiving captopril. About 90 percent of affected patients had evidence of prior renal disease or received relatively high doses of captopril (in excess of 150 mg/day), or both. The nephrotic syndrome occurred in about one-fifth of proteinuric patients. In most cases, proteinuria subsided or cleared within six months whether or not captopril was continued. Parameters of renal function, such as BUN and creatinine, were seldom altered in the patients with proteinuria.

5.4 Hypotension

Excessive hypotension was rarely seen in hypertensive patients but is a possible consequence of captopril use in salt/volume depleted persons (such as those treated vigorously with diuretics), patients with heart failure or those patients undergoing renal dialysis. (See DRUG INTERACTIONS (6.1).)

In heart failure, where the blood pressure was either normal or low, transient decreases in mean blood pressure greater than 20 percent were recorded in about half of the patients. This transient hypotension is more likely to occur after any of the first several doses and is usually well tolerated, producing either no symptoms or brief mild lightheadedness, although in rare instances it has been associated with arrhythmia or conduction defects. Hypotension was the reason for discontinuation of drug in 3.6 percent of patients with heart failure.

BECAUSE OF THE POTENTIAL FALL IN BLOOD PRESSURE IN THESE PATIENTS, THERAPY SHOULD BE STARTED UNDER VERY CLOSE MEDICAL SUPERVISION. A starting dose of 6.25 or 12.5 mg tid may minimize the hypotensive effect. Patients should be followed closely for the first two weeks of treatment and whenever the dose of captopril and/or diuretic is increased. In patients with heart failure, reducing the dose of diuretic, if feasible, may minimize the fall in blood pressure.

Hypotension is not *per se* a reason to discontinue captopril. Some decrease of systemic blood pressure is a common and desirable observation upon initiation of CAPOTEN (captopril) treatment in heart failure. The magnitude of the decrease is greatest early in the course of treatment; this effect stabilizes within a week or two, and generally returns to pretreatment levels, without a decrease in therapeutic efficacy, within two months.

5.5 Fetal/Neonatal Morbidity and Mortality

ACE inhibitors can cause fetal and neonatal morbidity and death when administered to pregnant women. Several dozen cases have been reported in the world literature. When pregnancy is detected, ACE inhibitors should be discontinued as soon as possible.

The use of ACE inhibitors during the second and third trimesters of pregnancy has been associated with fetal and neonatal injury,

including hypotension, neonatal skull hypoplasia, anuria, reversible or irreversible renal failure, and death. Oligohydramnios has also been reported, presumably resulting from decreased fetal renal function; oligohydramnios in this setting has been associated with fetal limb contractures, craniofacial deformation, and hypoplastic lung development. Prematurity, intrauterine growth retardation, and patent ductus arteriosus have also been reported, although it is not clear whether these occurrences were due to the ACE inhibitor exposure.

These adverse effects do not appear to have resulted from intrauterine ACE inhibitor exposure that has been limited to the first trimester. Mothers whose embryos and fetuses are exposed to ACE inhibitors only during the first trimester should be so informed. Nonetheless, when patients become pregnant, physicians should make every effort to discontinue the use of captopril as soon as possible.

Rarely (probably less often than once in every thousand pregnancies), no alternative to ACE inhibitors will be found. In these rare cases, the mothers should be apprised of the potential hazards to their fetuses, and serial ultrasound examinations should be performed to assess the intraamniotic environment.

If oligohydramnios is observed, captopril should be discontinued unless it is considered life-saving for the mother. Contraction stress testing (CST), a non-stress test (NST), or biophysical profiling (BPP) may be appropriate, depending upon the week of pregnancy. Patients and physicians should be aware, however, that oligohydramnios may not appear until after the fetus has sustained irreversible injury.

Infants with histories of in utero exposure to ACE inhibitors should be closely observed for hypotension, oliguria, and hyperkalemia. If oliguria occurs, attention should be directed toward support of blood pressure and renal perfusion. Exchange transfusion or dialysis may be required as a means of reversing hypotension and/or substituting for disordered renal function. While captopril may be removed from the adult circulation by hemodialysis, there is inadequate data concerning the effectiveness of hemodialysis for removing it from the circulation of neonates or children. Peritoneal dialysis is not effective for removing captopril; there is no information concerning exchange transfusion for removing captopril from the general circulation.

When captopril was given to rabbits at doses about 0.8 to 70 times (on a mg/kg basis) the maximum recommended human dose, low incidences of craniofacial malformations were seen. No teratogenic effects of captopril were seen in studies of pregnant rats and hamsters. On a mg/kg basis, the doses used were up to 150 times (in hamsters) and 625 times (in rats) the maximum recommended human dose.

5.6 Hepatic Failure

Rarely, ACE inhibitors have been associated with a syndrome that starts with cholestatic jaundice and progresses to fulminant hepatic necrosis and (sometimes) death. The mechanism of this syndrome is not understood. Patients receiving ACE inhibitors who develop jaundice or marked elevations of hepatic enzymes should discontinue the ACE inhibitor and receive appropriate medical follow-up.

5.7 Impaired Renal Function

Hypertension—Some patients with renal disease, particularly those with severe renal artery stenosis, have developed increases in BUN and serum creatinine after reduction of blood pressure with captopril. Captopril dosage reduction and/or discontinuation of diuretic may be required. For some of these patients, it may not be possible to normalize blood pressure and maintain adequate renal perfusion.

Heart Failure—About 20 percent of patients develop stable elevations of BUN and serum creatinine greater than 20 percent above normal or baseline upon long-term treatment with captopril. Less than 5 percent of patients, generally those with severe pre-existing renal disease, required discontinuation of treatment due to progressively increasing creatinine; subsequent improvement probably depends upon the severity of the underlying renal disease.

See CLINICAL PHARMACOLOGY (12), DOSAGE AND ADMINISTRATION (2.6), ADVERSE REACTIONS: Altered Laboratory Findings (8.1).

5.8 Hyperkalemia

Elevations in serum potassium have been observed in some patients treated with ACE inhibitors, including captopril. When treated with ACE inhibitors, patients at risk for the development of hyperkalemia include those with: renal insufficiency; diabetes mellitus; and those using concomitant potassium-sparing diuretics, potassium supplements or potassium-containing salt substitutes; or other drugs associated with increases in serum potassium. In a trial of type I diabetic patients with proteinuria, the incidence of withdrawal of treatment with captopril for hyperkalemia was 2% (4/207). In two trials of normotensive type I diabetic patients with microalbuminuria, no captopril group subjects had hyperkalemia (0/116). (See PATIENT COUNSELING INFORMATION (P); DRUG INTERACTIONS (6.5); ADVERSE REACTIONS: Altered Laboratory Findings (8.1).)

5.9 Cough

Cough has been reported with the use of ACE inhibitors. Characteristically, the cough is nonproductive, persistent and resolves after discontinuation of therapy. ACE inhibitor-induced cough should be considered as part of the differential diagnosis of cough.

5.10 Valvular Stenosis

There is concern, on theoretical grounds, that patients with aortic stenosis might be at particular risk of decreased coronary perfusion when treated with vasodilators because they do not develop as much afterload reduction as others.

5.11 Surgery/Anesthesia

In patients undergoing major surgery or during anesthesia with agents that produce hypotension, captopril will block angiotensin II formation secondary to compensatory renin release. If hypotension occurs and is considered to be due to this mechanism, it can be corrected by volume expansion.

5.12 Hemodialysis

Recent clinical observations have shown an association of hypersensitivity-like (anaphylactoid) reactions during hemodialysis with high-flux dialysis membranes (e.g., AN69) in patients receiving ACE inhibitors. In these patients, consideration should be given to using a different type of dialysis membrane or a different class of medication.

6 DRUG INTERACTIONS

6.1 Hypotension—Patients on Diuretic Therapy

Patients on diuretics and especially those in whom diuretic therapy was recently instituted, as well as those on severe dietary salt restriction or dialysis, may occasionally experience a precipitous reduction of blood pressure usually within the first hour after receiving the initial dose of captopril.

The possibility of hypotensive effects with captopril can be minimized by either discontinuing the diuretic or increasing the salt intake approximately one week prior to initiation of treatment with CAPOTEN or initiating therapy with small doses (6.25 or 12.5 mg). Alternatively, provide medical supervision for at least one hour after the initial dose. If hypotension occurs, the patient should be placed in a supine position and, if necessary, receive an intravenous infusion of normal saline. This transient hypotensive response is not a contraindication to further doses which can be given without difficulty once the blood pressure has increased after volume expansion.

6.2 Agents Having Vasodilator Activity

Data on the effect of concomitant use of other vasodilators in patients receiving CAPOTEN for heart failure are not available; therefore, nitroglycerin or other nitrates (as used for management of angina) or other drugs having vasodilator activity should, if possible, be discontinued before starting CAPOTEN. If resumed during CAPOTEN therapy, such agents should be administered cautiously, and perhaps at lower dosage.

6.3 Agents Causing Renin Release

Captopril's effect will be augmented by antihypertensive agents that cause renin release. For example, diuretics (e.g., thiazides) may activate the renin-angiotensin-aldosterone system.

6.4 Agents Affecting Sympathetic Activity

The sympathetic nervous system may be especially important in supporting blood pressure in patients receiving captopril alone or with diuretics. Therefore, agents affecting sympathetic activity (e.g., ganglionic blocking agents or adrenergic neuron blocking

agents) should be used with caution. Beta-adrenergic blocking drugs add some further antihypertensive effect to captopril, but the overall response is less than additive.

6.5 Agents Increasing Serum Potassium

Since captopril decreases aldosterone production, elevation of serum potassium may occur. Potassium-sparing diuretics such as spironolactone, triamterene, or amiloride, or potassium supplements should be given only for documented hypokalemia, and then with caution, since they may lead to a significant increase of serum potassium. Salt substitutes containing potassium should also be used with caution.

6.6 Inhibitors Of Endogenous Prostaglandin Synthesis

It has been reported that indomethacin may reduce the antihypertensive effect of captopril, especially in cases of low renin hypertension. Other nonsteroidal anti-inflammatory agents (e.g., aspirin) may also have this effect.

6.7 Lithium

Increased serum lithium levels and symptoms of lithium toxicity have been reported in patients receiving concomitant lithium and ACE inhibitor therapy. These drugs should be coadministered with caution and frequent monitoring of serum lithium levels is recommended. If a diuretic is also used, it may increase the risk of lithium toxicity.

6.8 Drug/Laboratory Test Interaction

Captopril may cause a false-positive urine test for acetone.

7 USE IN SPECIFIC POPULATIONS

7.1 Pregnancy Categories C (first trimester) and D (second and third trimesters) See WARNINGS/PRECAUTIONS: Fetal/Neonatal Morbidity and Mortality (5.5).

7.3 Lactating Women

Concentrations of captopril in human milk are approximately one percent of those in maternal blood. Because of the potential for serious adverse reactions in nursing infants from captopril, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of CAPOTEN (captopril) to the mother. (See USE IN SPECIFIC POPULATIONS: Pediatric Use (7.4).)

7.4 Pediatric Use

Safety and effectiveness in children have not been established. There is limited experience reported in the literature with the use of captopril in the pediatric population; dosage, on a weight basis, was generally reported to be comparable to or less than that used in adults.

Infants, especially newborns, may be more susceptible to the adverse hemodynamic effects of captopril. Excessive, prolonged and unpredictable decreases in blood pressure and associated complications, including oliguria and seizures, have been reported.

CAPOTEN (captopril) should be used in children only if other measures for controlling blood pressure have not been effective.

8 ADVERSE REACTIONS

Reported incidences are based on clinical trials involving approximately 7000 patients.

Renal: About one of 100 patients developed proteinuria (see WARNINGS/PRECAUTIONS (5.3)).

Each of the following has been reported in approximately 1 to 2 of 1000 patients and are of uncertain relationship to drug use: renal insufficiency, renal failure, nephrotic syndrome, polyuria, oliguria, and urinary frequency.

Hematologic: Neutropenia/agranulocytosis has occurred (see WARNINGS/PRECAUTIONS (5.2)). Cases of anemia, thrombocytopenia, and pancytopenia have been reported.

Dermatologic: Rash, often with pruritus, and sometimes with fever, arthralgia, and eosinophilia, occurred in about 4 to 7 (depending on renal status and dose) of 100 patients, usually during the first four weeks of therapy. It is usually maculopapular, and rarely urticarial. The rash is usually mild and disappears within a few days of dosage reduction, short-term treatment with an antihistaminic agent, and/or discontinuing therapy; remission may occur even if captopril is continued. Pruritus, without rash, occurs in about 2 of 100 patients. Between 7 and 10 percent of patients with skin rash have shown an eosinophilia and/or positive ANA

titers. A reversible associated pemphigoid-like lesion, and photo sensitivity, have also been reported.

Flushing or pallor has been reported in 2 to 5 of 1000 patients.

Cardiovascular: Hypotension may occur; see DRUG INTERACTIONS (6.1) for discussion of hypotension with captopril therapy. Tachycardia, chest pain, and palpitations have each been observed in approximately 1 of 100 patients.

Angina pectoris, myocardial infarction, Raynaud's syndrome, and congestive heart failure have each occurred in 2 to 3 of 1000 patients.

Dysgeusia: Approximately 2 to 4 (depending on renal status and dose) of 100 patients developed a diminution or loss of taste perception. Taste impairment is reversible and usually self-limited (2 to 3 months) even with continued drug administration. Weight loss may be associated with the loss of taste.

Angioedema: Angioedema involving the extremities, face, lips, mucous membranes, tongue, glottis or larynx has been reported in approximately one in 1000 patients. Angioedema involving the upper airways has caused fatal airway obstruction. (See PATIENT COUNSELING INFORMATION (P).)

Cough: Cough has been reported in 0.5-2% of patients treated with captopril in clinical trials. (See WARNINGS/PRECAUTIONS: Cough (5.9).)

The following have been reported in about 0.5 to 2 percent of patients but did not appear at increased frequency compared to placebo or other treatments used in controlled trials: gastric irritation, abdominal pain, nausea, vomiting, diarrhea, anorexia, constipation, aphthous ulcers, peptic ulcer, dizziness, headache, malaise, fatigue, insomnia, dry mouth, dyspnea, alopecia, paresthesias.

Other clinical adverse effects reported since the drug was marketed are listed below by body system. In this setting, an incidence or causal relationship cannot be accurately determined.

Body as a whole: Anaphylactoid reactions (see WARNINGS/PRECAUTIONS: Hemodialysis (5.12)).

General: Asthenia, gynecomastia.

Cardiovascular: Cardiac arrest, cerebrovascular accident/insufficiency, rhythm disturbances, orthostatic hypotension, syncope.

Dermatologic: Bullous pemphigus, erythema multiforme (including Stevens-Johnson syndrome), exfoliative dermatitis.

Gastrointestinal: Pancreatitis, glossitis, dyspepsia.

Hematologic: Anemia, including aplastic and hemolytic.

Hepatobiliary: Jaundice, hepatitis, including rare cases of necrosis, cholestasis.

Metabolic: Symptomatic hyponatremia.

Musculoskeletal: Myalgia, myasthenia.

Nervous/Psychiatric: Ataxia, confusion, depression, nervousness, somnolence.

Respiratory: Bronchospasm, eosinophilic pneumonitis, rhinitis.

Special Senses: Blurred vision.

Urogenital: Impotence.

As with other ACE inhibitors, a syndrome has been reported which may include: fever, myalgia, arthralgia, interstitial nephritis, vasculitis, rash or other dermatologic manifestations, eosinophilia and an elevated ESR.

Fetal/Neonatal Morbidity and Mortality

See WARNINGS/PRECAUTIONS: Fetal/Neonatal Morbidity and Mortality.

8.1 Altered Laboratory Findings

Serum Electrolytes: Hyperkalemia: small increases in serum potassium, especially in patients with renal impairment (see WARNINGS/PRECAUTIONS (5.8)).

Hyponatremia: particularly in patients receiving a low sodium diet or concomitant diuretics.

BUN/Serum Creatinine: Transient elevations of BUN or serum creatinine especially in volume or salt depleted patients or those with renovascular hypertension may occur. Rapid reduction of longstanding or markedly elevated blood pressure can result in decreases in the glomerular filtration rate and, in turn, lead to increases in BUN or serum creatinine.

Hematologic: A positive ANA has been reported.

Liver Function Tests: Elevations of liver transaminases, alkaline phosphatase, and serum bilirubin have occurred.

10 OVERDOSAGE

Correction of hypotension would be of primary concern.

Volume expansion with an intravenous infusion of normal saline is the treatment of choice for restoration of blood pressure.

While captopril may be removed from the adult circulation by hemodialysis, there is inadequate data concerning the effectiveness of hemodialysis for removing it from the circulation of neonates or children. Peritoneal dialysis is not effective for removing captopril; there is no information concerning exchange transfusion for removing captopril from the general circulation.

11 DESCRIPTION

CAPOTEN (captopril) is a specific competitive inhibitor of angiotensin I-converting enzyme (ACE), the enzyme responsible for the conversion of angiotensin I to angiotensin II.

CAPOTEN is designated chemically as 1-[(2S)-3-mercapto-2-methylpropionyl]-L-proline [MW 217.29].

Captopril is a white to off-white crystalline powder that may have a slight sulfurous odor; it is soluble in water (approx. 160 mg/mL), methanol, and ethanol and sparingly soluble in chloroform and ethyl acetate.

CAPOTEN is available in potencies of 12.5 mg, 25 mg, 50 mg, and 100 mg as scored tablets for oral administration. Inactive ingredients: microcrystalline cellulose, corn starch, lactose, and stearic acid.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

The mechanism of action of CAPOTEN has not yet been fully elucidated. Its beneficial effects in hypertension and heart failure appear to result primarily from suppression of the renin-angiotensin-aldosterone system. However, there is no consistent correlation between renin levels and response to the drug. Renin, an enzyme synthesized by the kidneys, is released into the circulation where it acts on a plasma globulin substrate to produce angiotensin I, a relatively inactive decapeptide. Angiotensin I is then converted by angiotensin converting enzyme (ACE) to angiotensin II, a potent endogenous vasoconstrictor substance. Angiotensin II also stimulates aldosterone secretion from the adrenal cortex, thereby contributing to sodium and fluid retention.

CAPOTEN prevents the conversion of angiotensin I to angiotensin II by inhibition of ACE, a peptidyl dipeptide carboxy hydrolase. This inhibition has been demonstrated in both healthy human subjects and in animals by showing that the elevation of blood pressure caused by exogenously administered angiotensin I was attenuated or abolished by captopril. In animal studies, captopril did not alter the pressor responses to a number of other agents, including angiotensin II and norepinephrine, indicating specificity of action.

ACE is identical to "bradykininase," and CAPOTEN may also interfere with the degradation of the vasodepressor peptide, bradykinin. Increased concentrations of bradykinin or prostaglandin E₂ may also have a role in the therapeutic effect of CAPOTEN.

Inhibition of ACE results in decreased plasma angiotensin II and increased plasma renin activity (PRA), the latter resulting from loss of negative feedback on renin release caused by reduction in angiotensin II. The reduction of angiotensin II leads to decreased aldosterone secretion, and, as a result, small increases in serum potassium may occur along with sodium and fluid loss.

The antihypertensive effects persist for a longer period of time than does demonstrable inhibition of circulating ACE. It is not known whether the ACE present in vascular endothelium is inhibited longer than the ACE in circulating blood.

12.2 Pharmacodynamics

Administration of CAPOTEN results in a reduction of peripheral arterial resistance in hypertensive patients with either no change, or an increase, in cardiac output. There is an increase in renal blood flow following administration of CAPOTEN and glomerular filtration rate is usually unchanged.

Reductions of blood pressure are usually maximal 60 to 90 minutes after oral administration of an individual dose of

CAPOTEN. The duration of effect is dose related. The reduction in blood pressure may be progressive, so to achieve maximal therapeutic effects, several weeks of therapy may be required. The blood pressure lowering effects of captopril and thiazide-type diuretics are additive. In contrast, captopril and beta-blockers have a less than additive effect.

Blood pressure is lowered to about the same extent in both standing and supine positions. Orthostatic effects and tachycardia are infrequent but may occur in volume depleted patients. Abrupt withdrawal of CAPOTEN has not been associated with a rapid increase in blood pressure.

12.3 Pharmacokinetics

After oral administration of therapeutic doses of CAPOTEN, rapid absorption occurs with peak blood levels at about one hour. The presence of food in the gastrointestinal tract reduces absorption by about 30 to 40 percent; captopril therefore should be given one hour before meals. Based on carbon-14 labeling, average minimal absorption is approximately 75 percent. In a 24-hour period, over 95 percent of the absorbed dose is eliminated in the urine; 40 to 50 percent is unchanged drug; most of the remainder is the disulfide dimer of captopril and captopril-cysteine disulfide.

Approximately 25 to 30 percent of the circulating drug is bound to plasma proteins. The apparent elimination half-life for total radioactivity in blood is probably less than 3 hours. An accurate determination of half-life of unchanged captopril is not, at present, possible, but it is probably less than 2 hours. In patients with renal impairment, however, retention of captopril occurs (see DOSAGE AND ADMINISTRATION (2.6)).

Studies in rats and cats indicate that CAPOTEN does not cross the blood-brain barrier to any significant extent.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis and Impairment of Fertility

Two-year studies with doses of 50 to 1350 mg/kg/day in mice and rats failed to show any evidence of carcinogenic potential. The high dose in these studies is 150 times the maximum recommended human dose of 450 mg, assuming a 50-kg subject. On a body-surface-area basis, the high doses for mice and rats are 13 and 26 times the maximum recommended human dose, respectively.

Studies in rats have revealed no impairment of fertility.

13.2 Animal Toxicology

Chronic oral toxicity studies were conducted in rats (2 years), dogs (47 weeks; 1 year), mice (2 years), and monkeys (1 year). Significant drug-related toxicity included effects on hematopoiesis, renal toxicity, erosion/ulceration of the stomach, and variation of retinal blood vessels.

Reductions in hemoglobin and/or hematocrit values were seen in mice, rats, and monkeys at doses 50 to 150 times the maximum recommended human dose (MRHD) of 450 mg, assuming a 50-mg subject. On a body-surface-area, these doses are 5 to 25 times maximum recommended human dose (MRHD). Anemia, leukopenia, thrombocytopenia, and bone marrow suppression occurred in dogs at doses 8 to 30 times MRHD on a body-weight basis (4 to 15 times MRHD on a surface-area basis). The reductions in hemoglobin and hematocrit values in rats and mice were only significant at 1 year and returned to normal with continued dosing by the end of the study. Marked anemia was seen at all dose levels (8 to 30 times MRHD) in dogs, whereas moderate to marked leukopenia was noted only at 15 and 30 times MRHD and thrombocytopenia at 30 times MRHD. The anemia could be reversed upon discontinuation of dosing. Bone marrow suppression occurred to a varying degree, being associated only with dogs that died or were sacrificed in a moribund condition in the 1 year study. However, in the 47-week study at a dose 30 times MRHD, bone marrow suppression was found to be reversible upon continued drug administration.

Captopril caused hyperplasia of the juxtaglomerular apparatus of the kidneys in mice and rats at doses 7 to 200 times MRHD on a body-weight basis (0.6 to 35 times MRHD on a surface-area basis); in monkeys at 20 to 60 times MRHD on a body-weight basis (7 to 20 times MRHD on a surface-area

basis); and in dogs at 30 times MRHD on a body-weight basis (15 times MRHD on a surface-area basis).

Gastric erosions/ulcerations were increased in incidence in male rats at 20 to 200 times MRHD on a body-weight basis (3.5 and 35 times MRHD on a surface-area basis); in dogs at 30 times MRHD on a body-weight basis (15 times on MRHD on a surface-area basis); and in monkeys at 65 times MRHD on a body-weight basis (20 times MRHD on a surface-area basis). Rabbits developed gastric and intestinal ulcers when given oral doses approximately 30 times MRHD on a body-weight basis (10 times MRHD on a surface-area basis) for only 5 to 7 days.

In the two-year rat study, irreversible and progressive variations in the caliber of retinal vessels (focal sacculations and constrictions) occurred at all dose levels (7 to 200 times MRHD) on a body-weight basis; 1 to 35 times MRHD on a surface-area basis in a dose-related fashion. The effect was first observed in the 88th week of dosing, with a progressively increased incidence thereafter, even after cessation of dosing.

14 CLINICAL STUDIES

Congestive Heart Failure: In patients with heart failure, significantly decreased peripheral (systemic vascular) resistance and blood pressure (afterload), reduced pulmonary capillary wedge pressure (preload) and pulmonary vascular resistance, increased cardiac output, and increased exercise tolerance time (ETT) have been demonstrated. These hemodynamic and clinical effects occur after the first dose and appear to persist for the duration of therapy. Placebo controlled studies of 12 weeks duration in patients who did not respond adequately to diuretics and digitalis show no tolerance to beneficial effects on ETT; open studies, with exposure up to 18 months in some cases, also indicate that ETT benefit is maintained. Clinical improvement has been observed in some patients where acute hemodynamic effects were minimal.

Left Ventricular Dysfunction After Myocardial Infarction: The Survival and Ventricular Enlargement (SAVE) study was a multicenter, randomized, double-blind, placebo-controlled trial conducted in 2,231 patients (age 21-79 years) who survived the acute phase of a myocardial infarction and did not have active ischemia. Patients had left ventricular dysfunction (LVD), defined as a resting left ventricular ejection fraction $\leq 40\%$, but at the time of randomization were not sufficiently symptomatic to require ACE inhibitor therapy for heart failure. About half of the patients had had symptoms of heart failure in the past. Patients were given a test dose of 6.25 mg oral CAPOTEN (captopril) and were randomized within 3-16 days post-infarction to receive either CAPOTEN or placebo in addition to conventional therapy. CAPOTEN was initiated at 6.25 mg or 12.5 mg tid and after two weeks titrated to a target maintenance dose of 50 mg tid. About 80% of patients were receiving the target dose at the end of the study. Patients were followed for a minimum of two years and for up to five years, with an average follow-up of 3.5 years.

Baseline blood pressure was 113/70 mm Hg and 112/70 mm Hg for the placebo and CAPOTEN groups, respectively. Blood pressure increased slightly in both treatment groups during the study and was somewhat lower in the CAPOTEN group (119/74 vs. 125/77 mm Hg at 1 yr).

Therapy with CAPOTEN improved long-term survival and clinical outcomes compared to placebo. The risk reduction for all cause mortality was 19% ($P = 0.02$) and for cardiovascular death was 21% ($P = 0.014$). Captopril treated subjects had 22% ($P = 0.034$) fewer first hospitalizations for heart failure. Compared to placebo, 22% fewer patients receiving captopril developed symptoms of overt heart failure. There was no significant difference between groups in total hospitalizations for all cause (2056 placebo; 2036 captopril).

CAPOTEN was well tolerated in the presence of other therapies such as aspirin, beta blockers, nitrates, vasodilators, calcium antagonists and diuretics.

Diabetic Nephropathy: In a multicenter, double-blind, placebo controlled trial, 409 patients, age 18-49 of either gender, with or without hypertension, with type I (juvenile type, onset before age 30) insulin-dependent diabetes mellitus, retinopathy, proteinuria ≥ 500 mg per day and serum creatinine ≤ 2.5 mg/dL, were ran-

domized to placebo or CAPOTEN (25 mg tid) and followed for up to 4.8 years (median 3 years). To achieve blood pressure control, additional antihypertensive agents (diuretics, beta blockers, centrally acting agents or vasodilators) were added as needed for patients in both groups.

The CAPOTEN group had a 51% reduction in risk of doubling of serum creatinine ($P < 0.01$) and a 51% reduction in risk for the combined endpoint of end-stage renal disease (dialysis or transplantation) or death ($P < 0.01$). CAPOTEN treatment resulted in a 30% reduction in urine protein excretion within the first 3 months ($P < 0.05$), which was maintained throughout the trial. The CAPOTEN group had somewhat better blood pressure control than the placebo group, but the effects of CAPOTEN on renal function were greater than would be expected from the group differences in blood pressure reduction alone. CAPOTEN was well-tolerated in this patient population.

In two multicenter, double-blind, placebo controlled studies, a total of 235 normotensive patients with insulin-dependent diabetes mellitus, retinopathy and microalbuminuria (20-200 $\mu\text{g}/\text{min}$) were randomized to placebo or CAPOTEN (50 mg bid) and followed for up to 2 years. CAPOTEN delayed the progression to overt nephropathy (proteinuria ≥ 500 mg/day) in both studies (risk reduction 67% to 76%; $P < 0.05$). CAPOTEN also reduced the albumin excretion rate. However, the long term clinical benefit of reducing the progression from microalbuminuria to proteinuria has not been established.

P PATIENT COUNSELING INFORMATION

Patients should be advised to immediately report to their physician any signs or symptoms suggesting angioedema (e.g., swelling of face, eyes, lips, tongue, larynx and extremities; difficulty in swallowing or breathing; hoarseness) and to discontinue therapy. (See WARNINGS/PRECAUTIONS (5.1).)

Patients should be told to report promptly any indication of infection (e.g., sore throat, fever), which may be a sign of neutropenia, or of progressive edema which might be related to proteinuria and nephrotic syndrome.

All patients should be cautioned that excessive perspiration and dehydration may lead to an excessive fall in blood pressure because of reduction in fluid volume. Other causes of volume depletion such as vomiting or diarrhea may also lead to a fall in blood pressure; patients should be advised to consult with the physician.

Patients should be advised not to use potassium-sparing diuretics, potassium supplements or potassium-containing salt substitutes without consulting their physician. (See WARNINGS/PRECAUTIONS (5.8); DRUG INTERACTIONS (6.5); ADVERSE REACTIONS (8).)

Patients should be warned against interruption or discontinuation of medication unless instructed by the physician.

Heart failure patients on captopril therapy should be cautioned against rapid increases in physical activity.

Patients should be informed that CAPOTEN (captopril) should be taken one hour before meals (see DOSAGE AND ADMINISTRATION (2.1)).

Pregnancy. Female patients of childbearing age should be told about the consequences of second- and third-trimester exposure to ACE inhibitors, and they should also be told that these consequences do not appear to have resulted from intrauterine ACE-inhibitor exposure that has been limited to the first trimester. These patients should be asked to report pregnancies to their physicians as soon as possible.



Federal Register

**Friday,
December 22, 2000**

Part IV

Environmental Protection Agency

40 CFR Part 63

**National Emission Standards for
Hazardous Air Pollutants: Surface Coating
of Large Appliances; Proposed Rule**

ENVIRONMENTAL PROTECTION AGENCY**40 CFR Part 63**

[FRL-6917-3]

RIN 2060-AG34

National Emission Standards for Hazardous Air Pollutants: Surface Coating of Large Appliances**AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Proposed rule.

SUMMARY: This action proposes national emission standards for hazardous air pollutants (NESHAP) for large appliance surface coating operations located at major sources of hazardous air pollutants (HAP). These proposed standards would implement section 112(d) of the Clean Air Act (CAA) by requiring these operations to meet HAP emission standards reflecting the application of the maximum achievable control technology (MACT). The HAP emitted by these operations include ethylbenzene, glycol ethers (including 2-butoxyethanol), hexane, methylene chloride, 4,4'-methylene diphenyl diisocyanate, methyl ethyl ketone, methyl isobutyl ketone, toluene, and xylene. Exposure to these substances has been demonstrated to cause adverse health effects such as irritation of the lung, eye, and mucus membranes, asthma, effects on the central nervous system, and cancer. In general, these findings have only been shown with concentrations higher than those typically in the ambient air. The adverse health effects associated with the exposure to these specific HAP are further described in the docket for this rulemaking. The proposed standards would reduce nationwide HAP emissions from major sources by approximately 45 percent.

DATES: *Comments.* Submit comments on or before February 20, 2001.

Public Hearing. If anyone contacts the EPA requesting to speak at a public hearing, they should do so by January 11, 2001. If requested, a public hearing will be held within approximately 30 days following publication of this notice in the **Federal Register**.

ADDRESSES: *Comments.* By U.S. Postal Service, send comments (in duplicate if possible) to: Air and Radiation Docket and Information Center (6102), Attention Docket Number A-97-41, U.S. EPA, 1200 Pennsylvania Avenue, NW, Washington, DC 20460. In person or by courier, deliver comments (in duplicate if possible) to: Air and Radiation docket and Information

Center (6102), Attention Docket Number A-97-41, U.S. EPA, 401 M Street, SW, Room M-1500, Washington, DC 20460. The EPA requests a separate copy also be sent to the contact person listed in **FOR FURTHER INFORMATION CONTACT**.

Public Hearing. If a public hearing is held, it will be held at our Office of Administration auditorium in Research Triangle Park, North Carolina. You should contact Ms. Janet Eck, Coatings and Consumer Products Group, Emission Standards Division (MD-13), U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711, telephone number (919) 541-7946, to request to speak at a public hearing or to find out if a hearing will be held.

Docket. Docket No. A-97-41 contains supporting information used in developing the proposed standards. The docket is located at the U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460 in Room M-1500, Waterside Mall (ground floor), and may be inspected from 8:30 a.m. to 5:30 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: Dr. Mohamed Serageldin, Coatings and Consumer Products Group, Emission Standards Division (MD-13), U.S. Environmental Protection Agency, Research Triangle Park, NC 27711; telephone number (919) 541-2379; facsimile number (919) 541-5689; electronic mail (e-mail) address: serageldin.mohamed@epa.gov.

SUPPLEMENTARY INFORMATION:

Comments. Comments and data may be submitted by e-mail to: a-and-r-docket@epa.gov. Electronic comments must be submitted as an ASCII file to avoid the use of special characters and encryption problems and will also be accepted on disks in WordPerfect® version 5.1, 6.1, or Corel 8 file format. All comments and data submitted in electronic form must note the docket number: A-97-41. No confidential business information (CBI) should be submitted by e-mail. Electronic comments may be filed online at many Federal Depository Libraries.

Commenters wishing to submit proprietary information for consideration must clearly distinguish such information from other comments and clearly label it as CBI. Send submissions containing such proprietary information directly to the following address, and not to the public docket, to ensure that proprietary information is not inadvertently placed in the docket: Dr. Mohamed Serageldin, c/o OAQPS Document Control Officer (Room 740B), U.S. Environmental

Protection Agency, 411 W. Chapel Hill Street, Durham NC 27701. The EPA will disclose information identified as CBI only to the extent allowed by the procedures set forth in 40 CFR part 2. If no claim of confidentiality accompanies a submission when it is received by EPA, the information may be made available to the public without further notice to the commenter.

Public Hearing. Persons interested in presenting oral testimony or inquiring as to whether a hearing is to be held should contact Ms. Janet Eck, Coatings and Consumer Products Group, Emission Standards Division (MD-13), U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711; telephone number (919) 541-7946 at least 2 days in advance of the public hearing. Persons interested in attending the public hearing should also contact Ms. Eck to verify the time, date, and location of the hearing. The public hearing will provide interested parties the opportunity to present data, views, or arguments concerning these proposed emission standards.

Docket. The docket is an organized and complete file of all the information considered by EPA in the development of this rulemaking. The docket is a dynamic file because material is added throughout the rulemaking process. The docketing system is intended to allow members of the public and industries involved to readily identify and locate documents so that they can effectively participate in the rulemaking process. Along with the proposed and promulgated standards and their preambles, the contents of the docket will serve as the record in the case of judicial review. (See section 307(d)(7)(A) of the CAA.) The regulatory text and other materials related to this rulemaking are available for review in the docket or copies may be mailed on request from the Air and Radiation Docket and Information Center by calling (202) 260-7548. A reasonable fee may be charged for copying docket materials.

World Wide Web (WWW). In addition to being available in the docket, an electronic copy of this proposed rule is also available on the WWW through the Technology Transfer Network (TTN). Following signature, a copy of the proposed rule will be posted on the TTN's policy and guidance page for newly proposed or promulgated rules at <http://www.epa.gov/ttn/oarpg>. The TTN provides information and technology exchange in various areas of air pollution control. If more information regarding the TTN is needed, call the TTN HELP line at (919) 541-5384.

Regulated Entities. The proposed source category definition includes facilities that apply coatings to large appliances or components of large appliances. In general, facilities that coat large appliances are covered under the Standard Industrial Classification

(SIC) and North American Industrial Classification System (NAICS) codes listed in the following table. However, facilities classified under other SIC or NAICS codes may be subject to the proposed standards if they meet the applicability criteria. Not all facilities

classified under the SIC and NAICS codes in the following table will be subject to the proposed standards because some of the classifications cover products outside the scope of the NESHAP for large appliances.

Product description	1987 SIC code	Equivalent 1997 NAICS code(s)	Equivalent 1997 NAICS product description
Household Cooking Equipment	3631	335221	Household Cooking Appliance Manufacturing.
Household Refrigerators and Home and Farm Freezers	3632	335222	Household Refrigerator and Home Freezer Manufacturing.
Household Laundry Equipment	3633	335224	Household Laundry Equipment Manufacturing.
Household Appliances; not elsewhere classified	3639	335228	Other Major Household Appliance Manufacturing.
Floor Waxing and Floor Polishing Machines	3639	335212	Household Vacuum Cleaner Manufacturing.
Air Conditioning and Warm Air Heating Equipment and Commercial Industrial Refrigeration Equipment.	3585	333415	Air Conditioning and Warm Air Heating Equipment and Commercial Industrial Refrigeration Equipment Manufacturing.
Motor Vehicle Air Conditioning	3585	336391	Motor Vehicle Air Conditioning Manufacturing.
Service Industry Machinery; not elsewhere classified ...	3589	333319	Other Commercial and Service Industry Machinery Manufacturing.

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be regulated by this action. To determine whether your coating operation is regulated by this action, you should examine the applicability criteria in § 63.4081 of the proposed rule.

If you have any questions regarding the applicability of this action to a particular entity, consult the person listed in the preceding **FOR FURTHER INFORMATION CONTACT** section.

Outline. The information presented in this preamble is organized as follows:

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 - B. What criteria are used in the development of NESHAP?
 - C. What are the health effects associated with HAP emissions from the surface coating of large appliances?
- #### II. Summary of the Proposed Rule
- A. What source categories are affected by this proposed rule?
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 - E. What are the emission limits, operating limits, and other standards?
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- A. How did we select the source category?
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E. Unfunded Mandates Reform Act of 1995

F. Regulatory Flexibility Act (RFA), as Amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), 5 U.S.C. 601, *et seq.*

G. Paperwork Reduction Act

H. National Technology Transfer and Advancement Act

I. Background

A. What Is the Source of Authority for Development of NESHAP?

Section 112 of the CAA requires us to list categories and subcategories of major sources and area sources of HAP and to establish NESHAP for the listed source categories and subcategories. The Large Appliance (Surface Coating) category of major sources was listed on July 16, 1992 (57 FR 31576) under the Surface Coating Processes industry

group. Major sources of HAP are those that emit or have the potential to emit equal to, or greater than, 10 tons per year (tpy) of any one HAP or 25 tpy of any combination of HAP.

B. What Criteria Are Used in the Development of NESHAP?

Section 112 of the CAA requires that we establish NESHAP for the control of HAP from both new and existing major sources. The CAA requires the NESHAP to reflect the maximum degree of reduction in emissions of HAP that is achievable. This level of control is commonly referred to as the MACT.

The MACT floor is the minimum control level allowed for NESHAP and is defined under section 112(d)(3) of the CAA. In essence, the MACT floor ensures that the standard is set at a level that assures that all major sources achieve the level of control at least as stringent as that already achieved by the better-controlled and lower-emitting sources in each source category or subcategory. For new sources, the MACT floor cannot be less stringent than the emission control that is achieved in practice by the best-controlled similar source. The MACT standards for existing sources can be less stringent than standards for new sources, but they cannot be less stringent than the average emission limitation achieved by the best-performing 12 percent of existing sources in the category or subcategory (or the best-performing five sources for categories or subcategories with fewer than 30 sources).

In developing MACT, we also consider control options that are more stringent than the floor. We may establish standards more stringent than

the floor based on the consideration of the cost of achieving the emission reductions, any non-air quality health and environmental impacts, and energy requirements.

C. What Are the Health Effects Associated With HAP Emissions From the Surface Coating of Large Appliances?

The HAP emitted from the surface coating of large appliances include ethylbenzene, glycol ethers (including 2-butoxyethanol), hexane, methylene chloride, 4,4'-methylene diphenyl diisocyanate, methyl ethyl ketone, methyl isobutyl ketone, toluene, and xylene. These compounds account for over 80 percent of the nationwide HAP emissions from this source category. The HAP that would be controlled with this proposed rule are associated with a variety of adverse health effects. These adverse health effects include chronic health disorders (e.g., irritation of the lung, eyes, and mucus membranes and effects on the central nervous system), and acute health disorders (e.g., lung irritation and congestion, alimentary effects such as nausea and vomiting, and effects on the central nervous system). The EPA has classified one of the HAP (methylene chloride) as a probable human carcinogen.

We do not have the type of current detailed data on each of the facilities covered by the emission standards for this source category, and the people living around the facilities, that would be necessary to conduct an analysis to determine the actual population exposures to the HAP emitted from these facilities and potential for resultant health effects. Therefore, we do not know the extent to which the adverse health effects described above occur in the populations surrounding these facilities. However, to the extent the adverse effects do occur, the proposed rule would reduce emissions and subsequent exposures.

II. Summary of the Proposed Rule

A. What Source Categories Are Affected by This Proposed rule?

The proposed rule would apply to you if you own or operate a large appliance surface coating facility that is a major source, or is located at a major source, or is part of a major source of HAP emissions. We have defined a large appliance surface coating facility as any facility engaged in the surface coating of any large appliance part or product.

You would not be subject to the proposed rule if your large appliance surface coating facility is located at an area source. An area source of HAP is

any facility that has the potential to emit HAP but is not a major source. You may establish area source status by limiting the source's potential to emit HAP through appropriate mechanisms available through your permitting authority.

The source category does not include research or laboratory facilities or janitorial, building, and facility maintenance operations. The source category also does not include coating applications using handheld nonrefillable aerosol containers.

B. What Is the Relationship to Other Rules?

Affected sources subject to the proposed rule may also be subject to other rules. We specifically request comments on how monitoring, recordkeeping, and reporting requirements can be consolidated for sources that are subject to more than one rule.

New Source Performance Standards—40 CFR Part 60, Subpart SS. The new source performance standards (NSPS) for large appliances apply to facilities that apply organic coatings to large appliances and that began construction, reconstruction, or modification after October 27, 1982. The pollutants regulated are volatile organic compounds (VOC). Emissions of VOC are limited to 0.9 kilogram HAP per liter (kg HAP/liter) of coating solids applied (7.52 pounds per gallon (lbs/gal)), and the affected source is each individual coating operation.

The proposed rule differs from the NSPS in three ways. First, the affected source for the proposed rule is defined broadly as the collection of all coating operations and related activities and equipment at the facility, whereas the affected facility for the NSPS is defined narrowly as each individual coating operation. The broader definition of an affected source allows a facility's emissions to be combined for compliance purposes. Second, the proposed rule regulates organic HAP. While most organic HAP emitted from large appliance surface coating operations are VOC, some VOC are not listed as HAP, and, therefore, the NSPS regulates a broader range of pollutants than the proposed NESHAP.

Third, the HAP emission limitations in the proposed rule are based on the amount of coating solids used at the affected source. The VOC limitations in the NSPS are based on the amount of coating solids actually applied to the large appliances, which necessitates estimates of transfer efficiency in the compliance calculations.

Because of the differences between the two rules, compliance with either rule cannot be deemed compliance with the other. A large appliance surface coating operation that meets the applicability requirements of both rules must comply with both. Overlapping reporting, recordkeeping, and monitoring requirements may be resolved through your title V permit.

Future national emission standards for the surface coating of miscellaneous metal parts and products. Large appliances often contain parts, such as metal handles, hinges, and fasteners, that have a wider use beyond large appliances. The coating of such metal parts would be subject to the proposed rule if the coating takes place at a facility that coats other large appliance parts or products; otherwise, the coating operation would be subject to the future NESHAP for the surface coating of miscellaneous metal parts and products.

Future national emission standards for the surface coating of plastic parts and products. Plastic parts and products may be components (e.g., plastic handles) of large appliances. The coating of such plastic parts would be subject to the proposed rule if the coating takes place at a facility that coats other large appliance parts or products; otherwise, the coating operation would be subject to the future NESHAP for the surface coating of plastic parts and products.

C. What Are the Primary Sources of Emissions and What Are the Emissions?

HAP Emission Sources. Emissions from coating applications account for approximately 80 percent of the HAP emissions from large appliance surface coating operations. The remaining emissions are primarily from cleaning operations. In most cases, HAP emissions from mixing and storage are relatively small. The organic HAP emissions associated with coatings (the term "coatings" includes protective and decorative coatings as well as adhesives) occur at several points. Coatings are most often applied either by using a spray gun in a spray booth or by dipping the substrate in a tank containing the coating. In a spray booth, volatile components evaporate from the coating as it is applied to the part and from the overspray. The coated part then passes through an open (flash-off) area where additional volatiles evaporate from the coating. Finally, the coated part passes through a drying/curing oven, or is allowed to air dry, where the remaining volatiles are evaporated.

Organic HAP emissions also occur from the activities undertaken during cleaning operations, where solvent is

used to remove coating residue or other unwanted materials. Cleaning in this industry includes cleaning of spray guns and transfer lines (e.g., tubing or piping), tanks, and the interior of spray booths. Cleaning also includes applying solvents to manufactured parts prior to coating application and to equipment (e.g., surface coating operations, cleaning rollers, pumps, conveyors, etc.).

Mixing and Storage. Organic HAP emissions can also occur from displacement of organic vapor-laden air in containers used to store HAP solvents or to mix coatings containing HAP solvents. The displacement of vapor-laden air can occur during the filling of containers and can be caused by changes in temperature or barometric pressure, or by agitation during mixing.

Organic HAP. Available emission data collected during the development of the proposed NESHAP show that the primary organic HAP emitted from the surface coating of large appliances include xylene, glycol ethers, toluene, methylene diphenyl diisocyanate, and methyl ethyl ketone. These compounds account for approximately 82 percent of this category's nationwide organic HAP emissions. Other significant organic HAP identified include methyl isobutyl ketone, hexane, and methylene chloride.

Inorganic HAP. Based on information reported in survey responses during the development of the proposed NESHAP, inorganic HAP, including chromium, cobalt, lead, and manganese compounds, are components of some specialty coatings used by this source category. No inorganic HAP were reported in cleaning materials. Most of the inorganic HAP components remain as solids in the dry coating film on the parts being coated or are deposited onto the walls, floor, and grates of the spray booths in which they are applied. Some of the inorganic HAP particles are entrained in the spray booth exhaust air. Spray booths in the large appliance industry typically have either water curtains or dry filters to remove overspray particles. Therefore, inorganic HAP emission levels are expected to be very low, and have not been quantified.

D. What Is the Affected Source?

We define an affected source as a stationary source, a group of stationary sources, or part of a stationary source to which a specific emission standard applies. The proposed standards define the affected source as the collection of all operations associated with the surface coating of large appliances or parts of large appliances. These operations include preparation of a coating for application (e.g., mixing with thinners); surface preparation of

the large appliances or part; coating application and flash-off; drying and/or curing of applied coatings; cleaning of equipment used in surface coating; storage of coatings, thinners, and cleaning materials; and handling and conveyance of waste materials from the surface coating operations.

E. What Are the Emission Limits, Operating Limits, and Other Standards?

We are proposing standards that would limit HAP emissions from the surface coating of large appliances. The proposed standards include emission limits and operating limits.

Emission Limits. We are proposing to limit organic HAP emissions from each new and reconstructed affected source to no more than 0.022 kg HAP/liter of coating solids used (0.18 lb/gal) in each monthly compliance period. The proposed limit for each existing affected source is 0.13 kg HAP/liter used (1.1 lb/gal). You can choose from several compliance options in the proposed rule to achieve the emission limits. You could comply by applying materials (coatings, thinners, and cleaning materials) that meet the emission limits, either individually or collectively, during each monthly compliance period. You could also use a capture system and add-on control device to meet the emission limits. You could also comply by using a combination of both approaches.

Operating Limits. If you reduce emissions by using a capture system and add-on control device (other than a solvent recovery system for which you conduct a liquid-liquid material balance), the proposed operating limits would apply to you. These limits are site-specific parameter limits that you determine during the initial performance test of the system. For capture systems that are not permanent total enclosures, you would establish average volumetric flow rates or duct static pressure limits for each capture device (or enclosure) in each capture system. For capture systems that are permanent total enclosures, you would establish limits on average facial velocity or pressure drop across openings in the enclosure.

For oxidizers, you would monitor the combustion temperature (for thermal oxidizers) or the temperature immediately before and after the catalyst bed (for catalytic oxidizers). For carbon adsorbers for which you do not conduct a liquid-liquid material balance, you would monitor the carbon bed temperature and the amount of steam or nitrogen used to desorb the bed. For condensers, you would monitor

the outlet gas temperature from the condenser.

The site-specific parameter limits that you establish must reflect operation of the capture system and control devices during a performance test that demonstrates achievement of the emission limits during representative operating conditions.

General Provisions. The General Provisions (40 CFR part 63, subpart A) also would apply to you as indicated in the proposed rule. The General Provisions codify certain procedures and criteria for all 40 CFR part 63 NESHAP. The General Provisions contain administrative procedures, preconstruction review procedures for new sources, and procedures for conducting compliance-related activities such as notifications, reporting and recordkeeping, performance testing, and monitoring. The proposed rule refers to individual sections of the General Provisions to emphasize key sections that are relevant. However, unless specifically overridden in the proposed rule, all of the applicable General Provisions requirements would apply to you.

F. What Are the Testing and Initial Compliance Requirements?

Compliance Dates. Existing affected sources would have to be in compliance with the final standards no later than [Date 3 years after the date the final rule is published in the **Federal Register**]. New and reconstructed sources would have to be in compliance upon startup of the affected source or no later than [Date the final rule is published in the **Federal Register**], whichever is later.

The proposed initial compliance period begins on the compliance date and ends on the last day of the first full calendar month following the compliance date; except that for new and reconstructed sources required to conduct performance tests, the initial compliance period ends on the last day of the first full calendar month following the performance test if the performance test is conducted later than the compliance date (the proposed rule allows the test to be conducted up to 180 days later). Being "in compliance" means that the owner or operator of the affected source meets the requirements to achieve the proposed emission limitations by the end of the initial compliance period. At the end of the initial compliance period, the owner or operator would use the data and records generated to determine whether or not the affected source is in compliance for that period. If the affected source does not meet the applicable limits and other

requirements, it is out of compliance for the entire initial compliance period.

Emission Limits. There are several proposed options for complying with the proposed emission limits, and the testing and initial compliance requirements vary accordingly.

Option 1: Compliance based on materials used in the affected source

If you demonstrate compliance based on the materials used, you would determine the mass of organic HAP and the volume fraction of coating solids in all materials used during the compliance period.

To determine the mass of organic HAP in coatings, thinners, and cleaning materials and the volume fraction of coating solids, you could either rely on manufacturer's data or on results from the test methods listed below. You may use alternative test methods provided you get EPA approval in accordance with the NESHAP General Provisions, 40 CFR 63.7(f). However, if there is any inconsistency between the test method results (either EPA's or an approved alternative) and manufacturer's data, the test method results would prevail for compliance and enforcement purposes.

- For organic HAP content, use Method 311 of 40 CFR part 63, appendix A;

- The proposed rule allows you to use non-aqueous volatile matter as a surrogate for organic HAP, which would include all organic HAP plus all other organic compounds, and excluding water. If you choose this option, use Method 24 of 40 CFR part 60, appendix A; and

- For volume fraction of coating solids, use either Equation 1 in § 63.4141 of the proposed rule, ASTM Method D2697-86 (1998), or ASTM Method D6093-97.

To demonstrate initial compliance based on the materials used, you would be required to demonstrate that either the organic HAP content of each coating meets the emission limits and that you use no organic HAP-containing thinners or cleaning materials, or that the total mass of organic HAP in all coatings, thinners, and cleaning materials divided by the total volume of coating solids meets the emission limits. For the latter option, you would be required to:

- Determine the quantity of each coating, thinner, and cleaning material used.

- Determine the mass of organic HAP in each coating, thinner, and cleaning material.

- Determine the volume fraction of coating solids for each coating.

- Calculate the total mass of organic HAP in all materials and total volume of coating solids for the compliance

period. You may subtract from the total mass of organic HAP the amount contained in waste materials you send to a hazardous waste treatment, storage, and disposal facility regulated under 40 CFR part 262, 264, 265, or 266.

- Calculate the ratio of the total mass of organic HAP for the materials used to the total volume of coating solids used.

- Record the calculations and results and include them in your Notification of Compliance Status.

Option 2: Compliance based on using a capture system and add-on control device

If you use a capture system and add-on control device, other than a solvent recovery system for which you conduct a liquid-liquid material balance, your testing and initial compliance requirements are as follows:

- Conduct an initial performance test to determine the capture and control efficiencies of the equipment and to establish operating limits to be achieved on a continuous basis. The performance test would have to be completed no later than the compliance date for existing sources and 180 days after the compliance date for new and reconstructed sources. You would also need to schedule it in time to obtain the results for use in completing your compliance determination for the initial compliance period.

- Determine the mass of organic HAP in each material and the volume fraction of coating solids for each coating used during the initial compliance period.

- Calculate the organic HAP emissions from the controlled coating operations using the capture and control efficiencies determined during the performance test and the total mass of organic HAP in materials used in controlled coating operations.

- Calculate the ratio of the total mass of HAP emissions to the total volume of coating solids used during the initial compliance period.

- Record the calculations and results and include them in your Notification of Compliance Status.

If you use a capture system and add-on control device, other than a solvent recovery system for which you conduct liquid-liquid material balances, you would determine both the efficiency of the capture system and the emission reduction efficiency of the control device. To determine the capture efficiency, you would either verify the presence of a permanent total enclosure using EPA Method 204 of 40 CFR part 51, appendix M (and all materials must be applied and dried within the enclosure); or use one of three protocols in § 63.4165 to measure capture efficiency. If you have a permanent total

enclosure and all materials are applied and dried within the enclosure and you route all exhaust gases from the enclosure to a control device, you would assume 100 percent capture.

To determine the emission reduction efficiency of the control device, you would conduct measurements of the inlet and outlet gas streams. The test would consist of three runs, each run lasting 1 hour, using the following EPA Methods in 40 CFR part 60, appendix A:

- Method 1 or 1A for selection of the sampling sites.

- Method 2, 2A, 2C, 2D, 2F, or 2G to determine the gas volumetric flow rate.

- Method 3, 3A, or 3B for gas analysis to determine dry molecular weight.

- Method 4 to determine stack moisture.

- Method 25 or 25A to determine organic volatile matter concentration.

Alternatively, any other test method or data that have been validated according to the applicable procedures in Method 301 of 40 CFR part 63, appendix A, and approved by the Administrator, could be used.

If you use a solvent recovery system, you could determine the overall control efficiency using a liquid-liquid material balance instead of conducting an initial performance test. If you use the material balance alternative, you would be required to measure the amount of all materials used in the affected source during the compliance period and determine the total volatile matter contained in these materials. You would also measure the amount of volatile matter recovered by the solvent recovery system during the compliance period. Then you would compare the amount recovered to the amount used to determine the overall control efficiency, and apply this efficiency to the organic HAP-to-coating solids ratio for the materials used. You would record the calculations and results and include them in your Notification of Compliance Status.

Operating Limits. As mentioned above, you would establish operating limits as part of the initial performance test of a capture system and control device, other than a solvent recovery system for which you conduct liquid-liquid material balances. The operating limits are the minimum or maximum (as applicable) values achieved for capture systems and control devices during the most recent performance test that demonstrated compliance with the emission limits. If you operate your capture system and control device at different sets of representative operating conditions, you must establish operating limits for the parameters for each different operating condition.

The proposed rule specifies the parameters to monitor for the types of emission control systems commonly used in the industry. You would be required to install, calibrate, maintain, and continuously operate all monitoring equipment according to manufacturer's specifications and ensure that the continuous parameter monitoring systems (CPMS) meet the requirements in § 63.4168 of the proposed rule. If you use control devices other than those identified in the proposed rule, you would submit the operating parameters to be monitored to the Administrator for approval. The authority to approve the parameters to be monitored is retained by EPA and is not delegated to States.

If you use a thermal or catalytic oxidizer, you would continuously monitor the appropriate temperature and record it at least every 15 minutes. For thermal oxidizers, the temperature monitor is placed in the firebox or in the duct immediately downstream of the firebox before any substantial heat exchange occurs. The operating limit would be the average temperature measured during the performance test, and for each consecutive 3-hour period the average temperature would have to be at or above this limit. For catalytic oxidizers, temperature monitors are placed immediately before and after the catalyst bed. The operating limits would be the average temperature just before the catalyst bed and the average temperature difference across the catalyst bed during the performance test, and for each 3-hour period the average temperature and the average temperature difference would have to be at or above these limits.

If you use a carbon adsorber and do not conduct liquid-liquid material balances to demonstrate compliance, you would monitor the carbon bed temperature after each regeneration and the total amount of steam or nitrogen used to desorb the bed for each regeneration. The operating limits would be the carbon bed temperature (not to be exceeded) and the amount of steam or nitrogen used for desorption (to be met as a minimum).

If you use a condenser, you would monitor the outlet gas temperature to ensure that the air stream is being cooled to a low enough temperature. The operating limit would be the average condenser outlet gas temperature measured during the performance test, and for each consecutive 3-hour period the average temperature would have to be at or below this limit.

For each capture system that is not a permanent total enclosure, you would establish operating limits for gas

volumetric flow rate or duct static pressure for each enclosure or capture device. The operating limit would be the average volumetric flow rate or duct static pressure during the performance test, to be met as a minimum. For each capture system that is a permanent total enclosure, the operating limit would require the average facial velocity of air through all natural draft openings to be at least 200 feet per minute or the pressure drop across the enclosure to be at least 0.007 inches water.

G. What Are the Continuous Compliance Provisions?

Emission Limits. If you demonstrate compliance with the proposed emission limits based on the materials used, you would demonstrate continuous compliance if, for each monthly compliance period, the ratio of organic HAP to coating solids is less than or equal to the emission limits. You would follow the same procedures for calculating the organic HAP to coating solids ratio that you used for the initial compliance period.

For each coating operation on which you use a capture system and control device, other than solvent recovery for which you conduct a liquid-liquid material balance, you would use the continuous parameter monitoring results for the month in determining the mass of organic HAP emissions. If the monitoring results indicate no deviations from the operating limits and there were no bypasses of the control device, you would assume the capture system and control device are achieving the same percent emission reduction efficiency as they did during the most recent performance test in which compliance was demonstrated. You would then apply this percent reduction to the total mass of organic HAP in materials used in controlled coating operations to determine the monthly emission rate from those operations. If there were any deviations from the operating limits during the month or any bypasses of the control device, you would account for them in the calculation of the monthly emission rate by assuming the capture system and control device were achieving zero emission reduction during the periods of deviation.

For each coating operation on which you use a solvent recovery system and conduct a liquid-liquid material balance each month, you would use the liquid-liquid material balance to determine control efficiency. To determine the overall control efficiency, you must measure the amount of all materials used during each month and determine the volatile matter content of these

materials. You must also measure the amount of volatile matter recovered by the solvent recovery system during the month, calculate the overall control efficiency, and apply it to the total mass of organic HAP in the materials used to determine total organic HAP emissions.

Operating Limits. If you use a capture system and control device, the proposed rule would require you to achieve on a continuous basis the operating limits you establish during the performance test. If the continuous monitoring shows that the capture system and control device are operating outside the range of values established during the performance test, you have deviated from the established operating limits.

If you operate a capture system and control device that allow emissions to bypass the control device, you would have to demonstrate that HAP emissions from each emission point within the affected source are being routed to the control device by monitoring for potential bypass of the control device. You may choose from the following four monitoring procedures:

- Flow control position indicator to provide a record of whether the exhaust stream is directed to the control device;
- Car-seal or lock-and-key valve closures to secure the bypass line valve in the closed position when the control device is operating;
- Valve closure continuous monitoring to ensure any bypass line valve or damper is closed when the control device is operating; or
- Automatic shutdown system to stop the coating operation when flow is diverted from the control device.

If the bypass monitoring procedures indicate that emissions are not routed to the control device, you have deviated from the emission limits.

Operations During Startup, Shutdown, and Malfunction. If you use a capture system and control device for compliance, you would be required to develop and operate according to a startup, shutdown, and malfunction plan during periods of startup, shutdown, and malfunction of the capture system and control device.

Emissions Reductions Plan for Mixing, Storage, and Waste Handling. If you use a capture system and add-on control device for compliance, you would be required to develop and operate according to a plan for reducing emissions from mixing operations, storage tanks or other containers, and waste handling operations. This plan would include a description of all steps taken to minimize emissions from these sources (e.g., using closed storage containers practices to minimize emissions during filling and transfer of

contents from containers, using spill minimization techniques, placing solvent-laden cloth in closed containers immediately after use, *etc.*). If you do not develop a plan for reducing HAP emissions or you do not implement the plan, this would be a deviation from the work practice standard. You would have to make the emissions reductions plan available for inspection if the Administrator requests to see it. Under the option where emissions are reduced by using lower-HAP or no-HAP materials, we are assuming that all the HAP in the materials entering the affected source are volatilized (emitted), unless the facility can show that a portion of the HAP released is recovered. Therefore, emissions from operations occurring within the affected source (*e.g.*, mixing operations) are accounted for in the estimate of total materials usage at the affected source. However, when you comply by using capture systems and add-on control devices, these systems and control devices may not be associated with some operations within the affected source, such as the mixing, storage, and waste handling operations. An emissions reductions plan is needed to assure that emissions are reduced from those uncontrolled operations using best available practices. When the plan is instituted as a work practice, it should provide a level of quality control and assurance.

H. What Are the Notification, Recordkeeping, and Reporting Requirements?

You are required to comply with the applicable requirements in the NESHAP General Provisions, subpart A of 40 CFR part 63, as described in the proposed rule. The General Provisions notification requirements include: initial notifications, notification of performance test if you are complying using a capture system and control device, notification of compliance status, and additional notifications required for affected sources with continuous monitoring systems. The General Provisions also require certain records and periodic reports.

Initial Notifications. If the proposed standards apply to you, you must send a notification to the EPA Regional Office in the region where your facility is located, and to your State agency, at least 1 year before the compliance date for existing sources and within 120 days after the date of initial startup for new and reconstructed sources, or 120 days after publication of the final rule, whichever is later. That report notifies us and your State agency that you have an existing facility that is subject to the

proposed standards or that you have constructed a new facility. Thus, it allows you and the permitting authority to plan for compliance activities. You would also need to send a notification of planned construction or reconstruction of a source that would be subject to the proposed rule and apply for approval to construct or reconstruct.

Notification of Performance Test. If you demonstrate compliance by using a capture system and control device for which you do not conduct a liquid-liquid material balance, you would conduct a performance test. The performance test would be required no later than the compliance date for an existing affected source, and no later than 180 days after startup or 180 days after publication of the final rule, whichever is later, for a new or reconstructed source. You must notify us (or the delegated State or local agency) at least 60 calendar days before the performance test is scheduled to begin, as indicated in the General Provisions for the NESHAP.

Notification of Compliance Status. Your compliance procedures would depend on which compliance option you choose. For each compliance option, you would send us a Notification of Compliance Status within 30 days after the end of the initial compliance period. In the notification, you would certify whether the affected source has complied with the proposed standards, identify the option(s) you used to demonstrate initial compliance, summarize the data and calculations supporting the compliance demonstration, and describe how you will determine continuous compliance.

If you elect to comply by using a capture system and control device for which you conduct performance tests, you must provide the results of the tests. Your notification would also include the measured range of each monitored parameter and the operating limits established during the performance test, and information showing whether the source has complied with its operating limits during the initial compliance period.

Recordkeeping Requirements. You would be required to keep records of reported information and all other information necessary to document compliance with the proposed rule for 5 years. As required under the General Provisions, records for the 2 most recent years must be kept on-site; the other 3 years' records may be kept off-site. Records pertaining to the design and operation of the control and monitoring equipment must be kept for the life of the equipment.

Depending on the compliance option that you choose, you may need to keep records of the following:

- Organic HAP content, volatile matter content, coating solids content, and quantity of the coatings, thinners, and cleaning materials used during each compliance period; and
- All documentation supporting initial notifications and notifications of compliance status.

If you demonstrate compliance by using a capture system and control device, you would also need to keep records of the following:

- The occurrence and duration of each startup, shutdown, or malfunction of the emission capture system and control device;
- All maintenance performed on the capture system and control device;
- Actions taken during startup, shutdown, and malfunction that are different from the procedures specified in the affected source's startup, shutdown, and malfunction plan;
- All information necessary to demonstrate conformance with the affected source's startup, shutdown, and malfunction plan when the plan procedures are followed;
- All information necessary to demonstrate conformance with the affected source's plan for minimizing emissions from mixing, storage, and waste handling operations;
- Each period during which a CPMS is malfunctioning or inoperative (including out-of-control periods);
- All required measurements needed to demonstrate compliance with the standards; and
- All results of performance tests.

The proposed rule would require you to collect and keep records according to certain minimum data requirements for the CPMS. Failure to collect and keep the specified minimum data would be a deviation that is separate from any emission limits, operating limits, or work practice standards.

Deviations, as determined from these records, would need to be recorded and also reported. A deviation is any instance when any requirement or obligation established by the proposed rule including, but not limited to, the emission limits, operating limits, and work practice standards, is not met.

If you use a capture system and control device to reduce HAP emissions, you would have to make your startup, shutdown, and malfunction plan available for inspection if the Administrator requests to see it. It would stay in your records for the life of the affected source or until the source is no longer subject to the proposed standards. If you revise the plan, you

would need to keep the previous superseded versions on record for 5 years following the revision.

Periodic Reports. Each reporting year is divided into two semiannual reporting periods. If no deviations occur during a semiannual reporting period, you would submit a semiannual report stating that the affected source has been in continuous compliance. If deviations occur, you would include them in the report as follows:

- Report each deviation from the monthly emission limit.
- If you are complying by using a thermal oxidizer, report all times when a consecutive 3-hour average temperature is below the operating limit.
- If you are complying by using a catalytic oxidizer, report all times when a consecutive 3-hour average temperature difference across the catalyst bed is below the operating limit, and also report all times when a 3-hour average temperature before the catalyst bed is below the operating limit.
- If you are complying by using oxidizers, or solvent recovery systems where liquid-liquid material balances are not conducted, report all times when the value of the site-specific operating parameter used to monitor the capture system performance was less than the operating limit established for the capture system.
- If you are complying by using a carbon adsorber for which you do not conduct liquid-liquid material balances, report all times when the steam or nitrogen flow is less than the operating limit and also report all times when the carbon bed temperature is more than the operating limit.
- If you are complying by using a condenser, report all times when a 3-hour average outlet temperature is higher than the operating limit.
- If your capture system contains bypass lines that could divert emissions from the control device to the atmosphere, report all times when emissions were not routed to the control device.
- Report other specific information on the periods of time the deviations occurred.

You would also have to include an explanation in each semiannual report if a change occurs that might affect the compliance status of the affected source, or you change to another option for meeting the emission limit.

Other Reports. You would be required to submit reports for periods of startup, shutdown, and malfunction of the capture system and control device. If the procedures you follow during any startup, shutdown, or malfunction are

inconsistent with your plan, you would report those procedures with your semiannual reports in addition to immediate reports required by § 63.10(d)(5)(ii).

III. Rationale for Selecting the Proposed Standards

A. How Did We Select the Source Category?

The surface coating of large appliances is a source category that is on the list of source categories to be regulated because it contains major sources which emit or have the potential to emit at least 10 tons of any one HAP or at least 25 tons of any combination of HAP annually. The proposed rule would control HAP emissions from both new and existing major sources. Area sources are not being regulated under this proposed rule.

The surface coating of large appliances as described in the listing includes any facility engaged in the surface coating of large appliance parts or products. We use the large appliance product lists contained in the SIC and NAICS code descriptions to describe the vast array of large appliance parts and products.

We intend the source category to include facilities for which the surface coating of large appliances is either their principal activity or an integral part of a production process that is the principal activity. Most coating operations are located at plant sites that are dedicated to these activities. However, some may be located at sites for which some other activity is principal. Collocated surface coating operations comparable to the types and sizes of the dedicated facilities, in terms of the coating operation and applicable emission control techniques, are included in the source category.

The source category does not include research or laboratory facilities or janitorial, building, and facility maintenance operations.

B. How did we select the regulated pollutants?

Organic HAP. Available emission data collected during the development of the proposed NESHAP show that the primary organic HAP emitted from the surface coating of large appliances include xylene, glycol ethers, toluene, methylene diphenyl diisocyanate, and methyl ethyl ketone. These compounds account for approximately 82 percent of this category's nationwide organic HAP emissions. However, many other organic HAP are used, or can be used, in large appliance coatings, thinners, and

cleaning materials. Therefore, the proposed rule would regulate emissions of all organic HAP.

Inorganic HAP. Although most of the coatings used in this source category do not contain inorganic HAP, some special purpose coatings used by this source category do contain inorganic HAP such as chromium, cobalt, lead, and manganese. Emissions of these materials to the atmosphere are minimal because the facilities in this source category employ either water curtains or dry filters that remove overspray particles from the spray booth exhaust. At this time, it does not appear that emissions of inorganic HAP from this source category warrant Federal regulation.

C. How Did We Select the Affected Source?

In selecting the affected source(s) for emission standards, our primary goal is to ensure that MACT is applied to HAP-emitting operations or activities within the source category being regulated. The affected source also serves to establish where new source MACT applies under a particular standard. Specifically, the General Provisions in subpart A of 40 CFR part 63 define the terms "construction" and "reconstruction" with reference to the term "affected source" and provide that new source MACT applies when construction or reconstruction of an affected source occurs. The collection of equipment and activities evaluated in determining MACT (including the MACT floor) is used in defining the affected source.

When an emission standard is based on a collection of emissions sources, or total facility emissions, we select an affected source based on that same collection of emission sources, or the total facility, as well. This approach for defining the affected source broadly is particularly appropriate for industries where a plantwide emission standard provides the opportunity and incentive for owners and operators to utilize control strategies that are more cost effective than if separate standards were established for each emission point within a facility.

Selection of Affected Source. The affected source for these proposed standards is broadly defined to include all operations associated with the coating of large appliances and the cleaning of product substrates or coating operation equipment. These operations include storage and mixing of coatings and other materials; surface preparation of the large appliances prior to coating application; coating application and flash-off, drying and curing of applied

coatings; cleaning operations; and waste handling operations.

In selecting the affected source, we considered, for each operation, the extent to which HAP-containing materials are used and the amount of HAP that are emitted. Cleaning and coating application, flash-off, and curing/drying operations account for the majority of HAP emissions at large appliance surface coating operations. These operations are included in the affected source.

We were not able to obtain data to adequately quantify HAP emissions from storage, mixing, and waste handling. However, solvents that are added to coatings as thinners, and other HAP-containing additives to coatings, may be emitted during mixing and storage. The level of emissions depends on the type of mixing and the type of storage container and the work practices used at the facility. Emissions from waste handling operations depend on the type of system used to collect and transport organic HAP-containing waste coatings, thinners, and cleaning materials in the facility. For example, solvent-laden rags that are used to clean spray booths or tanks could be a source of HAP emissions. The method used to isolate and store such rags affects the level of emissions to ambient air. Mixing, storage, and waste handling operations are included in the affected source.

A broad definition of the affected source was selected to provide maximum flexibility in complying with the proposed emission limits for organic HAP. In planning its total usage of HAP-containing materials, each facility can select among available coatings, thinners, and cleaning materials to comply with the proposed limits.

Additional information on the large appliance surface coating operations selected for regulation, and other operations, are included in the docket for the proposed standards.

D. How did we determine the basis and level of the proposed standards for existing and new sources?

The sections below present the rationale for determining the MACT floor, regulatory alternatives beyond the floor, and selection of the proposed standards for existing and new affected sources.

How did we determine the MACT floor technology? After we identify the specific source categories or subcategories of sources to regulate under section 112 of the CAA, we must develop emission standards for each category and subcategory. Section 112(d)(3) establishes a minimum

baseline or "floor" for standards. For new sources in a category or subcategory, the standards cannot be less stringent than the emission control that is achieved in practice by the best-controlled similar source. The standards for existing sources can be less stringent than standards for new sources, but they cannot be less stringent than the average emission limitation achieved by the best-performing 12 percent of existing sources (or the best-performing five sources for categories or subcategories with fewer than 30 sources).

Within the large appliance industry, organic HAP emission control for cleaning and surface coating operations is accomplished primarily through the use of lower-HAP coatings, thinners, and cleaning materials. Add-on capture and control systems for organic HAP are rarely used by the industry. While lower organic HAP materials have achieved broad use throughout the industry, each particular coating technology is not used at every facility. Rather, facilities use various combinations of low-HAP coatings, thinners, and cleaning materials. Thus, we judged the most reasonable approach to establishing a MACT floor to be the evaluation of a facility's organic HAP emissions from all coating-related operations. To account for differences in production levels from one facility to another, we normalized the organic HAP emission rate by the volume of coating solids used. We believe coating solids usage is an appropriate indicator of overall production levels.

We used information obtained from industry survey responses to estimate the sourcewide organic HAP emission rate from each survey respondent. We calculated total organic HAP emissions by assuming that 100 percent of the volatile components in all coatings (including adhesives), thinners, and cleaning materials (including surface preparation materials) are emitted. Major sources were identified as: those facilities that listed "major source" or "synthetic minor source" as their title V status on their questionnaire response; those facilities that reported their HAP emissions under "maximum design capacity" as greater than 9.1 megagrams per year (Mg/yr) (10 tpy); and other facilities that we judged to have the capacity to increase their HAP emissions to at least 9.1 Mg/yr, even though they did not identify themselves as major or synthetic minor sources. The final group of facilities were included because they reported actual HAP emissions of greater than 3 Mg (3.3 tons) during the reporting year and did not report a "maximum design capacity." If these facilities operate at full capacity

over multiple shifts each day, their annual emission rate may equal or exceed 9.1 Mg/yr.

The survey response information was used to determine the total volume of coating solids used by each source from all types of coatings. We included decorative, protective, and functional coatings in this total.

Using the sourcewide organic HAP emissions and the total volume of coating solids used for each survey respondent, we calculated the normalized organic HAP emissions (emission rate) in units of kilograms organic HAP per liter of coating solids used. The facilities were then ranked from the lowest emission rate to the highest, with the following exceptions. Facilities that reported the predominant use of powder coatings (greater than 90 percent of all coating solids usage) were excluded from the MACT floor calculations. While powder coating technology is a proven low-HAP coating technology, its applicability is not considered to be universal for all products manufactured within the source category. For those facilities whose products can be coated with this technology, the use of powder coatings is a very effective and efficient means of reducing HAP emissions. The degree of HAP reductions that can be achieved with the powder coating technology is close to 100 percent. However, because many large appliance parts and products cannot be satisfactorily coated with powder coating technology, we concluded that it would not be appropriate to define the MACT floors based primarily on their use. Facilities that used lesser amounts of powder coatings in combination with other low-HAP coating technologies were included in the MACT floor determination.

For some facilities, the organic HAP to coating solids ratio was very low due to the facilities' usage of unusually large quantities of low-HAP and non-HAP adhesives. The low- and non-HAP adhesives usage for these facilities ranged from 40 to 84 percent of all coating solids. While many facilities in the source category use adhesives (a functional coating), their use is not as widespread compared to the decorative and protective coatings usually associated with the appearance of large appliance products. On the average, adhesive usage among all facilities in the source category database is about 4 percent of the total solids used. We concluded that because of the specific function served by adhesives, the low-HAP adhesive technology employed in the facilities described above may not be transferable to the decorative and

protective coatings which account for the remaining 96 percent of coating solids usage in the industry. Thus, we concluded that the facilities using atypically large quantities of these adhesives relative to decorative and protective coatings should not be included in the floor determination of existing sources or new sources.

For the existing source MACT floor, the top 12 percent of the facilities were determined based on the number of facilities in the MACT floor database (95 database facilities $\times$ 12 percent = 11.4). Because the calculated value was greater than 11, we used data from 12 facilities to determine the MACT floor. The floor was calculated as the arithmetic average of the emission rates of the top 12 best-performing representative facilities.

This process resulted in a MACT floor equal to 0.13 kg HAP/liter of coating solids (1.1 lb/gal). The survey data showed no appreciable differences between the floor facilities and the remaining facilities in the database in terms of the substrates coated, the coating technologies used, or the applicability of control measures across the various operations. Therefore, we believe the floor level of control is achievable by all existing sources.

The best performing facility in our database has an emission rate of 0.022 kg HAP/liter of coating solids (0.18 lb/gal). This facility operates under SIC 3585 and manufactures supermarket display cases and equipment. This facility uses both solvent-based coatings and powder coatings and is considered similar to the other sources in the category in terms of the substrate coated and the coating technologies used. Therefore, the new source MACT floor was based on the data from this facility and was determined to be 0.022 kg HAP/liter (0.18 lb/gal) of coating solids.

How did we consider beyond-the-floor technology? After the floors have been determined for new and existing sources in a source category or subcategory, we must set emission standards that are technically achievable and no less stringent than the floors. Such standards must then be met by all sources within the category or subcategory. We identify and consider any reasonable regulatory alternatives that are "beyond-the-floor," taking into account emissions reductions, cost, non-air quality health and environmental impacts, and energy requirements. These alternatives may be different for new and existing sources because of different MACT floors, and separate standards may be established for new and existing sources.

We identified three regulatory alternatives more stringent than the MACT floor level of control for organic

HAP. These alternatives were conversion to powder coatings; conversion to liquid coatings that have a very low, or no, organic HAP content; and use of add-on capture systems and control devices.

Information indicates that several large appliance surface coating facilities have converted to using only powder coatings. Such facilities typically produce a single type of product (such as laundry equipment), do not require unusual finishes, and use a small number of colors. Many large appliance surface coating facilities, however, manufacture more than one product and often use a wide array of colors. Although powder coatings may be somewhat more durable than conventional liquid coatings, specialty finishes such as antique and crackle, as well as the palette of designer colors offered by some manufacturers, may not be adequately duplicated by powder coatings. Consequently, while powder coating is a proven technology that can be used in many situations, it is not universally applicable in the large appliance industry and was, therefore, rejected as a beyond-the-floor option.

Lower organic HAP liquid coatings fall into two primary categories. The most common category is coatings formulated with solvents that are not organic HAP (but may be VOC). The second category is those coatings that result from alternate technologies such as ultraviolet (UV)—curable coatings and electron beam (EB)—curable coatings. These coatings do not employ organic HAP or VOC to keep the pigment and other components of the coating in solution until curing. Therefore, organic HAP emissions are very small.

These lower organic HAP coatings are currently in production use in some industries, but their applicability in the large appliance industry is limited. Given the limited applicability of UV—curable and EB—curable coatings, we do not believe it is feasible to require the use of these coatings and rejected them as a beyond-the-floor option for organic HAP.

It is technically feasible to reduce emissions from affected sources by at least 95 percent through the use of capture systems and add-on control devices. Based on the model plants analysis used to estimate the impacts of the proposed rule, over half of the existing facilities will be required to achieve HAP emissions reductions of greater than 80 percent to meet the existing source MACT floor level of control. For these facilities, the incremental HAP reductions that could be achieved by using capture systems

and control devices to comply with a "beyond-the-floor" alternative of 95 percent reduction would range from about 0.30 Mg (0.33 tons) to about 1.7 Mg (1.9 tons). The estimated cost of a permanent total enclosure and a control device, such as an oxidizer, for these facilities could be as much as \$1 million. We believe the incremental emissions reductions that would be achieved at this time do not warrant the additional cost that each existing source would incur by using add-on control systems. Therefore, we rejected requiring capture systems and add-on control devices as a beyond-the-floor option for organic HAP.

How did we select the proposed standards? For existing sources, we based the proposed standards on the existing source MACT floor. As described earlier, we determined that beyond-the-floor options were not technically or economically feasible for all existing sources. For the same reasons, we based the proposed standards for new sources on the new source MACT floor.

The MACT levels of control for new and existing sources can be achieved in several different ways. Many sources would be able to use lower-HAP coatings, although they may not be available to meet the needs of every source. If a source is also using cleaning materials that contain organic HAP, then it may be able to switch to lower-HAP or non-HAP cleaning materials, which are widely available, to reduce the sourcewide organic HAP emissions rate to the MACT level. Other available options are the use of powder coatings or capture systems and add-on control devices to reduce emissions.

We note here that our assumption, used in the development of the MACT floors, that 100 percent of the organic HAP in the materials used are emitted by the affected source would not apply when the source sends waste organic HAP-containing materials to a facility for treatment or disposal. We made that assumption because the industry survey responses provided little information as to the amount of organic HAP recovered and recycled or treated and disposed. We, therefore, concluded that that practice may not be common within the large appliance industry. We recognize, however, that some large appliance facilities may conduct such activities and should be allowed to account for such activities in determining their emissions. Thus, the proposed rule allows you to reduce the organic HAP emissions by the amount of any organic HAP contained in waste treated or disposed at a hazardous waste treatment, storage, and disposal facility

that is regulated under 40 CFR part 262, 264, 265, or 266.

E. How did we select the format of the standards?

Numerical emission standards are required by section 112(h) of the CAA unless we can justify that it is not feasible to prescribe or enforce an emission standard, in which case a design, equipment, work practice, or operational standard can be set.

We selected the format of the standards to be mass of organic HAP per volume of coating solids. The performance-based nature of this proposed format would allow large appliance coating operation owners and operators flexibility in choosing any combination of means (including coating reformulation, use of lower-HAP or non-HAP materials, solvent elimination, work practices, and add-on control devices) to comply with the emission limits that is workable for their particular situations.

We selected volume of coating solids as a component of the proposed standards to normalize the rate of organic HAP emissions across all sizes and types of facilities. We selected the volume of coating solids used because it is directly related to the surface area coated (*i.e.*, the average dry film thickness of coatings on most large appliance parts or products is generally consistent) and, therefore, provides an equitable basis for all coatings, regardless of differences in coating densities. A format based on the mass or weight of coating solids (instead of volume) could result in inequitable standards for higher-density pigmented coatings, such as basecoats or enamels, compared to coatings with lower densities per unit volume.

Other choices for the format of the standards that we considered, but rejected, included a usage limit (mass per unit time) and a never-to-be-exceeded limit on the organic HAP content of coatings, solvents, or cleaning materials. As it is not our intent to limit a facility's production under these proposed standards, we rejected a usage limit. We also rejected a never-to-be-exceeded limit, as the proposed standards allow averaging of HAP emissions from the materials used during the compliance period.

F. How did we select the testing and initial compliance requirements?

The proposed standards would allow you to choose among several methods to demonstrate compliance with the proposed standards for organic HAP: coatings with low or no organic HAP; an overall organic HAP emission rate from

all coatings, thinners, and cleaning materials that is less than the applicable emission limit; or capture systems and control devices.

Coatings with Low or No Organic HAP. You would be required to document the organic HAP content of all coatings and show that each is less than the applicable emission limit. You would also have to show that each thinner and each cleaning material used contains no organic HAP. Method 311 is the method developed by EPA for determining the mass fraction of organic HAP in coatings and has been used in previous surface coating NESHAP. We have not identified any other methods that provide advantages over Method 311 for use in the proposed standards.

Method 24 is the method developed by EPA for determining the mass fraction of volatile matter for coatings and can be used if you choose to determine the non-aqueous volatile matter content as a surrogate for organic HAP. In past standards, VOC emission control measures have been implemented in coating industries, with Method 24 as the compliance method. We have not identified any other methods that provide advantages over Method 24 for use in the proposed standards.

The proposed requirements for determining volume fraction of coating solids would allow you to choose between calculating the value using Equation 1 in § 63.4141 of the proposed standards or measuring the volume with either ASTM Method D2697-86 (1998) or ASTM Method D6093-97.

Overall Organic HAP Emission Rate. To demonstrate initial compliance using this option, you would calculate the organic HAP emission rate for one or more coating operations in the affected source, based on the mass of organic HAP in all coatings, thinners, and cleaners and the volume of coating solids used during the compliance period, and demonstrate that it does not exceed the applicable emission limit. You would determine these values using the methods discussed previously.

Capture Systems and Control Devices. If you use a capture system and control device, other than a solvent recovery device for which you conduct a liquid-liquid material balance, you would be required to conduct an initial performance test of the system to determine its overall control efficiency. For a solvent recovery system for which you conduct a liquid-liquid material balance, you would determine the quantity of volatile matter applied and the quantity recovered during the initial compliance period to determine its overall control efficiency. For both

cases, the overall control efficiency would be combined with the monthly mass of organic HAP in the coatings and other materials used to calculate the monthly HAP emission rate in kg HAP/liter of coating solids. If you conduct a performance test, you would also determine parameter operating limits during the test. The test methods that the proposed standards would require for the performance test have been required under many standards of performance for industrial surface coating sources under 40 CFR part 60 and NESHAP under 40 CFR part 63. We have not identified any other methods that provide advantages over these methods.

G. How Did We Select the Continuous Compliance Requirements?

To ensure continuous compliance with the proposed organic HAP emission limits and/or operating limits, the proposed standards would require continuous parameter monitoring of capture systems and control devices and recordkeeping. We selected the following requirements based on reasonable cost, ease of execution, and usefulness of the resulting data to both the owners or operators and EPA for ensuring continuous compliance with the emission limits and/or operating limits.

We are proposing that certain parameters be continuously monitored for the types of capture systems and control devices commonly used in the industry. These monitoring parameters have been used in other standards for similar industries. The values of these parameters that correspond to compliance with the proposed emission limits are established during the initial or most recent performance test that demonstrates compliance. These values are your operating limits for the capture system and control device.

You would be required to determine 3-hour average values for most monitored parameters for the affected source. We selected this averaging period to reflect operating conditions during the performance test to ensure the control system is continuously operating at the same or better control level as during a performance test demonstrating compliance with the emission limits.

To demonstrate continuous compliance with the monthly emission limits, you would also need records of the quantity of coatings and other materials used and the data and calculations supporting your determination of their organic HAP content. If you conduct liquid-liquid material balances, you would need

records of the quantity of volatile matter used and the quantity recovered by the solvent recovery system each month.

H. How Did We Select the Notification, Recordkeeping, and Reporting Requirements?

You would be required to comply with the applicable requirements in the NESHAP General Provisions, subpart A of 40 CFR part 63, as described in Table 2 of the proposed subpart NNNN. We evaluated the General Provisions requirements and included those we determined to be the minimum notification, recordkeeping, and reporting necessary to ensure compliance with, and effective enforcement of, the proposed standards.

I. How Did We Select the Compliance Date?

You would be allowed 3 years to comply with the final standards for existing affected sources. This is the maximum period allowed by the CAA. We believe that 3 years for compliance is necessary to allow adequate time to accommodate the variety of compliance methods that existing sources may use. Most sources in this category would need this 3-year maximum amount of time to develop and test reformulated coatings, particularly those that may opt to comply using a different lower-emitting coating technology. We want to encourage the use of these pollution prevention technologies. In addition, time would be needed to establish records management systems required for enforcement purposes. Some sources may need the time to purchase and install emission capture and control systems. In such cases, you would need to obtain a permit for the use of add-on controls, which will require time for approval from the permitting authority.

The CAA requires that new or reconstructed affected sources comply with standards immediately upon startup or the effective date of the final rule, whichever is later.

IV. Summary of Environmental, Energy, and Economic Impacts

Model plants were developed to aid in the estimation of the impacts the proposed standards would have on the large appliance industry. Four model plants distinguished by size, as measured by the total volume of coating solids used, were developed. Impacts were then developed for each model plant, and these individual impacts were scaled to nationwide levels based on the number of facilities corresponding to each model plant size. We used the model plant approach because we did not have adequate data

to estimate impacts for each actual facility.

A variety of compliance methods are available to the industry to meet the proposed emission limits. We analyzed the information obtained from the industry survey responses, industry site visits, trade groups, and industry representatives to determine which compliance methods would most likely be used by existing and new sources. We expect that the most widely-used method for existing sources would be low-HAP content liquid coatings (coatings with HAP contents at or below the emission limits). Powder coatings, no-HAP cleaning materials, and add-on capture and control systems would likely be used by existing sources, but to a lesser extent. Various combinations of these methods may be used. New sources are largely expected to use powder coating technologies or a combination of low-HAP coatings and no-HAP cleaning materials.

For the purpose of assessing impacts, we assumed that all existing sources would convert to liquid coatings and thinners with lower-HAP content than presently used and no-HAP cleaning materials. We assumed that new sources would use either powder coatings or lower-HAP coatings and no-HAP cleaning materials.

We first estimated the impacts of the proposed emission limits on the four model plants. To scale up the model plant impacts to nationwide levels, we multiplied the individual model plant impacts by the estimated number of major sources in the United States corresponding to each plant size. We estimated that there are 74 existing major source facilities nationwide. For more information on how impacts were estimated, see Chapters 6 and 7 of the background information document, EPA-453/R-00-006.

A. What Are the Air Impacts?

For existing major sources, we estimated that compliance with the proposed emission limits would result in reductions of nationwide organic HAP emissions of 1,080 Mg/yr (1,191 tpy). This represents a reduction of 45 percent from the baseline organic HAP emissions of 2,394 Mg/yr (2,639 tpy).

For new sources, we have assumed that most, if not all, will use coating technologies that are considered to be "state-of-the-art" coatings (e.g., powder coatings and low-HAP liquid coatings). Powder coating technology has advanced rapidly in recent years and is gaining widespread acceptance in the large appliance industry. Powder coatings are not only very cost effective, their use eliminates the problems

associated with worker exposure to organic solvents. Many of the facilities in the database indicated that they were in the process of converting part or all of their coating operations to use powder coatings. Also, four of the most recently constructed facilities in the database are using powder coatings extensively and have HAP emission levels below the MACT level for new sources. For these reasons, we project the baseline emission levels for new sources to be at, or below, the requirements in the proposed standards. Therefore, we have assumed no emissions reductions from new sources attributable to the proposed standards.

B. What Are the Cost Impacts?

We have estimated the costs related to complying with the emission limitations and meeting the monitoring, recordkeeping, and reporting requirements. The costs to comply with the emission limitations include the increased cost of reformulated low-HAP coating materials, as well as any capital expenditures that would be required to facilitate the use of these materials. Alternatively, facilities could choose to purchase, install, and operate capture systems and add-on control devices. We have assumed for this analysis that all affected facilities will comply through the use of reformulated coatings, thinners, and cleaning materials, and that these materials can be utilized without the need for capital expenditures. Annual costs for meeting the monitoring, recordkeeping, and reporting requirements of the proposed rule have also been included.

Existing sources. To comply with the proposed standards, existing facilities will likely use reformulated coatings, thinners, and cleaning materials. Compliance costs were estimated to be the incremental cost difference between the materials currently used and the complying materials. Estimates of cost impacts were based on four model plants that were developed to represent the range of sizes and coating materials found throughout the industry. Each model plant was assumed to comply with the proposed standards by switching to non-HAP adhesives, surface preparation materials, and cleaning materials and reducing the HAP content of the coatings and thinners. The annual incremental cost of the reformulated raw materials ranged from approximately \$700 for model plant 1, representing the segment of industry with the lowest coating solids usage, to \$26,000 for model plant 4, representing the segment of industry that uses over 200,000 liters of coating solids. The nationwide cost impact was

estimated for each industry segment by multiplying the annual costs for each model plant by the number of facilities represented by that model plant. A total nationwide cost impact associated with material usage was estimated by summing the nationwide costs for each of the four industry segments. In addition, we included estimates for monitoring, recordkeeping, and reporting costs for all 74 affected sources.

We estimate total nationwide annual costs in the fifth year to comply with the proposed emission limits to be \$1.63 million for existing sources. These costs include approximately \$.48 million for direct costs associated with material usage and \$1.15 million for recordkeeping and reporting.

New sources. We estimate the number of new major sources to be four per year, based on an average of the number of new facilities constructed from 1993 to 1997. In the absence of the proposed standards, we anticipate that most, if not all, new sources will primarily use newer coating technologies such as powder coatings, higher solids, and low-HAP liquid coatings. Because these coatings are very cost effective and new facilities would likely choose to use them even in the absence of the proposed standards, no additional costs associated with material usage were assigned for complying with the proposed standards. Therefore, only the costs of monitoring, recordkeeping, and reporting have been assigned to new facilities.

We estimate the annual cost in the fifth year due to monitoring, recordkeeping, and reporting to be \$341,000. We estimated \$91,000 each year for the four new sources (\$23,000 per facility) for their initial year of monitoring, recordkeeping, and reporting. In each subsequent year of operation, the estimated monitoring, recordkeeping, and reporting cost is \$16,000 per facility.

C. What Are the Economic Impacts?

We performed an economic impact analysis (EIA) to provide an estimate of the facility and market impacts of the proposed standards as well as the social costs. In general, we expect the economic impacts of the proposed standards to be minimal, with price increases and production decreases of less than 0.01 percent. Based on a model referred to as a "perfectly competitive economic model" of this industry, we estimate social costs of approximately \$1.62 million in the fifth year for existing sources, with the burden being roughly equally shared by consumers and producers.

For affected facilities, the distribution of costs is slanted toward the lower impact levels with many facilities incurring only those related to monitoring, recordkeeping, and reporting. The EIA indicates that these regulatory costs are expected to represent only 0.01 percent of the value of product shipments, which should not cause producers to cease or alter their current operations. Hence, no firms or facilities are expected to become at risk of closure because of the proposed standards. International trade impacts are expected to be negligible because of the very small price increase (*i.e.*, 0.01 percent). Based on the projected characteristics and costs for new sources, we do not expect any differential impact on these sources. For more information, refer to the "Economic Impact Analysis of the Proposed NESHAP: Surface Coating of Large Appliances" (Docket No. A-97-41).

D. What Are the Non-Air Health, Environmental, and Energy Impacts?

Based on information from the industry survey responses, we found no indication that the use of low organic HAP content coatings, thinners, and cleaning materials at existing sources would result in any increase or decrease in non-air health, environmental, and energy impacts. There would be no change in the utility requirements associated with the use of these materials, so there would be no change in the amount of energy consumed as a result of the material conversion. Also, there would be no significant change in the amount of materials used or the amount of waste produced.

Because new sources are expected to comply with the proposed standards through the use of low-HAP coating technologies rather than add-on control devices, there would be no significant change in energy usage or waste production.

V. Administrative Requirements

A. Executive Order 12866, Regulatory Planning and Review

Under Executive Order 12866 (58 FR 51735, October 4, 1993), EPA must determine whether the regulatory action is "significant" and therefore subject to review by the Office of Management and Budget (OMB) and the requirements of the Executive Order. The Executive Order defines "significant regulatory action" as one that is likely to result in a rule that may:

(1) Have an annual effect on the economy of \$100 million or more or adversely affect in a material way the

economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities;

(2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs, or the rights and obligation of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

Pursuant to the terms of Executive Order 12866, it has been determined that this rule is not a "significant regulatory action" because none of the listed criteria apply to this action. Consequently, this action was not submitted to OMB for review under Executive Order 12866.

B. Executive Order 13132, Federalism

Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999), requires EPA to develop an accountable process to ensure "meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications." "Policies that have federalism implications" is defined in the Executive Order to include regulations that have "substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government."

Under section 6 of Executive Order 13132, EPA may not issue a regulation that has federalism implications, that imposes substantial direct compliance costs, and that is not required by statute, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by State and local governments, or EPA consults with State and local officials early in the process of developing the proposed regulation. The EPA also may not issue a regulation that has federalism implications and that preempts State law, unless the Agency consults with State and local officials early in the process of developing the proposed regulation.

This proposed rule does not have federalism implications. It will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132. Pursuant to the

terms of Executive Order 13132, it has been determined that this rule does not have "federalism implications," because it does not meet the necessary criteria. Thus, the requirements of section 6 of the Executive Order do not apply to this proposed rule.

C. Executive Order 13084, Consultation and Coordination With Indian Tribal Governments

Under Executive Order 13084, EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments, or EPA consults with those governments. If EPA complies by consulting, Executive Order 13084 requires EPA to provide to OMB, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected officials and other representatives of Indian tribal governments "to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities." Today's proposed rule does not significantly or uniquely affect the communities of Indian tribal governments. No tribal governments own or operate large appliance surface coating facilities. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this action.

D. Executive Order 13045, Protection of Children From Environmental Health Risks and Safety Risks

Executive Order 13045 (62 FR 19885, April 23, 1997) applies to any rule that: (1) Is determined to be "economically significant" as defined under Executive Order 12866, and (2) concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, EPA must evaluate the environmental health or safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency.

The EPA interprets Executive Order 13045 as applying only to those regulatory actions that are based on health or safety risks, such that the analysis required under section 5-501 of the Executive Order has the potential to influence the regulation. This proposed rule is not subject to Executive Order 13045 because it does not establish an environmental standard based on an assessment of health or safety risks. No children's risk analysis was performed because no alternative technologies exist that would provide greater stringency at a reasonable cost. Furthermore, this rule has been determined not to be "economically significant" as defined under Executive Order 12866.

E. Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104-4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments and the private sector. Under section 202 of the UMRA, EPA generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with "Federal mandates" that may result in expenditures by State, local, and tribal governments, in aggregate, or by the private sector, of \$100 million or more in any 1 year. Before promulgating an EPA rule for which a written statement is needed, section 205 of the UMRA generally requires EPA to identify and consider a reasonable number of regulatory alternatives and adopt the least-costly, most cost-effective, or least-burdensome alternative that achieves the objectives of the rule. The provisions of section 205 do not apply when they are inconsistent with applicable law. Moreover, section 205 allows EPA to adopt an alternative other than the least-costly, most cost-effective, or least-burdensome alternative if the Administrator publishes with the final rule an explanation why that alternative was not adopted. Before EPA establishes any regulatory requirements that may significantly or uniquely affect small governments, including tribal governments, it must have developed under section 203 of the UMRA a small government agency plan. The plan must provide for notifying potentially affected small governments, enabling officials of affected small governments to have meaningful and timely input in the development of EPA regulatory proposals with significant Federal intergovernmental mandates, and informing, educating, and advising

small governments on compliance with the regulatory requirements.

The EPA has determined that this proposed rule does not contain a Federal mandate that may result in expenditures of \$100 million or more for State, local, and tribal governments, in the aggregate, or the private sector in any 1 year. The maximum total annual cost of this rule for any year has been estimated to be slightly less than \$2 million. Thus, today's proposed rule is not subject to the requirements of sections 202 and 205 of the UMRA. In addition, EPA has determined that this proposed rule contains no regulatory requirements that might significantly or uniquely affect small governments because it contains no requirements that apply to such governments or impose obligations upon them. Therefore, today's proposed rule is not subject to the requirements of section 203 of the UMRA.

F. Regulatory Flexibility Act (RFA), as Amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), 5 U.S.C. 601, et seq.

The RFA generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedures Act or any other statute unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small organizations, and small governmental jurisdictions.

For the purposes of assessing the impacts of today's proposed rule on small entities, small entity is defined as: (1) A small business ranging from 100-1,000 employees or less than \$3.5 million in annual sales; (2) a small governmental jurisdiction that is a government of a city, county, town, school district, or special district with a population of less than 50,000; and (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.

In accordance with the RFA and SBREFA, EPA conducted an assessment of the proposed standards on small businesses within the large appliance coating industry. Based on Small Business Administration size definitions and reported sales and employment data, EPA's survey identified 221 facilities that apply surface coatings to large appliances. These facilities, which include major and area sources, are owned by 84 companies. Of these companies, 34 are small businesses. Although small

businesses represent about 40 percent of the companies within the source category, they are expected to incur only 10 percent of the total industry compliance costs. Under the proposed standards, the average annual compliance cost share of sales for small businesses is only 0.20 percent, with 26 of the 34 small businesses not expected to incur any additional costs because they are area sources or are permitted as synthetic minor HAP emission sources. After reviewing the range of costs to be borne by small businesses, EPA has determined the costs are typically small and, thus, certifies that this action will not have a significant impact on a substantial number of small entities.

Although this proposed rule will not have a significant economic impact on a substantial number of small entities, EPA has nonetheless worked aggressively to minimize the impact of this proposed rule on small entities, consistent with our obligations under the CAA. We solicited input from small entities during the data-gathering phase of the proposed rulemaking. We are proposing compliance options which give small entities flexibility in choosing the most cost effective and least burdensome alternative for their operation. For example, a facility could purchase and use low-HAP coatings (*i.e.*, pollution prevention) that meet the proposed standards instead of using add-on capture and control systems. This method of compliance can be demonstrated with minimum burden by using purchase and usage records. No testing of materials would be required, as the facility owner could show that their coatings meet the emission limits by providing formulation data supplied by the manufacturer.

We continue to be interested in the potential impacts of the proposed standards on small entities and welcome comments on issues related to such impacts. For more information, consult the docket for this project.

G. Paperwork Reduction Act

The information collection requirements in the proposed rule will be submitted for approval to the OMB under the Paperwork Reduction Act, 44 U.S.C. 3501, *et seq.* An Information Collection Request (ICR) document has been prepared by EPA (ICR No. 1954.01) and a copy may be obtained from Sandy Farmer by mail at the Collection Strategies Division (2822), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, NW, Washington, DC 20460, by email at farmer.sandy@epa.gov, or by calling (202) 260-2740. A copy may also be downloaded off the internet at <http://www.epa.gov/icr>. The information requirements are not effective until OMB approves them.

The information requirements are based on notification, recordkeeping, and reporting requirements in the NESHAP General Provisions (40 CFR part 63, subpart A), which are mandatory for all operators subject to national emission standards. These recordkeeping and reporting requirements are specifically authorized by section 114 of the CAA (42 U.S.C. 7414). All information submitted to EPA pursuant to the recordkeeping and reporting requirements for which a claim of confidentiality is made is safeguarded according to Agency policies set forth in 40 CFR part 2, subpart B.

The proposed standards would require maintaining records of all coatings, thinners, and cleaning materials data and calculations used to determine compliance. This information includes the volume used during each monthly compliance period, mass fraction organic HAP, density, and, for coatings only, volume fraction of coating solids. If an add-on control device is used, records must be kept of the capture efficiency of the capture system, destruction or removal efficiency of the add-on control device, and the monitored operating parameters. In addition, records must be kept of each calculation of the affected sourcewide emissions for each monthly compliance period and all data, calculations, test results, and other supporting information used to determine this value.

The monitoring, recordkeeping, and reporting burden in the fifth year after the effective date of the promulgated rule is estimated to be 32,000 labor hours at a cost of \$1.50 million for new and existing sources. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations are listed in 40 CFR part 9 and 48 CFR chapter 15. Under the Paperwork Reduction Act, EPA must consider the paperwork burden imposed by any information collection request in a proposed or final rule. The proposed standards will not impose any new information collection requirements beyond those specified in the ICR document. Comments are requested on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, including through the use of automated collection techniques. By U.S. Postal Service, send comments on the ICR to the Director, Collection Strategies Division; U.S. Environmental Protection Agency (2822); 1200 Pennsylvania Ave., NW, Washington, DC 20460 (or by courier, send comments on the ICR to the Director, Collection Strategies Division; U.S. Environmental Protection Agency (2822); 401 M Street, SW, Room 925H, West Tower; Washington, DC) and to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th St., NW., Washington, DC 20503, marked "Attention: Desk Officer for EPA." Include the ICR number in any correspondence. Since OMB is required to make a decision concerning the ICR between 30 and 60 days after December 22, 2000, a comment to OMB is best assured of having its full effect if OMB receives it by January 22, 2001. The final rule will respond to any OMB or public comments on the information collection requirements contained in this proposal.

H. National Technology Transfer and Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law No. 104-113, section 12(d) (15 U.S.C. 272 note), directs EPA to use voluntary consensus standards (VCS) in their regulatory and procurement activities unless to do so would be inconsistent with applicable law or otherwise impractical. The VCS are technical standards (*e.g.*, materials specifications, test methods, sampling procedures, business practices) developed or adopted by one or more voluntary consensus bodies. The NTTAA directs EPA to provide Congress, through annual reports to the OMB, with

explanations when an agency does not use available and applicable VCS.

This proposed rulemaking involves technical standards. The EPA proposes in this rule to use EPA Methods 1, 1A, 2, 2A, 2C, 2D, 2F, 2G, 3, 3A, 3B, 4, 24, 25, 25A, 204, 204A–F, 311, and 316. Consistent with the NTTAA, EPA conducted searches to identify VCS in addition to these EPA methods. No applicable VCS were identified for EPA Methods 1A, 2A, 2D, 2F, 2G, 204, 204A–F, and 316. The search and review results have been documented and are placed in the docket for this proposed rule.

Two VCS were identified for determining the volume of coating solids (nonvolatiles), and EPA proposes to use them in this rule. The standards are ASTM D2697–86 (Reapproved 1998), “Standard Test Method for Volume Nonvolatile Matter in Clear or Pigmented Coatings,” and ASTM D6093–97, “Standard Test Method for Percent Volume Nonvolatile Matter in Clear or Pigmented Coatings Using a Helium Gas Pycnometer.” These standards fill a void in EPA Method 24 which directs that the volume fraction of coating solids be calculated from the coating manufacturer’s formulation. The proposed rule does allow for the use of the volume fraction of coating solids calculated from the coating manufacturer’s formulation, however, test results will take precedence if they do not agree with calculated values.

Six VCS: ASTM D1475–90, ASTM D2369–95, ASTM D3792–91, ASTM D4017–96a, ASTM D4457–85 (Reapproved 1991), and ASTM D5403–93 are already incorporated by reference in EPA Method 24. In addition, we are separately specifying the use of ASTM D1475–90 for measuring the density of individual coating components, such as organic solvents. Five VCS: ASTM D1979–91, ASTM D3432–89, ASTM D4747–87, ASTM D4827–93, and ASTM PS 9–94 are incorporated by reference in EPA Method 311.

In addition to the VCS EPA proposes to use in this rule, the search for emission measurement procedures identified 17 other VCS. The EPA determined that 11 of these 17 standards were impractical alternatives to EPA test methods for the purposes of this proposed rulemaking. Therefore, EPA does not propose to adopt these standards today. The reason for this determination for the 11 methods are discussed below.

The standard ISO 10780:1994, “Stationary Source Emissions—Measurement of Velocity and Volume Flowrate of Gas Streams in Ducts,” is impractical as an alternative to EPA

Method 2 in this proposed rulemaking. This standard, ISO 10780:1994, recommends the use of L-shaped pitots, which historically have not been recommended by EPA because the S type design has large openings which are less likely to plug up with dust.

The standard ASTM D3464–96, “Standard Test Method Average Velocity in a Duct Using a Thermal Anemometer,” is impractical as an alternative to EPA Method 2 for the purposes of this proposed rulemaking primarily because applicability specifications are not clearly defined, e.g., range of gas composition, temperature limits. Also, the lack of supporting quality assurance data for the calibration procedures and specifications, and certain variability issues that are not adequately addressed by the standard limit EPA’s ability to make a definitive comparison of the method in these areas.

The standard EN 12619:1999, “Stationary Source Emissions—Determination of the Mass Concentration of Total Gaseous Organic Carbon at Low Concentrations in Flue Gases—Continuous Flame Ionization Detector Method,” is an impractical alternative to EPA Method 25A for the purposes of this proposed rulemaking. This standard is impractical because it does not measure solvent process vapors in concentrations greater than 40 parts per million (ppm) carbon. A method whose upper limit is 40 ppm carbon has a measurement range too limited to be useful in measuring source emissions.

Five of the 11 voluntary consensus standards are impractical alternatives to EPA test methods for the purposes of this proposed rulemaking because they are too general, too broad, or not sufficiently detailed to assure compliance with EPA regulatory requirements: ASME C00031 or PTC 19–10–1981—Part 10, “Flue and Exhaust Gas Analyses,” for EPA Method 3; ASTM 3796–90 (Reapproved 1996), “Standard Practice for Calibration of Type S Pitot Tubes,” for EPA Method 2; ASTM D3271–87, “Standard Practice for Direct Injection of Solvent-Reducible Paints into a Gas Chromatograph for Solvent Analysis,” for EPA Method 311; ASTM E337–84 (Reapproved 1996), “Standard Test Method for Measuring Humidity with a Psychrometer (the Measurement of Wet- and Dry-Bulb Temperatures),” for EPA Method 4; and CAN/CSA Z223.2—M86(1986), “Method for the Continuous Measurement of Oxygen, Carbon Dioxide, Carbon Monoxide, Sulphur Dioxide, and Oxides of Nitrogen in Enclosed Combustion Flue Gas Streams,” for EPA Method 3A.

Three of the 11 VCS are impractical alternatives to EPA test methods for the purposes of this proposed rulemaking because they lacked sufficient quality assurance and quality control requirements necessary for EPA compliance assurance requirements: ASTM D3154–91, “Standard Method for Average Velocity in a Duct (Pitot Tube Method),” for EPA Methods 1, 2, 2C, 3, 3B, and 4; ASTM D5835–95, “Standard Practice for Sampling Stationary Source Emissions for Automated Determination of Gas Concentration,” for EPA Method 3A; and ISO 10396:1993, “Stationary Source Emissions: Sampling for the Automated Determination of Gas Concentrations,” for EPA Method 3A.

The following six of the 17 VCS identified in this search were not available at the time the review was conducted for the purposes of this proposed rulemaking because they are under development by a voluntary consensus body: ASME/BSR MFC 12M, “Flow in Closed Conduits Using Multiport Averaging Pitot Primary Flowmeters,” for EPA Method 2; ASME/BSR MFC 13M, “Flow Measurement by Velocity Traverse,” for EPA Method 1 (and possibly 2); ISO/DIS 11890–1 Part 1, “Paints and Varnishes—Determination of Volatile Organic Compound (VOC) Content—Difference Method,” for EPA Method 24; ISO/DIS 11890–2 Part 2, “Paints and Varnishes—Determination of Volatile Organic Compound (VOC) Content—Gas Chromatographic Method,” for EPA Method 24; ISO/DIS 12039, “Stationary Source Emissions—Determination of Carbon Monoxide, Carbon Dioxide, and Oxygen—Automated Methods,” for EPA Method 3A; and ISO/FDIS 14965, “Air Quality—Determination of Total Nonmethane Organic Compounds—Cryogenic Preconcentration and Direct Flame Ionization Method,” for EPA Method 25A and parts of Method 25. While we are not proposing to include these six VCS in today’s proposal, EPA will consider the standards when final.

The EPA takes comment on compliance demonstration requirements proposed in this rulemaking and specifically invites the public to identify potentially applicable VCS. Commenters should also explain why this proposed rule should adopt these VCS in lieu of or in addition to EPA’s standards. Emission test methods and performance specifications submitted for evaluation should be accompanied with a basis for the recommendation, including method validation data and the procedure used to validate the candidate method (if a method other than Method 301, 40 CFR part 63, appendix A, was used).

Sections 63.4901, 63.3911, 63.4921, and Table 3 to subpart NNNN of the proposed standards list EPA testing methods included in the proposed rule. Under § 63.8 of subpart A of the General Provisions, a source may apply to EPA for permission to use alternative monitoring in place of any of the EPA testing methods.

List of Subjects in 40 CFR Part 63

Environmental protection, Administrative practice and procedure, Air pollution control, Hazardous substances, Intergovernmental relations, Reporting and recordkeeping requirements.

Dated: December 8, 2000.

Carol M. Browner,
Administrator.

For the reasons stated in the preamble, title 40, chapter I, part 63 of the Code of Federal Regulations is proposed to be amended as follows:

PART 63—[AMENDED]

1. The authority citation for part 63 continues to read as follows:

Authority: 42 U.S.C. 7401, *et seq.*

2. Part 63 is amended by adding subpart NNNN to read as follows:

Subpart NNNN—National Emission Standards for Hazardous Air Pollutants: Surface Coating of Large Appliances

Sec.

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What this Subpart Covers

§ 63.4080 What is the purpose of this subpart?

This subpart establishes national emission standards for hazardous air pollutants for large appliance surface

coating facilities. This subpart also establishes requirements to demonstrate initial and continuous compliance with the emission limitations.

§ 63.4081 Am I subject to this subpart?

(a) You are subject to this subpart if you own or operate a facility that applies coatings to large appliances and is a major source, is located at a major source, or is part of a major source of emissions of hazardous air pollutants (HAP), except as provided in paragraphs (a)(1)(i) and (ii) of this section.

(1) The large appliance surface coating source category includes any facility engaged in the surface coating of any large appliance part or product. Large appliance parts and products include, but are not limited to, heating and air conditioning units and parts, chillers, household refrigerators and home and farm freezers, household laundry equipment, household cooking equipment, dishwashers, floor waxers and polishers, garbage disposal units, trash compactors, and water heaters.

(i) The surface coating of small items such as metal or plastic handles, hinges, or fasteners that have a wider use beyond large appliances are not subject to this subpart if the surface coating occurs at a facility that does not apply coatings to other large appliance items.

(ii) The surface coating of large appliances conducted for the purpose of repairing or maintaining large appliances used by a facility and not for commerce is not subject to this subpart, unless organic HAP emissions from the surface coating itself are as high as the rates specified in paragraph (a)(4) of this section.

(2) The large appliance surface coating activities and equipment to which this subpart applies are listed in paragraphs (a)(2)(i) through (viii) of this section:

- (i) Surface preparation of the large appliance parts and products;
- (ii) Preparation of a coating for application (e.g., mixing in thinners and other components);
- (iii) Application of a coating to large appliance parts and products using, for example, spray guns or dip tanks;
- (iv) Flash-off, drying, or curing following the coating application operation;
- (v) Cleaning of equipment used in coating operations (e.g., application equipment, hangers, racks);
- (vi) Storage of coatings, thinners, and cleaning materials;
- (vii) Conveying of coatings, thinners, and cleaning materials from storage areas to mixing areas or coating application areas, either manually (e.g., in buckets) or by automated means (e.g.,

transfer through pipes using pumps); and

(viii) Handling and conveying of waste materials generated by coating operations.

(3) This subpart does not apply to research or laboratory facilities; janitorial, building, and facility maintenance operations; or coating applications using hand-held nonrefillable aerosol containers.

(4) A major source of HAP emissions is any stationary source or group of stationary sources located within a contiguous area and under common control that emits or has the potential to emit any single HAP at a rate of 9.07 megagrams (Mg) (10 tons) or more per year or any combination of HAP at a rate of 22.68 Mg (25 tons) or more per year.

(b) You are not subject to this subpart if your large appliance surface coating facility is located at, or is part of, an area source of HAP emissions. An area source of HAP emissions is any stationary source or group of stationary sources located within a contiguous area and under common control that is not a major source.

63.4082 What parts of my plant does this subpart cover?

(a) This subpart applies to each new, reconstructed, and existing affected source.

(b) The affected source is the collection of all of the items listed in paragraphs (b)(1) through (4) of this section that are part of the large appliance surface coating facility:

(1) All coating operations as defined in § 63.4181;

(2) All storage containers and mixing vessels in which organic-HAP-containing coatings, thinners, and cleaning materials are stored or mixed;

(3) All manual and automated equipment and containers used for conveying organic-HAP-containing coatings, thinners, and cleaning materials; and

(4) All storage containers and all manual and automated equipment and containers used for conveying organic-HAP-containing waste materials generated by a coating operation.

(c) An affected source is a new affected source if you commenced its construction after December 22, 2000, and the construction is of a completely new large appliance surface coating facility where previously no large appliance surface coating facility had existed.

(d) An affected source is reconstructed if you meet the criteria as defined in § 63.2.

(e) An affected source is existing if it is not new or reconstructed.

§ 63.4083 When do I have to comply with this subpart?

(a) If you have a new or reconstructed affected source, you must meet the applicable date in paragraph (a)(1) or (2) of this section:

(1) If the startup of your new or reconstructed affected source is before [the effective date of this subpart], you must comply with the requirements for new and reconstructed sources no later than [the effective date of this subpart].

(2) If the startup of your new or reconstructed affected source occurs after [the effective date of this subpart], you must comply with the requirements for new and reconstructed sources upon initial startup of your affected source.

(b) If you have an existing affected source, you must comply with the requirements for existing sources no later than [3 years after the effective date of this subpart].

(c) If you have an area source that increases its emissions or its potential to emit such that it becomes a major source of HAP emissions, you must meet the dates specified in paragraphs (c)(1) and (2) of this section.

(1) For any portion of the area source that becomes a new or reconstructed affected source, you must comply with the requirements for new and reconstructed sources upon initial startup or no later than [the effective date of this subpart], whichever is later.

(2) For any portion of the area source that becomes an existing affected source, you must comply with the requirements for existing sources no later than 1 year after the area source becomes a major source or [3 years after the effective date of this subpart], whichever is later.

(d) You must meet the notification requirements in § 63.4110 according to the dates specified in that section and in subpart A of this part. Some of the notifications must be submitted before the compliance dates described in paragraphs (a) through (c) of this section.

Emission Limitations

§ 63.4090 What emission limits must I meet?

(a) For an existing affected source, you must limit organic HAP emissions to the atmosphere to no more than 0.13 kilogram per liter (kg/liter) (1.1 pound per gallon (lb/gal) of coating solids used during each compliance period.

(b) For a new or reconstructed affected source, you must limit organic HAP emissions to the atmosphere to no more than 0.022 kg/liter (0.18 lb/gal) of coating solids used during each compliance period.

§ 63.4091 What are my options for meeting the emission limits?

To meet the emission limits in § 63.4090, you must use at least one of the three compliance options listed in paragraphs (a) through (c) of this section. You may apply any of the compliance options to an individual coating operation or to multiple coating operations as a group or to the entire affected source. You may use different compliance options for different coating operations or at different times on the same coating operation. However, you may not use different compliance options at the same time on the same coating operation. If you switch between compliance options for any coating operation or group of coating operations, you must document this switch as required by § 63.4130(c), and you must report it in the next semiannual compliance report required in § 63.4120.

(a) *Compliant material option.* Demonstrate that the organic HAP content of each coating used in the coating operation(s) is less than or equal to the applicable emission limit in § 63.4090 and that each thinner and each cleaning material used contains no organic HAP. You must meet all the requirements of §§ 63.4140, 63.4141, and 63.4142 to demonstrate compliance with the emission limit using this option.

(b) *Emission rate without add-on controls option.* Demonstrate that, based on data on the coatings, thinners, and cleaning materials used in the coating operation(s), the organic HAP emission rate for the coating operation(s) is less than or equal to the applicable emission limit in § 63.4090. You must meet all the requirements of §§ 63.4150, 63.4151, and 63.4152 to demonstrate compliance with the emission limit using this option.

(c) *Emission rate with add-on controls option.* Demonstrate that, based on data on the coatings, thinners, and cleaning materials used in the coating operation(s), and the emission capture and add-on control efficiencies achieved, the organic HAP emission rate for the coating operation(s) is less than or equal to the applicable emission limit in § 63.4090. If you use this compliance option, you must also demonstrate that all capture systems and control devices for the coating operation(s) meet the operating limits required in § 63.4092, except for solvent recovery systems for which you conduct liquid-liquid material balances according to § 63.4161(h); and that you meet the work practice standards required in § 63.4093. You must meet all the requirements of §§ 63.4160 through

63.4168 to demonstrate compliance with the emission limits, operating limits, and work practice standards using this option.

§ 63.4092 What operating limits must I meet?

(a) For any coating operation(s) on which you use the compliant material option or the emission rate without add-on controls option, you are not required to meet any operating limits. For any controlled coating operation(s) on which you use the emission rate with add-on controls option, except those for which you use a solvent recovery system and conduct a liquid-liquid material balance according to § 63.4161(h), you must meet the operating limits specified in Table 1 of this subpart. These operating limits apply to the emission capture and control systems on the coating operation(s) for which you use this option, and you must establish the operating limits during the performance test according to the procedures in § 63.4167. You must meet the operating limits at all times after you establish them.

(b) If you use a control device other than those listed in Table 1 of this subpart, or wish to monitor an alternative parameter and comply with a different operating limit, you must apply to the Administrator for approval of alternative monitoring under § 63.8(f).

§ 63.4093 What work practice standards must I meet?

For any coating operation(s) on which you use the compliant material option or the emission rate without add-on controls option, you are not required to meet any work practice standards. If you use the emission rate with add-on controls option, you must develop and implement a work practice plan to minimize organic HAP emissions from the storage, mixing, and conveying of coatings, thinners, and cleaning materials used in, and waste materials generated by, the controlled coating operation(s) for which you use this option; or you must meet an alternative standard as provided in paragraph (e) of this section. The plan must address at a minimum the elements specified in paragraphs (a) through (d) of this section.

(a) All organic-HAP-containing coatings, thinners, cleaning materials, and waste materials must be stored in closed containers.

(b) Spills of organic-HAP-containing coatings, thinners, cleaning materials, and waste materials must be minimized.

(c) Organic-HAP-containing coatings, thinners, cleaning materials, and waste

materials must be conveyed from one location to another in closed containers or pipes.

(d) Mixing vessels used for organic-HAP-containing coatings and other materials must be closed except when adding to, removing, or mixing the contents.

(e) As provided in § 63.6(g), we, EPA, may choose to grant you permission to use an alternative to the work practice standards in this section.

General Compliance Requirements

§ 63.4100 What are my general requirements for complying with this subpart?

(a) You must be in compliance with the emission limitations in this subpart as specified in paragraphs (a)(1) and (2) of this section.

(1) Any coating operation(s) for which you use the compliant material option or the emission rate without add-on controls option, as specified in § 63.4091(a) and (b), must be in compliance with the applicable emission limit in § 63.4090 at all times.

(2) Any coating operation(s) for which you use the emission rate with add-on controls option, as specified in § 63.4091(c), must be in compliance with the applicable emission limit in § 63.4090 at all times except during periods of startup, shutdown, and malfunction. Each controlled coating operation must be in compliance with the operating limits for emission capture systems and add-on control devices required by § 63.4092 at all times, except during periods of startup, shutdown, and malfunction, and except for solvent recovery systems for which you conduct liquid-liquid material balances according to § 63.4161(h). Each controlled coating operation must be in compliance with the work practice standards in § 63.4093 at all times.

(b) You must always operate and maintain your affected source, including air pollution control and monitoring equipment, according to the provisions in § 63.6(e)(1)(i).

(c) If your affected source uses an emission capture system and add-on control device, you must maintain a log detailing the operation and maintenance of the emission capture system, add-on control device, and continuous parameter monitors during the period between the compliance date specified for your affected source in § 63.4083 and the date when the initial emission capture system and add-on control device performance tests have been completed, as specified in § 63.4160. This requirement does not apply to a solvent recovery system for which you

conduct a liquid-liquid material balance according to § 63.4161(h).

(d) If your affected source uses an emission capture system and add-on control device, you must develop and implement a written startup, shutdown, and malfunction plan according to the provisions in § 63.6(e)(3). The plan must address the startup, shutdown, and corrective actions in the event of a malfunction of the emission capture system or the add-on control device. The plan must also address any coating operation equipment that may cause increased emissions or that would affect capture efficiency if the process equipment malfunctions, such as conveyors that move parts among enclosures.

§ 63.4101 What parts of the General Provisions apply to me?

Table 2 of this subpart shows which parts of the General Provisions in §§ 63.1 through 63.15 apply to you.

Notifications, Reports, and Records

§ 63.4110 What notifications must I submit?

(a) You must submit the notifications in §§ 63.7(b) and (c), 63.8(f)(4), and 63.9(b) through (e) and (h) that apply to you by the dates specified in those sections, except as provided in paragraphs (a)(1) and (2) of this section.

(1) You must submit the Initial Notification required by § 63.9(b) for an existing affected source no later than [1 year after the effective date of this subpart]. For a new or reconstructed affected source, you must submit the Initial Notification no later than 120 days after initial startup or [120 days after the effective date of this subpart], whichever is later.

(2) You must submit the Notification of Compliance Status required by § 63.9(h) no later than 30 calendar days following the end of the initial compliance period described in § 63.4140, § 63.4150, or § 63.4160 that applies to your affected source.

(b) The Notification of Compliance Status must contain the information specified in paragraphs (b)(1) through (9) of this section and in § 63.9(h).

(1) Company name and address.

(2) Statement by a responsible official with that official's name, title, and signature, certifying the truth, accuracy, and completeness of the content of the report.

(3) Date of the report and beginning and ending dates of the reporting period. The reporting period is the initial compliance period described in § 63.4140, § 63.4150, or § 63.4160 that applies to your affected source.

(4) Identification of the compliance option or options specified in § 63.4091 that you used on each coating operation during the initial compliance period.

(5) Statement of whether or not the affected source achieved the emission limitations for the initial compliance period.

(6) If you had a deviation, include the information in paragraphs (b)(6)(i) and (ii) of this section.

(i) A description of and statement of the cause of the deviation.

(ii) If you failed to meet the applicable emission limit in § 63.4090, include all the calculations you used to determine the kg organic HAP per liter coating solids. You do not need to submit information provided by the materials suppliers or manufacturers or test reports.

(7) For each of the data items listed in paragraphs (b)(7)(i) through (iv) of this section that is required by the compliance option(s) you used to demonstrate compliance with the emission limit, include an example of how you determined the value, including calculations and supporting data. Supporting data can include a copy of the information provided by the supplier or manufacturer of the example coating or material or a summary of the results of testing conducted according to § 63.4141(a), (b), or (c). You do not need to submit copies of any test reports.

(i) Mass fraction of organic HAP for one coating, for one thinner, and for one cleaning material.

(ii) Volume fraction of coating solids for one coating.

(iii) Density for one coating, one thinner, and one cleaning material, except that if you use the compliant material option, only the example coating density is required.

(iv) The information specified in § 63.4151(e)(4) for any waste materials sent to a treatment, storage, and disposal facility (TSDF), if you are claiming an allowance for organic HAP contained in those waste materials in Equation 1 of § 63.4151.

(8) The calculation of kg organic HAP per liter coating solids for the compliance option(s) you use, as specified in paragraphs (b)(8)(i) through (iii) of this section.

(i) For the compliant material option, provide an example calculation of the organic HAP content (H_c) for one coating, using Equation 2 of § 63.4141.

(ii) For the emission rate without add-on controls option, provide the calculation of the total mass of organic HAP emissions (H_e); the calculation of the total volume of coating solids (V_{sc}); and the calculation of the organic HAP

emission rate (H_{avg}), using Equations 1, 2, and 3, respectively, of § 63.4151.

(iii) For the emission rate with add-on controls option, provide the calculation of the total mass of organic HAP emissions (H_e) in the coatings, thinners, and cleaning materials used in the coating operation(s), using Equation 1 of § 63.4151; and the calculation of the organic HAP emission rate (H_{HAP}), using either Equation 4 of § 63.4161 or Equation 1 of § 63.4162, as applicable.

(9) For the emission rate with add-on controls option, you must include the information specified in paragraphs (b)(9)(i) through (iv) of this section.

(i) For each emission capture system, a summary of the data and copies of the calculations supporting the determination that the emission capture system is a permanent total enclosure (PTE) or a measurement of the emission capture system efficiency. Include a description of the protocol followed for measuring capture efficiency, summaries of any capture efficiency tests conducted, and any calculations supporting the capture efficiency determination. If you use the data quality objective (DQO) or lower confidence limit (LCL) approach, you must also include the statistical calculations to show you meet the DQO or LCL criteria in appendix A to subpart KK of this part. You do not need to submit complete test reports.

(ii) A summary of the results of each add-on control device performance test. You do not need to submit complete test reports.

(iii) A list of each emission capture system's and add-on control device's operating limits and a summary of the data used to calculate those limits.

(iv) A statement of whether or not you developed and implemented the work practice plan required by § 63.4093.

§ 63.4120 What reports must I submit?

You must submit semiannual compliance reports according to the requirements of this section. The reporting requirements of this section may be satisfied by reports required under other parts of the Clean Air Act (CAA or Act), as specified in paragraph (a)(5) of this section.

(a) Unless the Administrator has approved a different schedule for submission of reports under § 63.10(a), you must prepare and submit each semiannual compliance report according to the dates specified in paragraphs (a)(1) through (4) of this section.

(1) The first report must cover the first semiannual reporting period which begins the day after the end of the initial compliance period described in

§ 63.4140, § 63.4150, or § 63.4160 that applies to your affected source and ends on June 30 or December 31, whichever date is the first date following the end of the initial compliance period.

(2) Each subsequent semiannual compliance report must cover the subsequent semiannual reporting period from January 1 through June 30 or the semiannual reporting period from July 1 through December 31.

(3) Each semiannual compliance report must be postmarked or delivered no later than July 31 or January 31, whichever date is the first date following the end of the semiannual reporting period.

(4) For each affected source that is subject to permitting regulations pursuant to 40 CFR part 70 or 71, and if the permitting authority has established dates for submitting semiannual reports pursuant to 40 CFR 70.6(a)(3)(iii)(A) or 40 CFR 71.6(a)(3)(iii)(A), you may submit the first and subsequent compliance reports according to the dates the permitting authority has established instead of according to the date specified in paragraph (a)(3) of this section.

(5) Each affected source that has obtained a title V operating permit pursuant to 40 CFR part 70 or 71 must report all deviations as defined in this subpart in the semiannual monitoring report required by 40 CFR 70.6(a)(3)(iii)(A) or 40 CFR 71.6(a)(3)(iii)(A). If an affected source submits a compliance report pursuant to this section along with, or as part of, the semiannual monitoring report required by 40 CFR 70.6(a)(3)(iii)(A) or 40 CFR 71.6(a)(3)(iii)(A), and the compliance report includes all required information concerning deviations from any emission limitation in this subpart, submission of the compliance report shall be deemed to satisfy any obligation to report the same deviations in the semiannual monitoring report.

However, submission of a compliance report shall not otherwise affect any obligation the affected source may have to report deviations from permit requirements to the permit authority.

(b) The semiannual compliance report must contain the information specified in paragraphs (b)(1) through (4) of this section, and the information specified in paragraphs (c) through (j) of this section that is applicable to your affected source.

(1) Company name and address.

(2) Statement by a responsible official with that official's name, title, and signature, certifying the truth, accuracy, and completeness of the content of the report.

(3) Date of report and beginning and ending dates of the reporting period. The reporting period is the 6-month period ending on June 30 or December 31.

(4) Identification of the compliance option or options specified in § 63.4091 that you used on each coating operation during the reporting period. If you switched between compliance options during the reporting period, you must report the beginning and ending dates you used each option.

(c) If there were no deviations from the emission limitations in §§ 63.4090, 63.4092, and 63.4093 that apply to you, the semiannual compliance report must include a statement that there were no deviations from the emission limitations during the reporting period.

(d) If you use the compliant material option, and there was a deviation from the applicable emission limit in § 63.4090, the semiannual compliance report must contain the information in paragraphs (d)(1) through (4) of this section.

(1) Identification of each coating used that deviated from the emission limit, and each thinner and cleaning material used that contained organic HAP, and the dates and time periods each was used.

(2) The calculation of the organic HAP content (H_c , using Equation 2 of § 63.4141) for each coating identified in paragraph (d)(1) of this section. You do not need to submit background data supporting this calculation, for example, information provided by coating suppliers or manufacturers, or test reports.

(3) The determination of mass fraction of organic HAP for each thinner and cleaning material identified in paragraph (d)(1) of this section. You do not need to submit background data supporting this calculation, for example, information provided by material suppliers or manufacturers, or test reports.

(4) A statement of the cause of each deviation.

(e) If you use the emission rate without add-on controls option, and there was a deviation from the applicable emission limit in § 63.4090, the semiannual compliance report must contain the information in paragraphs (e)(1) through (3) of this section.

(1) The beginning and ending dates of each compliance period during which the organic HAP emission rate exceeded the emission limit.

(2) The calculations used to determine the organic HAP emission rate for the compliance period in which the deviation occurred. You must submit the calculations for Equations 1, 1A

through C, 2, and 3 in § 63.4151; and the calculation used to determine R_w according to § 63.4151(e)(4). You do not need to submit background data supporting these calculations, for example, information provided by materials suppliers or manufacturers, or test reports.

(3) A statement of the cause of each deviation.

(f) If you use the emission rate with add-on controls option and there were no periods during which the continuous parameter monitoring systems were out-of-control as specified in § 63.8(c)(7), the semiannual compliance report must include a statement that there were no periods during which the continuous parameter monitoring systems were out-of-control during the reporting period.

(g) If you use the emission rate with add-on controls option, and there was a deviation from an emission limitation (including any periods when emissions bypassed the add-on control device and were diverted to the atmosphere), the semiannual compliance report must contain the information in paragraphs (g)(1) through (14) of this section. This includes periods of startup, shutdown, and malfunction during which deviations occurred.

(1) The beginning and ending dates of each compliance period during which the organic HAP emission rate exceeded the applicable emission limit in § 63.4090.

(2) The calculations used to determine the organic HAP emission rate for each compliance period in which a deviation occurred. You must submit the calculations that apply to you, including Equations 1, 1A through C, and 2 of § 63.4151; Equations 1, 1A through C, 2, and 3 of § 63.4161; and either Equation 4 of § 63.4161 or Equation 1 of § 63.4162, as applicable. You do not need to submit the background data supporting these calculations, for example information provided by materials suppliers or manufacturers, or test reports.

(3) The date and time that each malfunction started and stopped.

(4) A brief description of the continuous parameter monitoring system.

(5) The date of the latest continuous parameter monitoring system certification or audit.

(6) The date and time that each continuous parameter monitoring system was inoperative, except for zero (low-level) and high-level checks.

(7) The date, time, and duration that each continuous parameter monitoring system was out-of-control, including the information in § 63.8(c)(8).

(8) The date and time that each deviation from an operating limit in Table 1 of this subpart; date and duration of any bypass of the add-on control device; and whether each deviation occurred during a period of startup, shutdown, or malfunction or during another period.

(9) A summary of the total duration of each deviation from an operating limit in Table 1 of this subpart and bypass of the add-on control device during the semiannual reporting period and the total duration as a percent of the total source operating time during that semiannual reporting period.

(10) A breakdown of the total duration of the deviations from the operating limits in Table 1 of this subpart and bypasses of the add-on control device during the semiannual reporting period into those that were due to startup, shutdown, control equipment problems, process problems, other known causes, and other unknown causes.

(11) A summary of the total duration of continuous parameter monitoring system downtime during the semiannual reporting period and the total duration of continuous parameter monitoring system downtime as a percent of the total source operating time during that semiannual reporting period.

(12) A description of any changes in the continuous parameter monitoring system, coating operation, emission capture system, or add-on control device since the last semiannual reporting period.

(13) For each deviation from the work practice standards, a description of the deviation; the date, time, and duration of the deviation; and the actions you took to correct the deviation.

(14) A statement of the cause of each deviation.

(h) If you use the emission rate with add-on controls option, you must submit reports of performance test results for emission capture systems and add-on control devices no later than 60 days after completing the tests as specified in § 63.10(d)(2).

(i) [Reserved]

(j) If you use the emission rate with add-on controls option and you have a startup, shutdown, or malfunction during the semiannual reporting period, you must submit the reports specified in paragraphs (j)(1) and (2) of this section.

(1) If your actions were consistent with your startup, shutdown, and malfunction plan, you must include the information specified in § 63.10(d) in the semiannual compliance report.

(2) If your actions were not consistent with your startup, shutdown, and malfunction plan, you must submit an

immediate startup, shut down, and malfunction report as described in paragraph (j)(2)(i) and (ii) of this section.

(i) You must describe the actions taken during the event in a report delivered by facsimile or by telephone to the Administrator within 2 working days after starting actions that are inconsistent with the plan.

(ii) You must submit a letter to the Administrator within 7 working days after the end of the event, unless you have made alternative arrangements with the Administrator as specified in § 63.10(d)(5)(ii). The letter must contain the information specified in § 63.10(d)(5)(ii).

§ 63.4130 What records must I keep?

You must collect and keep a record of the data and information specified in this section. Failure to collect and keep these records is a deviation from the applicable standard.

(a) A copy of each notification and report that you submitted to comply with this subpart, and the documentation supporting each notification and report.

(b) A current copy of information provided by materials suppliers or manufacturers, such as manufacturer's formulation data or test data used to determine the mass fraction of organic HAP and density for coatings, thinners, and cleaning materials and the volume fraction of coating solids. If you conducted testing to determine mass fraction of organic HAP, density, or volume fraction of coating solids, you must keep a copy of the complete test report. If you use information provided to you by the manufacturer or supplier of the material that was based on testing, you must keep the summary sheet of results provided to you by the manufacturer or supplier. You are not required to obtain the test report or other supporting documentation from the manufacturer or supplier.

(c) For each compliance period, a record of the time periods (beginning and ending dates) and the coating operations at which each compliance operation was used, and a record of all calculations of kg organic HAP per liter of coating solids for the compliance option(s) you used, as specified in paragraphs (c)(1) through (3) of this section.

(1) For the compliant material option, the calculation of the organic HAP content (H_c) for each coating, using Equation 2 of § 63.4141.

(2) For the emission rate without add-on controls option, the calculation of the total mass of organic HAP emissions (H_e), the calculation of the total volume of coating solids (V_{st}), and the

calculation of the organic HAP emission rate (H_{avg}), using Equations 1, 2, and 3, respectively, of § 63.4151.

(3) For the emission rate with add-on controls option, the calculation of the total mass of organic HAP emissions (H_e) in the coatings, thinners, and cleaning materials used, using Equation 1 of § 63.4151; the calculation of the mass of organic HAP emissions reduced by emission capture systems and add-on control devices (H_c and H_{CSR}), using Equations 1 and 3, respectively, of § 63.4161; and the calculation of the organic HAP emission rate (H_{HAP}), using either Equation 4 of § 63.4161 or Equation 1 of § 63.4162, as applicable.

(d) A record of the name and volume of each coating, thinner, and cleaning material used during each compliance period.

(e) A record of the mass fraction of organic HAP for each coating, thinner, and cleaning material used during each compliance period.

(f) A record of the volume fraction of coating solids for each coating used during each compliance period.

(g) A record of the density for each coating used during each compliance period; and, if you use either the emission rate without add-on controls or the emission rate with add-on controls compliance option, the density for each thinner and cleaning material used during each compliance period.

(h) If you are claiming an allowance for organic HAP in waste materials sent to a TSDF according to § 63.4151(e)(4), you must keep records of the mass of organic HAP in the waste materials sent to a TSDF during each compliance period with supporting calculations and documentation, including the waste manifest for each shipment and any additional documentation that provides the information in paragraphs (h)(1) through (5) of this section.

(1) The date of the shipment and the TSDF to which the waste was shipped;

(2) A brief description of the waste, including the operations producing the waste;

(3) The amount of waste in the shipment;

(4) The kg organic HAP contained in the shipment, including calculations of the HAP content; and

(5) Any information used to calculate the kg organic HAP contained in the shipment that is not shown on the waste manifest.

(i) [Reserved]

(j) You must keep records of the date, time, and duration of each deviation.

(k) If you use the emission rate with add-on controls option, you must keep the records specified in paragraphs (k)(1) through (9) of this section.

(1) For each deviation, a record of whether the deviation occurred during a period of startup, shutdown, or malfunction.

(2) The records in § 63.6(e)(3)(iii) through (v) related to startup, shutdown, and malfunction.

(3) The records required to show continuous compliance with each operating limit specified in Table 1 of this subpart that applies to you.

(4) If you operate under multiple operating conditions that affect emission capture system efficiency or add-on control device organic HAP destruction or removal efficiency, and you are using different emission capture system efficiency or add-on control device organic HAP destruction or removal efficiency factors for each condition, then you must keep records of the data needed to calculate the organic HAP emission rate for each compliance period, as described by Equation 1 in § 63.4162.

(5) For each capture system that is a PTE, the data and documentation needed to support a determination that the capture system meets the criteria in Method 204 of appendix M to 40 CFR part 51 for a PTE and has a capture efficiency of 100 percent, as specified in § 63.4165(a).

(6) For each capture system that is not a PTE, the data and documentation needed to determine capture efficiency according to the procedures specified in §§ 63.4164 and 63.4165(b), (c), or (d) including the records specified in paragraphs (k)(6)(i) through (iii) of this section that apply to you.

(i) *Records for a liquid-to-fugitive protocol using a temporary total enclosure or building enclosure.* Records of the mass of total volatile hydrocarbon (TVH) as measured by Method 204A or F of appendix M to 40 CFR part 51 for each material used in the coating operation, and the total TVH for all materials used during each capture efficiency test run, including a copy of the test report. Records of the mass of TVH emissions not captured by the capture system that exited the temporary total enclosure or building enclosure during each capture efficiency test run, as measured by Method 204D or E of appendix M to 40 CFR part 51, including a copy of the test report. Records documenting that the enclosure used for the capture efficiency test met the criteria in Method 204 of appendix M to 40 CFR part 51 for either a temporary total enclosure or a building enclosure.

(ii) *Records for a gas-to-gas protocol using a temporary total enclosure or a building enclosure.* Records of the mass of TVH emissions captured by the

emission capture system as measured by Method 204B or C of appendix M to 40 CFR part 51 at the inlet to the add-on control device, including a copy of the test report. Records of the mass of TVH emissions not captured by the capture system that exited the temporary total enclosure or building enclosure during each capture efficiency test run, as measured by Method 204D or E of appendix M to 40 CFR part 51, including a copy of the test report. Records documenting that the enclosure used for the capture efficiency test met the criteria in Method 204 of appendix M to 40 CFR part 51 for either a temporary total enclosure or a building enclosure.

(iii) *Records for an alternative protocol.* Records needed to document a capture efficiency determination using an alternative method or protocol as specified in § 63.4165(e), if applicable.

(7) The records specified in paragraphs (k)(7)(i) and (ii) of this section for each add-on control device organic HAP destruction or removal efficiency determination as specified in § 63.4166.

(i) Records of each add-on control device performance test conducted according to §§ 63.4164 and 63.4166.

(ii) Records of the coating operation conditions during the add-on control device performance test needed to document that the performance test was conducted under representative operating conditions.

(8) Records of the data and calculations needed to establish the emission capture and add-on control device operating limits as specified in § 63.4167 and to document compliance with the operating limits as specified in Table 1 of this subpart.

(9) A record of the work practice plan required by § 63.4093, and documentation that you are implementing the plan on a continuous basis.

§ 63.4131 In what form and for how long must I keep my records?

(a) Your records must be in a form suitable and readily available for expeditious review, according to § 63.10(b)(1). Where appropriate, the records may be maintained as electronic spreadsheets or as a database.

(b) As specified in § 63.10(b)(1), you must keep each record for 5 years following the date of each occurrence, measurement, maintenance, corrective action, report, or record.

(c) You must keep each record on site for at least 2 years after the date of each occurrence, measurement, maintenance, corrective action, report, or record, according to § 63.10(b)(1). You can keep

the records off site for the remaining 3 years.

Compliance Requirements for the Compliant Material Option

§ 63.4140 By what date must I conduct the initial compliance demonstration?

You must complete the compliance demonstration for the initial compliance period according to the requirements in § 63.4141. The initial compliance period begins on the applicable compliance date specified in § 63.4083 and ends on the last day of the first full calendar month after the compliance date. The initial compliance demonstration includes the calculations showing that you used no coating with an organic HAP content that exceeded the applicable limit in § 63.4090, and documentation that you used no thinners or cleaning materials that contained organic HAP as determined by the procedures listed in § 63.4141(a) during the compliance period.

§ 63.4141 How do I demonstrate initial compliance with the emission limitations?

You may use the compliant material option for any individual coating operation, for any group of coating operations in the affected source, or for all the coating operations in the affected source. You must use either the emission rate without add-on controls option or the emission rate with add-on controls option for any coating operation(s) in the affected source for which you do not use this option. To demonstrate initial compliance using the compliant material option, the coating operation or group of coating operations must use no coating with an organic HAP content that exceeds the applicable emission limit in § 63.4090 and must use no thinner or cleaning material that contains organic HAP, as determined according to this section. Any coating operation(s) for which you use the compliant material option is not required to meet the operating limits or work practice standards required in §§ 63.4092 and 63.4093, respectively. To demonstrate initial compliance with the emission limitations using the compliant material option, you must meet all the requirements of this section for the coating operation(s) using this option. Use the procedures in this section on each coating, thinner, and cleaning material in the condition it is in when it is received from its manufacturer or supplier and prior to any alteration.

(a) *Determine the mass fraction of organic HAP for each material used.* You must determine the mass fraction of organic HAP for each coating, thinner, and cleaning material used during the

compliance period by using one of the options in paragraphs (a)(1) through (5) of this section.

(1) *Method 311 (appendix A to 40 CFR part 63).* You may use Method 311 for determining the mass fraction of organic HAP. Use the procedures specified in paragraphs (a)(1)(i) and (ii) of this section when performing a Method 311 test.

(i) Count each organic HAP that is measured to be present at 0.1 percent by mass or more for Occupational Safety and Health Administration (OSHA)—defined carcinogens as specified in 29 CFR 1910.1200(d)(4) and at 1.0 percent by mass or more for other compounds. For example, if toluene (not an OSHA carcinogen) is measured to be 0.5 percent of the material by mass, you don't have to count it. Express the mass fraction of each organic HAP you count as a value truncated to four places after the decimal point (for example, 0.3791).

(ii) Calculate the total mass fraction of organic HAP in the test material by adding up the individual organic HAP mass fractions and truncating the result to three places after the decimal point (for example, 0.763).

(2) *Method 24 (appendix A to 40 CFR part 60).* For coatings, you may use Method 24 to determine the mass fraction of nonaqueous volatile matter and use that value as a substitute for mass fraction of organic HAP.

(3) *Alternative method.* You may use an alternative test method for determining the mass fraction of organic HAP once the Administrator has approved it. You must follow the procedure in § 63.7(f) to submit an alternative test method for approval.

(4) *Information from the supplier or manufacturer of the material.* You may rely on information other than that generated by the test methods specified in paragraphs (a)(1) through (3) of this section, such as manufacturer's formulation data. Count each organic HAP that is present at 0.1 percent by mass or more for OSHA-defined carcinogens as specified in 29 CFR 1910.1200(d)(4) and at 1.0 percent by mass or more for other compounds. For example, if toluene (not an OSHA carcinogen) is 0.5 percent of the material by mass, you don't have to count it. If there is a disagreement between such information and results of the test methods specified in paragraphs (a)(1) through (3) of this section, then the test method results will take precedence.

(5) *Solvent blends.* Solvent blends may be listed as single components for some materials in data provided by manufacturers or suppliers. Solvent blends may contain organic HAP which

must be counted toward the total organic HAP mass fraction of the materials. When test data for solvent blends are not available, you may use the value for mass fraction of organic HAP listed in Table 3 or 4 of this subpart. If you use the tables, you must use the values in Table 3 for all solvent blends that match Table 3 entries, and you may only use Table 4 if the solvent blends in the materials you use do not match any of the solvent blends in Table 3 and you only know whether the blend is aliphatic or aromatic. However, if the results of Method 311 indicate higher values than those listed on Table 3 or 4 of this subpart, the Method 311 results will take precedence.

(b) *Determine the volume fraction of coating solids for each coating.* You must determine the volume fraction of coating solids (liters of coating solids per liter of coating) for each coating used during the compliance period by a test, by information provided by the supplier or the manufacturer of the material, or by calculation as specified in paragraphs (b)(1) through (3) of this section. The results obtained with paragraph (b)(1) of this section will take precedence if they do not agree with the results obtained with paragraph (b)(2) or (3) of this section.

(1) *ASTM Method D2697-86(1998) or D6093-97.* You may use ASTM Method D2697-86(1998) or D6093-97 to determine the volume fraction of coating solids for each coating. Multiply the nonvolatile volume percent obtained with the methods by 100 to calculate volume fraction of coating solids.

(2) *Information from the supplier or manufacturer of the material.* You may obtain the volume fraction of coating solids for each coating from the supplier or manufacturer.

(3) *Calculation of volume fraction of coating solids, V_s .* If the volume fraction of coating solids cannot be determined using the options in paragraphs (b)(1) and (2) of this section, you must determine it using Equation 1 of this section:

$$V_s = 1 - \frac{m_{\text{volatiles}}}{D_{\text{avg}}} \quad (\text{Eq. 1})$$

Where:

V_s = Volume fraction of coating solids, liters coating solids per liter coating.

$m_{\text{volatiles}}$ = Total volatile matter content of the coating, including HAP, volatile organic compounds (VOC), water, and exempt compounds, determined according to Method 24 in appendix A of 40 CFR part 60, grams volatile matter per liter coating.

D_{avg} = Average density of volatile matter in the coating, grams volatile matter per liter volatile matter, determined from test results using ASTM Method D1475-98, information from the supplier or manufacturer of the material, or reference sources providing density or specific gravity data for pure materials. If there is disagreement between ASTM Method D1475-98 test results and other information sources, the test results will take precedence.

(c) *Determine the density of each coating.* Determine the density of each coating used during the compliance period from test results using ASTM Method D1475-98, information from the supplier or manufacturer of the material, or reference sources providing density or specific gravity data for pure materials. If there is disagreement between ASTM Method D1475-98 test results and other information sources, the test results will take precedence.

(d) *Calculate the organic HAP content of each coating.* Calculate H_c , the organic HAP content, kg organic HAP per liter coating solids, of each coating used during the compliance period, using Equation 2 of this section:

$$H_c = (D_c)(W_c)/V_s \quad (\text{Eq. 2})$$

Where:

H_c = Organic HAP content of the coating, kg organic HAP per liter coating solids.

D_c = Density of coating, kg coating per liter coating, determined according to paragraph (c) of this section.

W_c = Mass fraction of organic HAP in the coating, kg organic HAP per kg coating, determined according to paragraph (a) of this section.

V_s = Volume fraction of coating solids, liters coating solids per liter coating, determined according to paragraph (b) of this section.

(e) *Compliance demonstration.* The calculated organic HAP content, H_c , for each coating used during the initial compliance period must be less than or equal to the applicable emission limit in § 63.4090; and each thinner and cleaning material used during the initial compliance period must contain no organic HAP, determined according to paragraph (a) of this section. You must keep all records required by §§ 63.4130 and 63.4131. As part of the Notification of Compliance Status required in § 63.4110, you must identify the coating operation(s) for which you used the compliant material option and submit a statement that the coating operation(s) was (were) in compliance with the emission limitations during the initial compliance period because you used no

coatings for which the organic HAP content exceeds the applicable emission limit in § 63.4090, and you used no thinners or cleaning materials that contain organic HAP.

§ 63.4142 How do I demonstrate continuous compliance with the emission limitations?

(a) For each compliance period, to demonstrate continuous compliance, you must use no coating for which the organic HAP content, H_c , determined using Equation 2 of § 63.4141, exceeds the applicable emission limit in § 63.4090, and use no thinner or cleaning material that contains organic HAP, determined according to § 63.4141(a). Each calendar month following the initial compliance period described in § 63.4140 is a compliance period.

(b) If you choose to comply with the emission limitations by using the compliant material option, the use of any coating, thinner, or cleaning material that does not meet the criteria specified in paragraph (a) of this section is a deviation from the emission limitations that must be reported as specified in §§ 63.4110(b)(6) and 63.4120(d).

(c) As part of each semiannual compliance report required by § 63.4120, you must submit a statement that you were in compliance with the emission limitations during the reporting period because you used no thinners or cleaning materials that contained organic HAP, and you used no coatings for which the organic HAP content exceeded the applicable emission limit in § 63.4090.

(d) You must maintain records as specified in §§ 63.4130 and 63.4131.

Compliance Requirements for the Emission Rate Without Add-On Controls Option

§ 63.4150 By what date must I conduct the initial compliance demonstration?

You must complete the compliance demonstration for the initial compliance period according to the requirements of § 63.4151. The initial compliance period begins on the applicable compliance date specified in § 63.4083 and ends on the last day of the first full calendar month after the compliance date. The initial compliance demonstration includes the calculations showing that the organic HAP emission rate for the initial compliance period was equal to or less than the applicable emission limit in § 63.4090.

§ 63.4151 How do I demonstrate initial compliance with the emission limitations?

You may use the emission rate without add-on controls option for any individual coating operation, for any group of coating operations in the affected source, or for all the coating operations in the affected source. You must use either the compliant material option or the emission rate with add-on controls option for any coating operation(s) in the affected source for which you do not use this option. To demonstrate initial compliance using the emission rate without add-on controls option, the coating operation(s) must meet the applicable emission limit in § 63.4090 but not the operating limits or work practice standards in §§ 63.4092 and 63.4093, respectively. You must meet all the requirements of this section to demonstrate initial compliance with the applicable emission limit in § 63.4090 for the coating operation(s). When calculating the organic HAP emission rate according to this section, do not include any coatings, thinners, or cleaning materials used on coating operations for which you use the compliant material option or the emission rate with add-on controls option.

(a) *Determine the mass fraction of organic HAP for each material.* Determine the mass fraction of organic HAP for each coating, thinner, and cleaning material used during the compliance period according to the requirements in § 63.4141(a).

(b) *Determine the volume fraction of coating solids for each coating.* Determine the volume fraction of coating solids for each coating used during the compliance period according to the requirements in § 63.4141(b).

(c) *Determine the density of each material.* Determine the density of each coating, thinner, and cleaning material used during the compliance period according to the requirements in § 63.4141(c).

(d) *Determine the volume of each material used during the compliance period.* Determine the volume (liters) of each coating, thinner, and cleaning material used during the compliance period by measurement or usage records.

(e) *Calculate the mass of organic HAP emissions during the compliance period.* The mass of organic HAP emissions, H_e , is the combined mass of organic HAP contained in all coatings, thinners, and cleaning materials used during the compliance period minus the organic HAP in certain waste materials. Calculate H_e using Equation 1 of this section.

$$H_e = A + B + C - R_w \quad (\text{Eq. 1})$$

Where:

H_e = The total mass of organic HAP emissions during the compliance period, kg.

A = The total mass of organic HAP in the coatings used during the compliance period, kg, as calculated in Equation 1A of this section.

B = The total mass of organic HAP in the thinners used during the compliance period, kg, as calculated in Equation 1B of this section.

C = The total mass of organic HAP in the cleaning materials used during the compliance period, kg, as calculated in Equation 1C of this section.

R_w = The total mass of organic HAP in waste materials sent to a hazardous waste TSDF for treatment or disposal, kg, determined according to paragraph (e)(4) of this section. (You may assign a value of zero to R_w if you do not wish to use this allowance.)

(1) Calculate A , the kg organic HAP in the coatings used during the compliance period using Equation 1A of this section:

$$A = \sum_{i=1}^m (\text{Vol}_{c,i}) (D_{c,i}) (W_{c,i}) \quad (\text{Eq. 1A})$$

Where:

$\text{Vol}_{c,i}$ = Total volume of coating, i , used during the compliance period, liters.

$D_{c,i}$ = Density of coating, i , kg coating per liter coating.

$W_{c,i}$ = Mass fraction of organic HAP in coating, i , kg organic HAP per kg coating.

m = Number of different coatings used during the compliance period.

(2) Calculate B , the kg of organic HAP in the thinners used during the compliance period using Equation 1B of this section:

$$B = \sum_{j=1}^n (\text{Vol}_{t,j}) (D_{t,j}) (W_{t,j}) \quad (\text{Eq. 1B})$$

Where:

$\text{Vol}_{t,j}$ = Total volume of thinner, j , used during the compliance period, liters.

$D_{t,j}$ = Density of thinner, j , kg per liter.

$W_{t,j}$ = Mass fraction of organic HAP in thinner, j , kg organic HAP per kg thinner.

n = Number of different thinners used during the compliance period.

(3) Calculate C , the kg organic HAP in the cleaning materials used during the

compliance period using Equation 1C of this section:

$$C = \sum_{k=1}^p (\text{Vol}_{s,k}) (D_{s,k}) (W_{s,k}) \quad (\text{Eq. 1C})$$

Where:

$\text{Vol}_{s,k}$ = Total volume of cleaning material, k , used during the compliance period, liters.

$D_{s,k}$ = Density of cleaning material, k , kg per liter.

$W_{s,k}$ = Mass fraction of organic HAP in cleaning material, k , kg organic HAP per kg material.

p = Number of different cleaning materials used during the compliance period.

(4) Determine the mass of organic HAP contained in waste materials sent to a TSDF (R_w). If you choose to account for the mass of organic HAP contained in waste materials sent to a hazardous waste TSDF in the calculation of H_e (Equation 1 of this section), then you must include in your Notification of Compliance Status the information specified in paragraphs (e)(4)(i) through (iv) of this section. You may use this allowance only if the waste materials are generated by the coating operations for which you use Equation 1 of this section and are sent to a facility that is regulated as a TSDF under 40 CFR part 262, 264, 265, or 266. You must not make an allowance for organic HAP contained in wastewater.

(i) The name and address of each TSDF to which the waste material was sent during the compliance period and a statement of which regulations under 40 CFR parts 262, 264, 265, and 266 apply to the facility.

(ii) A description of the waste material sent to each TSDF, including the operations producing the waste material streams, the amount of waste materials sent to the TSDF during the compliance period, and the mass of organic HAP contained in these waste materials.

(iii) The methodology used to determine the total amount of waste materials sent to the TSDF during the compliance period and the mass of organic HAP contained in these waste materials. This must include the sources for all data used in the determination, methods used to generate the data, and frequency of testing or monitoring.

(iv) To the extent that waste manifests include the information specified in paragraphs (e)(4)(i) through (iii) of this section, they may be used as part of the documentation of the amount of waste materials and organic HAP content of waste materials sent to the TSDF.

(f) *Calculate the total volume of coating solids used during the*

compliance period. Determine V_{st} , the total volume of coating solids used, liters, which is the combined volume of coating solids for all the coatings used during the compliance period, using Equation 2 of this section.

$$V_{st} = \sum_{i=1}^m (Vol_{c,i})(V_{s,i}) \quad (\text{Eq. 2})$$

Where:

V_{st} = Total volume of coating solids used during the compliance period, liters.

$Vol_{c,i}$ = Total volume of coating, i, used during the compliance period, liters.

$V_{s,i}$ = Volume fraction of coating solids for coating, i, liters solids per liter coating, determined according to § 63.4141(b).

m = Number of coatings used during the compliance period.

(g) *Calculate the organic HAP emission rate during the compliance period.* Calculate H_{avg} the organic HAP emission rate, kg organic HAP per liter coating solids used, using Equation 3 of this section:

$$H_{avg} = \frac{H_e}{V_{st}} \quad (\text{Eq. 3})$$

Where:

H_{avg} = The organic HAP emission rate for the compliance period, kg organic HAP per liter coating solids.

H_e = Total mass organic HAP emissions from all materials used during the compliance period, kg, as calculated by Equation 1 of this section.

V_{st} = Total volume coating solids used during the compliance period, liters, as calculated by Equation 2 of this section.

(h) *Compliance demonstration.* The organic HAP emission rate for the initial compliance period, H_{avg} must be less than or equal to the applicable emission limit in § 63.4090. You must keep all records as required by §§ 63.4130 and 63.4131. As part of the Notification of Compliance Status required by § 63.4110, you must identify the coating operation(s) for which you used the emission rate without add-on controls option and submit a statement that the coating operation(s) was (were) in compliance with the emission limitations during the initial compliance period because the organic HAP emission rate was less than or equal to the applicable emission limit in § 63.4090.

§ 63.4152 How do I demonstrate continuous compliance with the emission limitations?

(a) To demonstrate continuous compliance, the organic HAP emission rate for each compliance period, determined according to the procedures in § 63.4151(a) through (g), must be less than or equal to the applicable emission limit in § 63.4090. Each calendar month following the initial compliance period described in § 63.4150 is a compliance period.

(b) If the organic HAP emission rate for any compliance period exceeded the applicable emission limit in § 63.4090, this is a deviation from the emission limitations for that compliance period and must be reported as specified in §§ 63.4110(b)(6) and 63.4120(e).

(c) As part of each semiannual compliance report required by § 63.4120, you must submit a statement that you were in compliance with the emission limitations during the reporting period because the organic HAP emission rate for each compliance period was less than or equal to the applicable emission limit in § 63.4090.

(d) You must maintain records as specified in §§ 63.4130 and 63.4131.

Compliance Requirements for the Emission Rate With Add-On Controls Option

§ 63.4160 By what date must I conduct performance tests and other initial compliance demonstrations?

(a) *Existing sources.* For an existing affected source, you must meet the requirements of paragraphs (a)(1) through (3) of this section.

(1) Except for solvent recovery systems for which you conduct liquid-liquid material balances according to § 63.4161(h), you must conduct a performance test of each capture system and add-on control device according to the procedures in §§ 63.4164, 63.4165, and 63.4166, and establish the operating limits required by § 63.4092, no later than the compliance date specified in § 63.4083. For a solvent recovery system for which you conduct liquid-liquid material balances according to § 63.4161(h), you must initiate the first material balance no later than the compliance date specified in § 63.4083.

(2) You must develop and begin implementing the work practice plan required by § 63.4093 no later than the compliance date specified in § 63.4083.

(3) You must complete the compliance demonstration for the initial compliance period according to the requirements of § 63.4161. The initial compliance period begins on the applicable compliance date specified in § 63.4083 and ends on the last day of the

first full calendar month after the compliance date. The initial compliance demonstration includes the results of emission capture system and add-on control device performance tests conducted according to §§ 63.4164, 63.4165, and 63.4166; results of liquid-liquid material balances conducted according to § 63.4161(h); calculations showing whether the organic HAP emission rate for the initial compliance period was equal to or less than the emission limit in § 63.4090(a); the operating limits established during the performance tests and the results of the continuous parameter monitoring required by § 63.4168; and documentation of whether you developed and implemented the work practice plan required by § 63.4093.

(b) *New and reconstructed affected sources.* For a new or reconstructed affected source, you must meet the requirements of paragraphs (b)(1) through (4) of this section.

(1) Except for solvent recovery systems for which you conduct liquid-liquid material balances according to § 63.4161(h), you must conduct a performance test of each capture system and add-on control device according to the procedures in §§ 63.4164, 63.4165, and 63.4166, and establish the operating limits required by § 63.4092, no later than 180 days after startup or 180 days after the effective date of this subpart, whichever is later. For a solvent recovery system for which you conduct liquid-liquid material balances according to § 63.4161(h), you must initiate the first material balance no later than 180 days after startup or 180 days after the effective date of this subpart, whichever is later.

(2) You must develop and begin implementing the work practice plan required by § 63.4093 no later than the compliance date specified in § 63.4083.

(3) You must complete the compliance demonstration for the initial compliance period according to the requirements of § 63.4161. The initial compliance period begins on the applicable compliance date specified in § 63.4083 and ends on the last day of the first full calendar month after the compliance date, or the date you conduct the performance tests of the emission capture systems and add-on control devices, or initiate the first liquid-liquid material balance for a solvent recovery system, whichever is later. The initial compliance demonstration includes the results of emission capture system and add-on control device performance tests conducted according to §§ 63.4164, 63.4165, and 63.4166; results of liquid-liquid material balances conducted

according to § 63.4161(h); calculations showing whether the organic HAP emission rate for the initial compliance period was equal to or less than the emission limit in § 63.4090(b); the operating limits established during the performance tests and the results of the continuous parameter monitoring required by § 63.4168; and documentation of whether you developed and implemented the work practice plan required by § 63.4093.

(4) You do not need to comply with the operating limits for the emission capture system and add-on control device required by § 63.4092 until after you have completed the performance tests specified in paragraph (b)(1) of this section. Instead, you must maintain a log detailing the operation and maintenance of the emission capture system, add-on control device, and continuous parameter monitors during the period between the compliance date and the performance test. All continuous parameter monitoring systems must be installed and operating on the applicable compliance date specified in § 63.4083. You must begin complying with the operating limits for your affected source on the date you complete the performance tests specified in paragraph (b)(1) of this section. This requirement does not apply to solvent recovery systems for which you conduct liquid-liquid material balances.

§ 63.4161 How do I demonstrate initial compliance?

You may use the emission rate with add-on controls option for any coating operation, for any group of coating operations in the affected source, or for all of the coating operations in the affected source. You may include both controlled and uncontrolled coating operations in a group for which you use this option. You must use either the compliant material option or the emission rate without add-on controls option for any coating operation(s) in the affected source for which you do not use this option. To demonstrate initial compliance, the coating operation(s) for which you use the emission rate with add-on controls option must meet the applicable emission limit in § 63.4090, and each controlled coating operation

must meet the operating limits and work practice standards required in §§ 63.4092 and 63.4093, respectively. You must meet all the requirements of this section to demonstrate initial compliance with the emission limitations. When calculating the organic HAP emission rate according to this section, do not include any coatings, thinners, or cleaning materials used on coating operations for which you use the compliant material option or the emission rate without add-on controls option.

(a) *Compliance with operating limits.* Except as provided in § 63.4160(b)(4), you must establish and demonstrate continuous compliance during the initial compliance period with the operating limits required by § 63.4092, using the procedures specified in §§ 63.4167 and 63.4168.

(b) *Compliance with work practice requirements.* You must develop, implement, and document your implementation of the work practice plan required by § 63.4093 during the initial compliance period as specified in § 63.4130.

(c) *Compliance with emission limits.* You must follow the procedures in paragraphs (d) through (l) of this section to demonstrate compliance with the applicable emission limit in § 63.4090.

(d) *Determine the mass fraction of organic HAP, density, volume used, and volume of coating solids.* Follow the procedures specified in § 63.4151(a) through (d) to determine the mass fraction of organic HAP, density, and volume of each coating, thinner, and cleaning material used during the compliance period; and the volume fraction of coating solids for each coating used during the compliance period.

(e) *Calculate the total mass of organic HAP emissions before add-on controls.* Using Equation 1 of § 63.4151, calculate the total mass of organic HAP emissions, H_e , before add-on controls from all coatings, thinners, and cleaning materials used during the compliance period.

(f) *Calculate the organic HAP emission reduction for each controlled coating operation.* Determine the mass of organic HAP emissions reduced for

each controlled coating operation during the compliance period. The emissions reduction determination quantifies the total organic HAP emissions that pass through the emission capture system and are destroyed or removed by the add-on control device. Use the procedures in paragraph (g) of this section to calculate the mass of organic HAP emissions reduction for each controlled coating operation using an emission capture system and add-on control device other than a solvent recovery system for which you conduct liquid-liquid material balances. For each controlled coating operation using a solvent recovery system for which you conduct a liquid-liquid material balance, use the procedures in paragraph (h) of this section to calculate the organic HAP emissions reduction.

(g) *Calculate the organic HAP emissions, H_c , reduction for controlled coating operations not using liquid-liquid material balance.* For each controlled coating operation using an emission capture system and add-on control device other than a solvent recovery system for which you conduct liquid-liquid material balances, calculate H_c , using Equation 1 of this section, by applying the emission capture system efficiency and add-on control device efficiency to the mass of organic HAP contained in the coatings, thinners, and cleaning materials that are used in the coating operation served by the emission capture system and add-on control device during the compliance period. If an operating parameter for the emission capture system or add-on control device deviates from the operating limits specified in § 63.4092, then you must assume zero efficiency for the emission capture system and add-on control device during the deviation. For the purposes of completing the compliance calculations, you must treat the materials used during a deviation on a controlled coating operation as if they were used on an uncontrolled coating operation for the time period of the deviation. You must not include those materials in the calculations of organic HAP emissions reduction in Equation 1 of this section.

$$H_c = (A_1 + B_1 + C_1) \left(\frac{CE}{100} \times \frac{DRE}{100} \right) \quad (\text{Eq. 1})$$

Where:

H_c = Mass of organic HAP emissions reduction for the controlled coating

operation during the compliance period, kg.
 A_1 = The total mass of organic HAP in the coatings used in the controlled

coating operation, kg, as calculated in Equation 1A of this section.
 B_1 = The total mass of organic HAP in the thinners used in the controlled

coating operation, kg, as calculated in Equation 1B of this section.

C_I = The total mass of organic HAP in the cleaning materials used in the controlled coating operation during the compliance period, kg, as calculated in Equation 1C of this section.

CE = The capture efficiency of the emission capture system vented to the add-on control device, percent. Use the test methods and procedures specified in §§ 63.4164 and 63.4165 to measure and record capture efficiency.

DRE = Organic HAP destruction or removal efficiency of the add-on control device, percent. Use the test methods and procedures in §§ 63.4164 and 63.4166 to measure and record the organic HAP destruction or removal efficiency.

(1) Calculate A_I , the mass of organic HAP in the coatings used in the controlled coating operation, kg, using Equation 1A of this section:

$$A_I = \sum_{i=1}^m (\text{Vol}_{c,i})(D_{c,i})(W_{c,i}) \quad (\text{Eq. 1A})$$

Where:

$\text{Vol}_{c,i}$ = Total volume of coating, i, used, liters.

$D_{c,i}$ = Density of coating, i, kg per liter.

$W_{c,i}$ = Mass fraction of organic HAP in coating, i, kg per kg.

m = Number of different coatings used.

(2) Calculate B_I , the mass of organic HAP in the thinners used in the controlled coating operation, kg, using Equation 1B of this section:

$$B_I = \sum_{j=1}^n (\text{Vol}_{t,j})(D_{t,j})(W_{t,j}) \quad (\text{Eq. 1B})$$

Where:

R_V = Volatile organic matter collection and recovery efficiency of the solvent recovery system during the compliance period, percent.

M_{VR} = Mass of volatile organic matter recovered by the solvent recovery system during the compliance period, kg.

Vol_i = Volume of coating, i, used in the coating operation controlled by the solvent recovery system during the compliance period, liters.

$\text{Vol}_{t,j}$ = Total volume of thinner, j, used, liters.

$D_{t,j}$ = Density of thinner, j, kg per liter.

$W_{t,j}$ = Mass fraction of organic HAP in thinner, j, kg per kg.

n = Number of different thinners used.

(3) Calculate C_I , the mass of organic HAP in the cleaning materials used in the controlled coating operation during the compliance period, kg, using Equation 1C of this section:

$$C_I = \sum_{k=1}^p (\text{Vol}_{s,k})(D_{s,k})(W_{s,k}) \quad (\text{Eq. 1C})$$

Where:

$\text{Vol}_{s,k}$ = Total volume of cleaning material, k, used, liters.

$D_{s,k}$ = Density of cleaning material, k, kg per liter.

$W_{s,k}$ = Mass fraction of organic HAP in cleaning material, k, kg per kg.

p = Number of different cleaning materials used.

(h) Calculate the organic HAP emissions reduction for controlled coating operations using liquid-liquid material balance, H_{CSR} . For each controlled coating operation using a solvent recovery system for which you conduct liquid-liquid material balances, calculate H_{CSR} by applying the volatile organic matter collection and recovery efficiency to the mass of organic HAP contained in the coatings, thinners, and cleaning materials that are used in the coating operation controlled by the solvent recovery system during the compliance period. Perform a liquid-liquid material balance for each compliance period as specified in paragraphs (h)(1) through (6) of this section.

(1) For each solvent recovery system, install, calibrate, maintain, and operate according to the manufacturer's specifications, a device that indicates

the cumulative amount of volatile organic matter recovered by the solvent recovery system each compliance period. The device must be initially certified by the manufacturer to be accurate to within ± 2.0 percent.

(2) For each solvent recovery system, determine the mass, M_{VR} , of volatile organic matter recovered for the compliance period, kg, based on measurement with the device required in paragraph (h)(1) of this section.

(3) Determine the mass fraction, C_V , of volatile organic matter for each coating used in the coating operation controlled by the solvent recovery system during the compliance period, kg volatile organic matter per kg coating. You may determine the volatile organic matter mass fraction using Method 24 of 40 CFR part 60, appendix A, or an EPA approved alternative method, or you may use information provided by the manufacturer or supplier of the coating. In the event of any inconsistency between information provided by the manufacturer or supplier and the results of Method 24 of 40 CFR part 60, appendix A, or an approved alternative method, the test method results will govern.

(4) Determine the density of each coating, thinner, and cleaning material used in the coating operation controlled by the solvent recovery system during the compliance period, kg per liter, according to § 63.4151(c).

(5) Measure the volume of each coating, thinner, and cleaning material used in the coating operation controlled by the solvent recovery system during the compliance period, liters.

(6) Calculate the solvent recovery system's volatile organic matter collection and recovery efficiency, R_V , using Equation 2 of this section:

$$R_V = 100 \frac{M_{VR}}{\sum_{i=1}^m \text{Vol}_i D_i C_{vi} + \sum_{j=1}^n \text{Vol}_j D_j + \sum_{k=1}^p \text{Vol}_k D_k} \quad (\text{Eq. 2})$$

Where:

R_V = Volatile organic matter collection and recovery efficiency of the solvent recovery system during the compliance period, percent.

M_{VR} = Mass of volatile organic matter recovered by the solvent recovery system during the compliance period, kg.

Vol_i = Volume of coating, i, used in the coating operation controlled by the solvent recovery system during the compliance period, liters.

D_i = Density of coating, i, kg per liter.

C_{vi} = Mass fraction of volatile organic matter for coating, i, kg volatile organic matter per kg coating.

Vol_j = Volume of thinner, j, used in the coating operation controlled by the solvent recovery system during the compliance period, liters.

D_j = Density of thinner, j, kg per liter.

Vol_k = Volume of cleaning material, k, used in the coating operation controlled by the solvent recovery

system during the compliance period, liters.

D_k = Density of cleaning material, k, kg per liter.

m = Number of different coatings used in the coating operation controlled by the solvent recovery system during the compliance period.

n = Number of different thinners used in the coating operation controlled by the solvent recovery system during the compliance period.

p = Number of different cleaning materials used in the coating operation controlled by the solvent recovery system during the compliance period.

(7) Calculate the mass of organic HAP emissions reduction for the coating operation controlled by the solvent recovery system during the compliance period, H_{CSR} , using Equation 3 of this section:

$$H_{CSR} = (A_I + B_I + C_I) \left(\frac{R_v}{100} \right) \quad (\text{Eq. 3})$$

Where:

H_{CSR} = Mass of organic HAP emissions reduction for the coating operation controlled by the solvent recovery

system during the compliance period, kg.

A_I = The total mass of organic HAP in the coatings used in the coating operation controlled by the solvent recovery system, kg, calculated using Equation 1A of this section.

B_I = The total mass of organic HAP in the thinners used in the coating operation controlled by the solvent recovery system, kg, calculated using Equation 1B of this section.

C_I = The total mass of organic HAP in the cleaning materials used in the coating operation controlled by the solvent recovery system, kg, calculated using Equation 1C of this section.

R_v = Volatile organic matter collection and recovery efficiency of the

solvent recovery system, percent, from Equation 2 of this section.

(i) [Reserved]

(j) *Calculate the total volume of coating solids used.* Determine V_{st} , the total volume of coating solids used, liters, which is the combined volume of coating solids for all the coatings used during the compliance period, using Equation 2 of § 63.4151.

(k) *Calculate the organic HAP emission rate.* Determine H_{HAP} , the organic HAP emission rate to the atmosphere, kg organic HAP per liter coating solids used during the compliance period, using either Equation 4 of this section or Equation 1 of § 63.4162.

$$H_{HAP} = \frac{H_e - \sum_{i=1}^q (H_{C,i}) - \sum_{j=1}^r (H_{CSR,j})}{V_{st}} \quad (\text{Eq. 4})$$

Where:

H_e = Total mass of organic HAP emissions before add-on controls from all the coatings, thinners, and cleaning materials used during the compliance period, kg, determined according to paragraph (e) of this section.

$H_{C,i}$ = Total mass of organic HAP emissions reduction for controlled coating operation, i, during the compliance period, kg, from Equation 1 of this section.

$H_{CSR,j}$ = Total mass of organic HAP emissions reduction for controlled coating operation, j, during the compliance period, kg, from Equation 3 of this section.

V_{st} = Total volume of coating solids used during the compliance period, liters, from Equation 2 of § 63.4151.

q = Number of controlled coating operations except those controlled with a solvent recovery system.

r = Number of coating operations controlled with a solvent recovery system.

(l) *Compliance demonstration.* To demonstrate initial compliance with the emission limit, H_{HAP} , calculated using either Equation 4 of this section or Equation 1 of § 63.4162, must be less than or equal to the applicable emission limit in § 63.4090. You must keep all records as required by §§ 63.4130 and 63.4131. As part of the Notification of Compliance Status required by § 63.4110, you must identify the coating operation(s) for which you used the emission rate with ad-on controls option

and submit a statement that the coating operation(s) was (were) in compliance with the emission limitations during the initial compliance period because the organic HAP emission rate was less than or equal to the applicable emission limit in § 63.4090, and you achieved the operating limits required by § 63.4092 and the work practice standards required by § 63.4093.

§ 63.4162 How do I determine the organic HAP emission rate for a controlled coating operation not using a material balance if I operate it under different sets of representative operating conditions?

(a) If a controlled coating operation for which you do not conduct liquid-liquid material balances, its emission capture system, or its add-on control device will be operated at multiple sets of representative operating conditions that result in different capture system or add-on control device efficiencies during the compliance period, you must determine the organic HAP emission rate according to either paragraph (b) or (c) of this section. The cases described in paragraphs (a)(1) and (2) of this section are examples of such operating conditions.

(1) You use a single add-on control device to reduce emissions from two or more coating operations, and the number of coating operations vented to the add-on control device is variable during the compliance period. This case also includes situations where you have more than one capture device on the same coating operation, and the number of capture devices or one of the capture

devices vented to the control device is changed during the compliance period.

(2) The coatings or cleaning materials you apply, or the products to which you apply them, differ during the compliance period, and the differences are such that the emission capture efficiency or add-on control device efficiency changes. This case includes a change in the shape or size of the product coated such that there is a change in capture efficiency of the capture system. This case also includes a change in the materials that results in an inlet concentration to the add-on control device that is sufficiently lower such that the percent reduction the control device can achieve changes, or a change in the volatility of the organic HAP in the materials used such that a lower proportion of the HAP is captured by the capture system, and a higher amount is not captured by the capture system.

(b) If you conduct your performance test under the representative operating conditions that are expected to result in the lowest emission capture system and add-on control device efficiencies, as allowed under § 63.4164(b)(2), then determine the organic HAP emission rate according to the procedures and equations in § 63.4161. You do not need to follow paragraph (c) of this section.

(c) If you conduct your performance test under multiple sets of representative operating conditions to establish different emission capture system and add-on control device efficiencies for each set of operating conditions, as allowed under

§ 63.4164(b)(1), then determine the organic HAP emission rate according to paragraphs (c)(1) and (2) of this section.

(1) You must use Equation 1 of this section for determining H_{HAP} , the organic HAP emission rate to the

atmosphere, kg organic HAP per liter coating solids used.

$$H_{HAP} = \frac{H_e - \sum_{i=1}^q (H_{C, i_1} + H_{C, i_2} + \dots + H_{C, i_n}) - \sum_{j=1}^r (H_{CSR_j})}{V_{st}} \quad (\text{Eq. 1})$$

Where:

H_e = Total mass of organic HAP emissions before add-on controls from all coatings, thinners, and cleaning materials used during the compliance period, kg, determined according to § 63.4161(e).

$H_{C,i1}$, $H_{C,i2}$, $H_{C,in}$ = Total mass of organic HAP emissions reduction, kg, for controlled coating operation, i , while operating under each operating condition, n , during the compliance period, from Equation 1 of § 63.4161.

$H_{CSR,j}$ = Total mass of organic HAP emissions reduction, kg, from coating operation, j , controlled by a solvent recovery system, from Equation 3 of § 63.4161.

V_{st} = Total volume of coating solids used during the compliance period, liters, from Equation 2 of § 63.4151.

n = Number of different operating conditions that affect emission capture system efficiency or add-on control device organic HAP destruction or removal efficiency under which the coating operation operated during the compliance period.

q = Number of controlled coating operations not controlled by a solvent recovery system.

r = Number of different coating operations controlled by a solvent recovery system.

(2) To determine the H_{Cn} in Equation 1 of this section, follow the steps in paragraphs (c)(2)(i) through (iii) of this section.

(i) Use Equation 1 of § 63.4161 to calculate the H_{Cn} for each operating condition of each controlled coating operation.

(ii) For the factors A_i , B_i , and C_i in Equation 1 of § 63.4161, use the mass of organic HAP contained in the coatings, thinners, and cleaning materials used in each controlled coating operation while operating under each operating condition, n .

(iii) In Equation 1 of § 63.4161, use the emission capture system efficiency and add-on control device organic HAP destruction or removal efficiency that apply under each operating condition, n . These efficiencies for each operating

condition are determined from the performance test required by § 63.4160.

§ 63.4163 How do I demonstrate continuous compliance with the emission limitations?

(a) To demonstrate continuous compliance with the applicable emission limit in § 63.4090, the organic HAP emission rate for each compliance period, determined according to the procedures in § 63.4161 (and in § 63.4162, if applicable), must be equal to or less than the applicable emission limit in § 63.4090. Each calendar month following the initial compliance period described in § 63.4160 is a compliance period.

(b) If the organic HAP emission rate for any compliance period exceeded the applicable emission limit in § 63.4090, this is a deviation from the emission limitation for that compliance period and must be reported as specified in §§ 63.4110(b)(6) and 63.4120(g).

(c) You must demonstrate continuous compliance with each operating limit required by § 63.4092 that applies to you, as specified in Table 1 of this subpart.

(1) If an operating parameter is out of the allowed range specified in Table 1 of this subpart, this is a deviation from the operating limit that must be reported as specified in §§ 63.4110(b)(6) and 63.4120(g).

(2) If an operating parameter deviates from the operating limit specified in Table 1 of this subpart, then you must assume that the emission capture system and add-on control device were achieving zero efficiency during the time period of the deviation. For the purposes of completing the compliance calculations specified in §§ 63.4161 and 63.4162, you must treat the materials used during a deviation on a controlled coating operation as if they were used on an uncontrolled coating operation for the time period of the deviation. You must not include those materials in the calculation of organic HAP emissions reduction in Equation 1 of § 63.4161.

(d) You must meet the requirements for bypass lines in § 63.4168(b). If any bypass line is opened and emissions are diverted to the atmosphere when the coating operation is running, this is a deviation that must be reported as

specified in §§ 63.4110(b)(6) and 63.4120(g). For the purposes of completing the compliance calculations specified in §§ 63.4161 and 63.4162, you must treat the materials used during a deviation on a controlled coating operation as if they were used on an uncontrolled coating operation for the time period of the deviation. You must not include those materials in the calculation of organic HAP emissions reduction in Equation 1 of § 63.4161.

(e) You must demonstrate continuous compliance with the work practice standards in § 63.4093. If you did not develop a work practice plan, or you did not implement the plan, or you did not keep the records required by § 63.4130(k)(9), this is a deviation from the work practice standards that must be reported as specified in §§ 63.4110(b)(6) and 63.4120(g).

(f) As part of each semiannual compliance report required in § 63.4120, you must submit a statement that you were in compliance with the emission limitations during the reporting period because the organic HAP emission rate for each compliance period was less than or equal to the applicable emission limit in § 63.4090, and you achieved the operating limits required by § 63.4092 and the work practice standards required by § 63.4093 during each compliance period.

(g) During periods of startup, shutdown, and malfunction of the emission capture system, add-on control device, or coating operation that may affect emission capture or control device efficiency, you must operate in accordance with the startup, shutdown, and malfunction plan required by § 63.4100(d).

(h) Consistent with §§ 63.6(e) and 63.7(e)(1), deviations that occur during a period of startup, shutdown, or malfunction of the emission capture system, add-on control device, or coating operation that may affect emission capture or control device efficiency are not violations if you demonstrate to the Administrator's satisfaction that you were operating in accordance with the startup, shutdown, and malfunction plan. The Administrator will determine whether deviations that occur during a period of

startup, shutdown, or malfunction are violations according to the provisions in § 63.6(e).

(i) [Reserved]

(j) You must maintain records as specified in §§ 63.4130 and 63.4131.

§ 63.4164 What are the general requirements for performance tests?

(a) You must conduct each performance test according to the requirements in § 63.7(e)(1) and under the conditions in paragraphs (a)(1) and (2) of this section, except as provided in paragraph (b) of this section:

(1) *Representative coating operation operating conditions.* You must conduct the performance test under representative operating conditions for the coating operation. Operations during periods of startup, shutdown, or malfunction and periods of nonoperation do not constitute representative conditions. You must record the process information that is necessary to document operating conditions during the test and explain why the conditions are representative of normal operation.

(2) *Representative emission capture system and add-on control device operating conditions.* You must conduct the performance test when the emission capture system and add-on control device are operating at a representative flow rate, and the add-on control device is operating at a representative inlet concentration. You must record information that is necessary to document emission capture system and add-on control device operating conditions during the test and explain why the conditions are representative of normal operation.

(b) If the coating operation, emission capture system, or add-on control device will be operated at different sets of representative operating conditions, you must conduct the performance test according to either paragraph (b)(1) or (2) of this section:

(1) Test at each of the representative operating conditions and establish emission capture system and add-on control device efficiencies and operating limits for each operating condition. To demonstrate continuous compliance following the performance test, record the conditions under which the process, emission capture system, and add-on control device are operating during each

time period of operation, and calculate the organic HAP emission rate as described in § 63.4162.

(2) Test at the representative operating conditions that are expected to result in the lowest emission capture system and add-on control device efficiencies and establish efficiencies and operating limits based on this test. Use these efficiencies in the emission calculations in § 63.4161.

(c) You must conduct each performance test of an emission capture system according to the requirements in § 63.4165 and of an add-on control device according to the requirements in § 63.4166.

(d) The performance test to determine add-on control device organic HAP destruction or removal efficiency must consist of three runs as specified in § 63.7(e)(3) and each run must last at least 1 hour.

§ 63.4165 How do I determine the emission capture system efficiency?

You must use the procedures and test methods in this section to determine capture efficiency as part of the performance test required by § 63.4160.

(a) *Assuming 100 percent capture efficiency.* You may assume the capture system efficiency is 100 percent if both of the conditions in paragraphs (a)(1) and (2) of this section are met:

(1) The capture system meets the criteria in Method 204 of appendix M to 40 CFR part 51 for a PTE and directs all the exhaust gases from the enclosure to an add-on control device.

(2) All coatings, thinners, and cleaning materials used in the coating operation are applied within the capture system; coating solvent flash-off and coating, curing, and drying occurs within the capture system; and the removal of or evaporation of cleaning materials from the surfaces they are applied to occurs within the capture system. For example, this criterion is not met if parts enter the open shop environment when being moved between a spray booth and a curing oven.

(b) *Measuring capture efficiency.* If the capture system does not meet both of the criteria in paragraphs (a)(1) and (2) of this section, then you must use one of the three protocols described in paragraphs (c), (d), and (e) of this section to measure capture efficiency.

The capture efficiency measurements use TVH capture efficiency as a surrogate for organic HAP capture efficiency. For the protocols in paragraphs (c) and (d) of this section, the capture efficiency measurement must consist of three test runs and each run must last at least 3 hours and through a complete production run as long as the production run does not exceed 8 hours.

(c) *Liquid-to-uncaptured-gas protocol using a temporary total enclosure or building enclosure.* The liquid-to-uncaptured-gas protocol compares the mass of liquid TVH in materials used in the coating operation, referred to as TVH_{used}, to the mass of TVH emissions not captured by the emission capture system, referred to as TVH_{uncaptured}. Use a temporary total enclosure or a building enclosure and the procedures in paragraphs (c)(1) through (6) of this section to measure emission capture system efficiency using the liquid-to-uncaptured-gas protocol.

(1) Either use a building enclosure or construct an enclosure around the coating operation where coatings, thinners, and cleaning materials are applied, and all areas where emissions from these applied coatings and materials subsequently occur, such as flash-off, curing, and drying areas. The areas of the coating operation where capture devices collect emissions for routing to an add-on control device, such as the entrance and exit areas of an oven or spray booth, must also be inside the enclosure. The enclosure must meet the applicable definition of a temporary total enclosure or building enclosure in Method 204 of appendix M to 40 CFR part 51.

(2) Use Method 204A or 204F of appendix M to 40 CFR part 51 to determine the mass fraction, kg TVH per kg material, of TVH liquid input from each coating, thinner, and cleaning material used in the coating operation during each capture efficiency test run. To make the determination, substitute TVH for each occurrence of the term VOC in the methods.

(3) Use Equation 1 of this section to calculate TVH_{used}, the total mass of TVH liquid input from all the coatings, thinners, and cleaning materials used in the coating operation during each capture efficiency test run.

$$\text{TVH}_{\text{used}} = \sum_{i=1}^n (\text{TVH}_i)(\text{Vol}_i)(D_i) \quad (\text{Eq. 1})$$

Where:

TVH_i = Mass fraction of TVH in coating, thinner, or cleaning material, i, that is used in the coating operation during the capture efficiency test run, kg TVH per kg material.

Vol_i = Total volume of coating, thinner, or cleaning material, i, used in the coating operation during the capture efficiency test run, liters.

D_i = Density of coating, thinner, or cleaning material, i, kg material per liter material.

n = number of different coatings, thinners, and cleaning materials

used in the coating operation during the capture efficiency test run.

(4) Use Method 204D or E of appendix M to 40 CFR part 51 to measure TVH_{uncaptured}, the total mass, kg, of TVH emissions that are not captured by the emission capture system; they are measured as they exit the temporary total enclosure or building enclosure during each capture efficiency test run. To make the measurement, substitute TVH for each occurrence of the term VOC in the methods.

(i) Use Method 204D if the enclosure is a temporary total enclosure.

(ii) Use Method 204E if the enclosure is a building enclosure. During the capture efficiency measurement, all organic compound emitting operations inside the building enclosure, other than the coating operation for which capture efficiency is being determined, must be shut down, but all fans and blowers must be operating normally.

(5) For each capture efficiency test run, determine the percent capture efficiency, CE, of the emission capture system using Equation 2 of this section:

$$CE = \frac{(TVH_{\text{used}} - TVH_{\text{uncaptured}})}{TVH_{\text{used}}} \times 100 \quad (\text{Eq. 2})$$

Where:

TVH_{used} = The total mass of TVH liquid input used in the coating operation during the capture efficiency test run, kg.

TVH_{uncaptured} = The total mass of TVH that is not captured by the emission capture system and that exits from the temporary total enclosure or building enclosure during the capture efficiency test run, kg.

(6) Determine the capture efficiency of the emission capture system as the average of the capture efficiencies measured in the three test runs.

(d) *Gas-to-gas protocol using a temporary total enclosure or a building enclosure.* The gas-to-gas protocol compares the mass of TVH emissions captured by the emission capture system, referred to as TVH_{captured}, to the mass of TVH emissions not captured, referred to as TVH_{uncaptured}. Use a temporary total enclosure or a building enclosure and the procedures in paragraphs (d)(1) through (5) of this section to measure emission capture system efficiency using the gas-to-gas protocol.

(1) Either use a building enclosure or construct an enclosure around the coating operation where coatings, thinners, and cleaning materials are

applied, and all areas where emissions from these applied coatings and materials subsequently occur, such as flash-off, curing, and drying areas. The areas of the coating operation where capture devices collect emissions generated by the coating operation for routing to an add-on control device, such as the entrance and exit areas of an oven or a spray booth, must also be inside the enclosure. The enclosure must meet the applicable definition of a temporary total enclosure or building enclosure in Method 204 of appendix M to 40 CFR part 51.

(2) Use Method 204B or 204C of appendix M to 40 CFR part 51 to measure TVH_{captured}, the total mass, kg, of TVH emissions captured by the emission capture system during each capture efficiency test run as measured at the inlet to the add-on control device. To make the measurement, substitute TVH for each occurrence of the term VOC in the methods.

(i) The sampling points for the Method 204B or 204C measurement must be upstream from the add-on control device and must represent total emissions routed from the capture system and entering the add-on control device.

(ii) If multiple emission streams from the capture system enter the add-on

control device without a single common duct, then the emissions entering the add-on control device must be simultaneously measured in each duct and the total emissions entering the add-on control device must be determined.

(3) Use Method 204D or 204E of appendix M to 40 CFR part 51 to measure TVH_{uncaptured}, the total mass, kg, of TVH emissions that are not captured by the emission capture system; they are measured as they exit the temporary total enclosure or building enclosure during each capture efficiency test run. To make the measurement, substitute TVH for each occurrence of the term VOC in the methods.

(i) Use Method 204D if the enclosure is a temporary total enclosure.

(ii) Use Method 204E if the enclosure is a building enclosure. During the capture efficiency measurement, all organic compound emitting operations inside the building enclosure, other than the coating operation for which capture efficiency is being determined, must be shut down, but all fans and blowers must be operating normally.

(4) For each capture efficiency test run, determine the percent capture efficiency, CE, of the emission capture system using Equation 3 of this section:

$$CE = \frac{TVH_{\text{captured}}}{(TVH_{\text{captured}} + TVH_{\text{uncaptured}})} \times 100 \quad (\text{Eq. 3})$$

Where:

TVH_{captured} = The total mass of TVH captured by the emission capture system as measured at the inlet to the add-on control device during

the emission capture efficiency test run, kg.

TVH_{uncaptured} = The total mass of TVH that is not captured by the emission capture system and that exits from the temporary total enclosure or

building enclosure during the capture efficiency test run, kg.

(5) Determine the capture efficiency of the emission capture system as the average of the capture efficiencies measured in the three test runs.

(e) *Alternative capture efficiency protocol.* As an alternative to the procedures specified in paragraphs (c) and (d) of this section, you may determine capture efficiency using any other capture efficiency protocol and test methods that satisfy the criteria of either the DQO or LCL approach as described in appendix A to subpart KK of this part.

§ 63.4166 How do I determine the add-on control device emission destruction or removal efficiency?

(a) For all types of add-on control devices, use the test methods as specified in paragraphs (a)(1) through (5) of this section.

(1) Use Method 1 or 1A of appendix A to 40 CFR part 60, as appropriate, to select sampling sites and velocity traverse points.

(2) Use Method 2, 2A, 2C, 2D, 2F, or 2G of appendix A to 40 CFR part 60, as appropriate, to measure gas volumetric flow rate.

(3) Use Method 3, 3A, or 3B of appendix A to 40 CFR part 60, as appropriate, for gas analysis to determine dry molecular weight.

(4) Use Method 4 of appendix A to 40 CFR part 60, to determine stack gas moisture.

(5) Methods for determining gas volumetric flow rate, dry molecular weight, and stack gas moisture must be performed, as applicable, during each test run.

(b) Measure total gaseous organic mass emissions as carbon at the inlet and outlet of the add-on control device simultaneously, using Method 25 or 25A of appendix A to 40 CFR part 60. Use Method 25A instead of Method 25 if you expect the total gaseous organic concentration as carbon to be 50 parts per million (ppm) or less at the control device outlet. Use the same method for both the inlet and outlet measurements.

(c) If two or more add-on control devices are used for the same emission stream, then you must measure emissions at the outlet of each device. For example, if one add-on control device is a concentrator with an outlet for the high-volume, dilute stream that has been treated by the concentrator, and a second add-on control device is an oxidizer with an outlet for the low-volume, concentrated stream that is treated with the oxidizer, you must measure emissions at both outlets.

(d) For each test run, determine the total gaseous organic emissions mass flow rates for the inlet and the outlet of the add-on control device, using Equation 1 of this section:

$$M_f = Q_{sd} C_c [12][0.0416][10^{-6}] \quad (\text{Eq. 1})$$

Where:

M_f = The total gaseous organic emissions mass flow rate, kg/per hour (h).

C_c = The concentration of organic compounds as carbon in the vent gas, as determined by Method 25 or Method 25A, parts per million by volume (ppmv), dry basis.

Q_{sd} = The volumetric flow rate of gases entering or exiting the control device, as determined by Method 2, 2A, 2C, 2D, 2F, or 2G, dry standard cubic meters/hour (dscm/h).

0.0416 = Conversion factor for molar volume, kg-mol per cubic meter (m^3) (@ 293 Kelvin (K) and 760 millimeters of mercury (mmHg)).

(e) For each test run, determine the add-on control device organic emissions destruction or removal efficiency, DRE, using Equation 2 of this section.

$$DRE = \frac{M_{fi} - M_{fo}}{M_{fi}} \quad (\text{Eq. 2})$$

Where:

M_{fi} = The total gaseous organic emissions mass flow rate at the inlet to the control device, using Equation 1 of this section, kg/h.

M_{fo} = The total gaseous organic emissions mass flow rate at the outlet of the control device, using Equation 1 of this section, kg/h.

(f) Determine the emission destruction or removal efficiency of the add-on control device as the average of the efficiencies determined in the three test runs and calculated in Equation 2 of this section.

§ 63.4167 How do I establish the emission capture system and add-on control device operating limits during the performance test?

During the performance test required by § 63.4160 and described in §§ 63.4164, 63.4165, and 63.4166, you must establish the operating limits required by § 63.4092 according to this section, unless you have received approval for alternative monitoring and operating limits under § 63.8(f) as specified in § 63.4092.

(a) *Thermal oxidizers.* If your control device is a thermal oxidizer, establish the operating limits according to paragraphs (a)(1) and (2) of this section.

(1) During the performance test, you must monitor and record the combustion temperature at least once every 15 minutes during each of the three test runs. You must monitor the temperature in the firebox of the thermal oxidizer or immediately

downstream of the firebox before any substantial heat exchange occurs.

(2) Use the data collected during the performance test to calculate and record the average combustion temperature maintained during the performance test. This average combustion temperature is the minimum operating limit for your thermal oxidizer, unless you are determining operating limits for multiple operating conditions as specified in § 63.4164(b)(1) and paragraph (f) of this section.

(b) *Catalytic oxidizers.* If your control device is a catalytic oxidizer, establish the operating limits according to paragraphs (b)(1) and (2) of this section.

(1) During the performance test, you must monitor and record the temperature just before the catalyst bed and the temperature difference across the catalyst bed at least once every 15 minutes during each of the three test runs.

(2) Use the data collected during the performance test to calculate and record the average temperature just before the catalyst bed and the average temperature difference across the catalyst bed maintained during the performance test. These are the minimum operating limits for your catalytic oxidizer, unless you are determining operating limits for multiple operating conditions as specified in § 63.4164(b)(1) and paragraph (f) of this section.

(c) *Carbon adsorbers.* If your control device is a carbon adsorber, establish the operating limits according to paragraphs (c)(1) and (2) of this section.

(1) You must monitor and record the total regeneration desorbing gas (e.g., steam or nitrogen) mass flow for each regeneration cycle, and the carbon bed temperature after each carbon bed regeneration and cooling cycle, for the regeneration cycle either immediately preceding or immediately following the performance test.

(2) The operating limits for your carbon adsorber are the minimum total desorbing gas mass flow recorded during the regeneration cycle, and the maximum carbon bed temperature recorded after the cooling cycle, unless you are determining operating limits for multiple operating conditions as specified in § 63.4164(b)(1) and paragraph (f) of this section.

(d) *Condensers.* If your control device is a condenser, establish the operating limits according to paragraphs (d)(1) and (2) of this section.

(1) During the performance test, you must monitor and record the condenser outlet (product side) gas temperature at least once every 15 minutes during each of the three test runs.

(2) Use the data collected during the performance test to calculate and record the average condenser outlet (product side) gas temperature maintained during the performance test. This average condenser outlet gas temperature is the maximum operating limit for your condenser, unless you are determining operating limits for multiple operating conditions as specified in § 63.4164(b)(1) and paragraph (f) of this section.

(e) *Emission capture system.* For each capture device that is not part of a PTE that meets the criteria of § 63.4165(a), establish an operating limit for either the gas volumetric flow rate or duct static pressure, as specified in paragraphs (e)(1) and (2) of this section. The operating limit for a PTE is specified in Table 1 of this subpart.

(1) During the capture efficiency determination required by § 63.4160 and described in §§ 63.4164 and 63.4165, you must monitor and record either the gas volumetric flow rate or the duct static pressure for each separate capture device in your emission capture system at least once every 15 minutes during each of the three test runs at a point in the duct between the capture device and the add-on control device inlet.

(2) Calculate and record the average gas volumetric flow rate or duct static pressure for the three test runs for each capture device. This average gas volumetric flow rate or duct static pressure is the minimum operating limit for that specific capture device, unless you are determining operating limits for multiple operating conditions as specified in § 63.4164(b)(1) and paragraph (f) of this section.

(f) *Multiple operating conditions.* If you are determining operating limits for multiple operating conditions for the emission capture system or add-on control device as specified in § 63.4164(b)(1), you must conduct a performance test under each operating condition and establish the operating limits for the parameters under each operating condition according to paragraphs (f)(1) and (2) of this section.

(1) You must monitor and record the value of the parameter that corresponds to the applicable operating limit during the performance test under each operating condition.

(2) The average parameter value recorded during the performance test under each condition is the operating limit for that parameter when the coating operation is operating under that condition.

§ 63.4168 What are the requirements for continuous monitoring system (CMS) installation, operation, and maintenance?

(a) *General.* You must install, operate, and maintain each continuous parameter monitoring system specified in paragraphs (b) through (f) of this section according to paragraphs (a)(1) through (6) of this section.

(1) The continuous parameter monitoring system must complete a minimum of one cycle of operation for each successive 15-minute period. You must have a minimum of four successive cycles of continuous parameter monitoring system operation in 1 hour.

(2) You must determine the average of all recorded readings for each successive 3-hour period of the emission capture system and add-on control device operation.

(3) You must record the results of each inspection, calibration, and validation check of the continuous parameter monitoring system.

(4) You must maintain the continuous parameter monitoring system at all times and have available necessary parts for routine repairs of the monitoring equipment.

(5) You must operate the continuous parameter monitoring system and collect emission capture system and add-on control device parameter data at all times that a controlled coating operation is operating, except during monitoring malfunctions, associated repairs, and required quality assurance or control activities (including, if applicable, calibration checks and required zero and span adjustments).

(6) You must not use emission capture system or add-on control device parameter data recorded during monitoring malfunctions, associated repairs, out-of-control periods, or required quality assurance or control activities when calculating data averages. You must use all the data collected during all other periods in calculating the data averages for determining compliance with the emission capture system and add-on control device operating limits.

(7) A monitoring malfunction is any sudden, infrequent, not reasonably preventable failure of the continuous parameter monitoring system to provide valid data. Monitoring failures that are caused in part by poor maintenance or careless operation are not malfunctions. Any period for which the monitoring system is out-of-control and data are not available for required calculations is a deviation from the monitoring requirements.

(b) *Capture system bypass line.* You must meet the requirements of

paragraphs (b)(1) and (2) of this section for each emission capture system that contains bypass lines that could divert emissions away from the control device to the atmosphere.

(1) You must monitor or secure the valve or closure mechanism controlling the bypass line in a nondiverting position in such a way that the valve or closure mechanism cannot be opened without creating a record that the valve was opened. The method used to monitor or secure the valve or closure mechanism must meet one of the requirements specified in paragraphs (b)(2)(i) through (iv) of this section.

(i) *Flow control position indicator.* Install, calibrate, maintain, and operate according to the manufacturer's specifications a flow control position indicator that provides a record indicating whether the emissions are directed to the control device or diverted from the add-on control device. The time of occurrence and flow control position must be recorded, as well as every time the flow direction is changed. The flow control position indicator must be installed at the entrance to any bypass line that could divert the emissions away from the add-on control device to the atmosphere.

(ii) *Car-seal or lock-and-key valve closures.* Secure any bypass line valve in the closed position with a car-seal or a lock-and-key type configuration. You must visually inspect the seal or closure mechanism at least once every month to ensure that the valve is maintained in the closed position, and the emissions are not diverted away from the add-on control device to the atmosphere.

(iii) *Valve closure continuous monitoring.* Ensure that any bypass line valve is in the closed (non-diverting) position through continuous monitoring of valve position. You must inspect the monitoring system at least once every month to verify that the monitor will indicate valve position.

(iv) *Automatic shutdown system.* Use an automatic shutdown system in which the coating operation is stopped when flow is diverted by the bypass line away from the add-on control device to the atmosphere when the coating operation is running. You must inspect the automatic shutdown system at least once every month to verify that it will detect diversions of flow and shutdown the coating operation.

(2) If any bypass line is opened, you must include a description of why the bypass line was opened and the length of time it remained open in the semiannual compliance reports required in § 63.4120.

(c) *Thermal oxidizers and catalytic oxidizers.* If you are using a thermal

oxidizer or catalytic oxidizer as an add-on control device, you must comply with the requirements in paragraphs (c)(1) through (3) of this section:

(1) For a thermal oxidizer, install a gas temperature monitor in the firebox of the thermal oxidizer or in the duct immediately downstream of the firebox before any substantial heat exchange occurs.

(2) For a catalytic oxidizer, install gas temperature monitors both upstream and downstream of the catalyst bed. The temperature monitors must be in the gas stream immediately before and after the catalyst bed to measure the temperature difference across the bed.

(3) For all thermal oxidizers and catalytic oxidizers, you must meet the requirements in paragraphs (a) and (c)(3)(i) through (vii) of this section for each gas temperature monitoring device.

(i) Locate the temperature sensor in a position that provides a representative temperature.

(ii) Use a temperature sensor with a measurement sensitivity of 4 degrees Fahrenheit or 0.75 percent of the temperature value, whichever is larger.

(iii) Shield the temperature sensor system from electromagnetic interference and chemical contaminants.

(iv) If a gas temperature chart recorder is used, it must have a measurement sensitivity in the minor division of at least 20 degrees Fahrenheit.

(v) Perform an electronic calibration at least semiannually according to the procedures in the manufacturer's owners manual. Following the electronic calibration, you must conduct a temperature sensor validation check in which a second or redundant temperature sensor placed nearby the process temperature sensor must yield a reading within 30 degrees Fahrenheit of the process temperature sensor's reading.

(vi) Conduct calibration and validation checks any time the sensor exceeds the manufacturer's specified maximum operating temperature range or install a new temperature sensor.

(vii) At least monthly, inspect all components for integrity and all electrical connections for continuity, oxidation, and galvanic corrosion.

(d) *Carbon adsorbers.* If you are using a carbon adsorber as an add-on control device, you must monitor the total regeneration desorbing gas (e.g., steam or nitrogen) mass flow for each regeneration cycle, the carbon bed temperature after each regeneration and cooling cycle, and comply with paragraphs (a) and (d)(1) and (2) of this section.

(1) The regeneration desorbing gas mass flow monitor must be an integrating device having a measurement sensitivity of plus or minus 10 percent, capable of recording the total regeneration desorbing gas mass flow for each regeneration cycle.

(2) The carbon bed temperature monitor must have a measurement sensitivity of 1 percent of the temperature recorded or 1 degree Fahrenheit, whichever is greater, and must be capable of recording the temperature within 15 minutes of completing any carbon bed cooling cycle.

(e) *Condensers.* If you are using a condenser, you must monitor the condenser outlet (product side) gas temperature and comply with paragraphs (a) and (e)(1) and (2) of this section.

(1) The gas temperature monitor must have a measurement sensitivity of 1 percent of the temperature recorded or 1 degree Fahrenheit, whichever is greater.

(2) The temperature monitor must provide a gas temperature record at least once every 15 minutes.

(f) *Emission capture system monitoring.* The capture system monitoring system must comply with the applicable requirements in paragraphs (f)(1) and (2) of this section.

(1) For each flow measurement device, you must meet the requirements in paragraphs (a) and (f)(1)(i) through (v) of this section.

(i) Locate a flow sensor in a position that provides a representative flow measurement in the duct from each capture device in the emission capture system to the add-on control device.

(ii) Use a flow sensor with a measurement sensitivity of 2 percent of the flow rate.

(iii) Reduce swirling flow or abnormal velocity distributions due to upstream and downstream disturbances.

(iv) Conduct a flow sensor calibration check at least semiannually.

(v) At least monthly, inspect all components for integrity, all electrical connections for continuity, and all mechanical connections for leakage.

(2) For each pressure drop measurement device, you must comply with the requirements in paragraphs (a) and (f)(2)(i) through (vii) of this section.

(i) Locate the pressure sensor(s) in or as close to a position that provides a representative measurement of the pressure drop across each opening you are monitoring.

(ii) Minimize or eliminate pulsating pressure, vibration, and internal and external corrosion.

(iii) Use a gauge with a measurement sensitivity of 0.5 inch of water or a transducer with a measurement sensitivity of 1 percent of the pressure range.

(iv) Check pressure tap pluggage daily.

(v) Using a manometer, check gauge calibration quarterly and transducer calibration monthly.

(vi) Conduct calibration checks any time the sensor exceeds the manufacturer's specified maximum operating pressure range or install a new pressure sensor.

(vii) At least monthly, inspect all components for integrity, all electrical connections for continuity, and all mechanical connections for leakage.

Other Requirements and Information

§ 63.4180 Who implements and enforces this subpart?

(a) This subpart can be administered by us, the U.S. EPA, or a delegated authority such as your State, local, or tribal agency. If the U.S. EPA Administrator has delegated authority to your State, local, or tribal agency (as well as the U.S. EPA), then that agency has the authority to administer and enforce this subpart. You should contact your EPA Regional Office to find out if this subpart is delegated to your State, local, or tribal agency.

(b) In delegating implementation and enforcement authority of this subpart to a State, local, or tribal agency under subpart E of this part, the authorities contained in paragraph (c) of this section are retained by the Administrator of EPA and are not transferred to the State, local, or tribal agency.

(c) The authorities that will not be delegated to State, local, or tribal agencies are as follows:

(1) Approval of alternatives to the work practice standards in § 63.4093 under § 63.6(g).

(2) Approval of major alternatives to test methods under § 63.7(e)(2)(ii) and (f) and as defined in § 63.90.

(3) Approval of major alternatives to monitoring under § 63.8(f) and as defined in § 63.90.

(4) Approval of major alternatives to recordkeeping and reporting under § 63.10(f) and as defined in § 63.90.

§ 63.4181 What definitions apply to this subpart?

Terms used in this subpart are defined in the CAA, in 40 CFR 63.2, the General Provisions of this part, and in this section as follows:

Add-on control means an air pollution control device, such as a thermal oxidizer or carbon adsorber, that

reduces pollution in an air stream by destruction or removal before discharge to the atmosphere.

Capture device means a hood, enclosure, room, floor sweep, or other means of containing or collecting emissions and directing those emissions into an add-on air pollution control device.

Capture efficiency means the portion (expressed as a percentage) of the pollutants from an emission source that is delivered to an add-on control device.

Capture system means one or more capture devices intended to collect emissions generated by a coating operation in the use of coatings and cleaning materials, both at the point of application and at subsequent points where emissions from the coatings and cleaning materials occur, such as flashoff, drying, or curing. As used in this subpart, multiple capture devices that collect emissions generated by a coating operation are considered a single capture system.

Cleaning material means a solvent used to remove contaminants and other materials, such as dirt, grease, oil, and dried or wet coating, from a substrate before or after coating application or from equipment associated with a coating operation, such as spray booths, spray guns, racks, tanks, and hangers. Thus, it includes cleaning materials used for both substrates and equipment.

Coating means a material applied to a substrate for decorative, protective, or functional purposes. Such materials include, but are not limited to, paints, sealants, caulks, inks, adhesives, and maskants. Decorative, protective, or functional materials that consist only of protective oils, acids, bases, or any combination of these substances are not considered coatings for the purposes of this subpart.

Coating operation means any equipment used to prepare a substrate for coating application (surface preparation) or to clean it after coating application; to apply coating to a substrate (coating application); or to clean coating operation equipment and storage, mixing, and conveying equipment (equipment cleaning). A single coating operation may include any combination of these types of equipment, but always includes at least the point at which a coating or cleaning material is applied and all subsequent points where organic HAP emissions from that coating or cleaning material occur. There may be multiple coating operations in an affected source.

Coating solids means the nonvolatile portion of the coating that makes up the dry film.

Continuous parameter monitoring system means the total equipment that may be required to meet the data acquisition and availability requirements of this subpart, used to sample, condition (if applicable), analyze, and provide a record of coating operation, or capture system, or add-on control device parameters.

Controlled coating operation means a coating operation from which some or all of the organic HAP emissions are routed through an emission capture system and add-on control device.

Deviation means any instance in which an affected source subject to this subpart, or an owner or operator of such a source:

(1) Fails to meet any requirement or obligation established by this subpart, including but not limited to any emission limit, or operating limit, or work practice standard;

(2) Fails to meet any term or condition that is adopted to implement an applicable requirement in this subpart and that is included in the operating permit for any affected source required to obtain such a permit; or

(3) Fails to meet any emission limit, or operating limit, or work practice standard in this subpart during startup, shutdown, or malfunction, regardless of whether or not such failure is permitted by this subpart.

Emission limitation means an emission limit, operating limit, or work practice standard.

Enclosure means a structure that surrounds a source of emissions and captures and directs the emissions to an add-on control device.

Exempt compound means a specific compound that is not considered a VOC due to negligible photochemical reactivity. The exempt compounds are listed in 40 CFR 51.100(s).

Manufacturer's formulation data means data on a material (such as a coating) that are supplied by the material manufacturer based on knowledge of the ingredients used to manufacture that material, rather than based on testing of the material. Manufacturer's formulation data may include, but are not limited to, information on density, organic HAP content, and coating solids content.

Mass fraction of organic HAP means the ratio of the mass of organic HAP to the mass of a material in which it is contained; kg of organic HAP per kg of material.

Organic HAP content means the mass of organic HAP per volume of coating solids for a coating, calculated using Equation 2 of § 63.4141. The organic HAP content is determined for the coating in the condition it is in when

received from its manufacturer or supplier and does not account for any alteration after receipt.

Permanent total enclosure (PTE) means a permanently installed enclosure that meets the criteria of Method 204 of appendix M, 40 CFR part 51, for a PTE and that directs all the exhaust gases from the enclosure to an add-on control device.

Protective oil means an organic material that is applied to a substrate for the purpose of providing lubrication or protection from corrosion without forming a solid film. This definition of protective oils includes, but is not limited to, lubricating oils, evaporative oils (including those that evaporate completely), and extrusion oils.

Research or laboratory facility means a facility whose primary purpose is for research and development of new processes and products, that is conducted under the close supervision of technically trained personnel, and is not engaged in the manufacture of final or intermediate products for commercial purposes, except in a de minimis manner.

Responsible official means responsible official as defined in 40 CFR 70.2.

Startup, initial means the first time equipment is brought online in a facility.

Surface preparation means cleaning of part or all of a substrate to prepare it for coating application.

Temporary total enclosure means an enclosure constructed for the purpose of measuring the capture efficiency of pollutants emitted from a given source as defined in Method 204 of appendix M, 40 CFR part 51.

Thinner means an organic solvent that is added to a coating after the coating is received from the supplier.

Total volatile hydrocarbon (TVH) means the total amount of nonaqueous volatile organic material determined according to Methods 204A through 204C of appendix M to 40 CFR part 51 and substituting the term TVH each place in the methods where the term VOC is used. The TVH includes both VOC and non-VOC.

Uncontrolled coating operation means a coating operation from which none of the organic HAP emissions are routed through an emission capture system and add-on control device.

Volatile organic compound (VOC) means any compound defined as VOC in 40 CFR 51.100(s).

Volume fraction of coating solids means the ratio of the volume of coating solids (also known as volume of nonvolatiles) to the volume of coating;

liters of coating solids per liter of coating.

Wastewater means water that is generated in a coating operation and is

collected, stored, or treated prior to being discarded or discharged.

Tables

TABLE 1 TO SUBPART NNNN. OPERATING LIMITS IF USING THE EMISSION RATE WITH ADD-ON CONTROLS OPTION

For the following device . . .	You must meet the following operating limit . . .	And you must demonstrate continuous compliance with the operating limit by . . .
(1) Thermal oxidizer	The average combustion temperature in any 3-hour period must not fall below the combustion temperature limit established according to § 63.4167(a).	(i) Collecting the combustion temperature data according to § 63.4168(c); and (ii) Reducing the data to 3-hour block averages; and (iii) Maintaining the 3-hour average combustion temperature at or above the temperature limit.
(2) Catalytic oxidizer	(a) The average temperature measured just before the catalyst bed in any 3-hour period must not fall below the limit established according to § 63.4167(b). (b) The average temperature difference across the catalyst bed in any 3-hour period must not fall below the temperature difference limit established according to § 63.4167(b).	(i) Collecting the temperature data according to § 63.4168(c); and (ii) Reducing the data to 3-hour block averages; and (iii) Maintaining the 3-hour average temperature before the catalyst bed at or above the temperature limit.
(3) Carbon adsorber	(a) The total regeneration desorbing gas (e.g., steam or nitrogen) mass flow for each carbon bed regeneration cycle must not fall below the total regeneration desorbing gas mass flow limit established according to § 63.4167(c). (b) The temperature of the carbon bed, after completing each regeneration and any cooling cycle, must not exceed the carbon bed temperature limit established according to § 63.4167(c).	(i) Collecting the temperature data according to § 63.4168(c); and (ii) Reducing the data to 3-hour block averages; and (iii) Maintaining the 3-hour average temperature difference at or above the temperature difference limit.
(4) Condenser	The average condenser outlet (product side) gas temperature in any 3-hour period must not exceed the temperature limit established according to § 63.4167(d).	(i) Measuring the total regeneration desorbing gas (e.g., steam or nitrogen) mass flow for each regeneration cycle according to § 63.4168(d); and (ii) Maintaining the total regeneration desorbing gas mass flow at or above the mass flow limit.
(5) Emission capture system that is a PTE according to § 63.4165(a).	The direction of the air flow at all times must be into the enclosure; and in any 3-hour period, either the average facial velocity of air through all natural draft openings in the enclosure must be at least 3,600 meters per minute (200 feet per minute), OR the pressure drop across the enclosure must be at least 0.013 mmHg (0.007 inch H ₂ O), as established in Method 204 of appendix M to 40 CFR part 51.	(i) Collecting the condenser outlet (product side) gas temperature according to § 63.4168(e); and (ii) Reducing the data to 3-hour block averages; and (iii) Maintaining the 3-hour average gas temperature at the outlet at or below the temperature limit.
(6) Emission capture system that is not a PTE according to § 63.4165(a).	The average gas volumetric flow rate or duct static pressure in each duct between a capture device and add-on control device inlet in any 3-hour period must not fall below the average volumetric flow rate or duct static pressure limit established for that capture device according to § 63.4167(e).	(i) Collecting the direction of air flow, and either the facial velocity of air through all natural draft openings according to § 63.4168(f)(1) or the pressure drop across the enclosure according to § 63.4168(f)(2); and (ii) Reducing the data for facial velocity or pressure drop to 3-hour block averages; and (iii) Maintaining the 3-hour average facial velocity of air flow through all natural draft openings or the pressure drop at or above the facial velocity limit or pressure drop limit, and maintaining the direction of air flow into the enclosure at all times.

TABLE 2 TO SUBPART NNNN.—APPLICABILITY OF GENERAL PROVISIONS TO SUBPART NNNN

Citation	Subject	Applicable to subpart NNNN	Explanation
§ 63.1(a)(1)–(14)	General Applicability	Yes.	Applicability to subpart NNNN is also specified in § 63.4081.
§ 63.1(b)(1)–(3)	Initial Applicability Determination	Yes	
§ 63.1(c)(1)	Applicability After Standard Established	Yes.	Area sources are not subject to subpart NNNN.
§ 63.1(c)(2)–(3)	Applicability of Permit Program for Area Sources	No	
§ 63.1(c)(4)–(5)	Extensions and Notifications	Yes.	

TABLE 2 TO SUBPART NNNN.—APPLICABILITY OF GENERAL PROVISIONS TO SUBPART NNNN—Continued

Citation	Subject	Applicable to subpart NNNN	Explanation
§ 63.1(e)	Applicability of Permit Program Before Relevant Standard is Set.	Yes.	
§ 63.2	Definitions	Yes	Additional definitions are specified in § 63.4181.
§ 63.3(a)–(c)	Units and Abbreviations	Yes.	
§ 63.4(a)(1)–(5)	Prohibited Activities	Yes.	
§ 63.4(b)–(c)	Circumvention/ Severability	Yes.	
§ 63.5(a)	Construction/ Reconstruction	Yes.	
§ 63.5(b)(1)–(6)	Requirements for Existing, Newly Constructed, and Reconstructed Sources.	Yes.	
§ 63.5(d)	Application for Approval of Construction/ Reconstruction.	Yes.	
§ 63.5(e)	Approval of Construction/ Reconstruction	Yes.	
§ 63.5(f)	Approval of Construction/ Reconstruction Based on Prior State Review.	Yes.	
§ 63.6(a)	Compliance With Standards and Maintenance Requirements—Applicability.	Yes.	
§ 63.6(b)(1)–(7)	Compliance Dates for New and Reconstructed Sources.	Yes.	Section 63.4083 specifies the compliance dates.
§ 63.6(c)(1)–(5)	Compliance Dates for Existing Sources	Yes	Section 63.4083 specifies the compliance dates.
§ 63.6(e)(1)–(2)	Operation and Maintenance	Yes.	
§ 63.6(e)(3)	Startup, Shutdown, and Malfunction Plan	Yes	Only sources using an add-on control device to comply with the standard must complete startup, shutdown, and malfunction plans.
63.6(f)(1)	Compliance Except During Startup, Shutdown, and Malfunction.	Yes	Applies only to sources using an add-on control device to comply with the standard
63.6(f)(2)–(3)	Methods for Determining Compliance	Yes.	
63.6(g)(1)–(3)	Use of an Alternative Standard	Yes.	
63.6(h)	Compliance With Opacity/Visible Emission Standards.	No	Subpart NNNN does not establish opacity standards and does not require continuous opacity monitoring systems (COMS).
63.6(i)(1)–(16)	Extension of Compliance	Yes.	
63.6(j)	Presidential Compliance Exemption	Yes.	
63.7(a)(1)	Performance Test Requirements—Applicability.	Yes	Applies to all affected sources. Additional requirements for performance testing are specified in §§ 63.4164, 63.4165, and 63.4166.
63.7(a)(2)	Performance Test Requirements—Dates	Yes	Applies only to performance tests for capture system and control device efficiency at sources using these to comply with the standard. Section 63.4160 specifies the schedule for performance test requirements that are earlier than those specified in § 63.7(a)(2).
63.7(a)(3)	Performance Tests Required By the Administrator.	Yes.	
63.7(b)–(e)	Performance Test Requirements—Notification, Quality Assurance, Facilities Necessary for Safe Testing, Conditions During Test.	Yes	Applies only to performance tests for capture system and control device efficiency at sources using these to comply with the standard.
63.7(f)	Performance Test Requirements—Use of Alternative Test Method.	Yes	Applies to all test methods except those used to determine capture system efficiency.
63.7(g)–(h)	Performance Test Requirements—Data Analysis, Recordkeeping, Reporting, Waiver of Test.	Yes	Applies only to performance tests for capture system and control device efficiency at sources using these to comply with the standard.
§ 63.8(a)(1)–(3)	Monitoring Requirements—Applicability ..	Yes	Applies only to monitoring of capture system and control device efficiency at sources using these to comply with the standard. Additional requirements for monitoring are specified in 63.4168.
§ 63.8(a)(4)	Additional Monitoring Requirements	No	Subpart NNNN does not have monitoring requirements for flares.
§ 63.8(b)	Conduct of Monitoring	Yes.	

TABLE 2 TO SUBPART NNNN.—APPLICABILITY OF GENERAL PROVISIONS TO SUBPART NNNN—Continued

Citation	Subject	Applicable to subpart NNNN	Explanation
§ 63.8(c)(1)–(3)	CMS Operation and Maintenance	Yes	Applies only to monitoring of capture system and control device efficiency at sources using these to comply with the standard. Additional requirements for CMS operations and maintenance are specified in § 63.4168.
§ 63.8(c)(4)	Continuous Monitoring Systems	No	Section 63.4168 specifies the requirements for the operation of CMS for capture systems and control devices at sources using these to comply.
§ 63.8(c)(5)	COMS	No	Subpart NNNN does not have opacity or visible emission standards.
§ 63.8(c)(6)	CMS Requirements	No	Section 63.4168 specifies the requirements for monitoring systems for capture systems and control devices at sources using these to comply.
§ 63.8(c)(7)–(8)	CMS Out of Control Periods and Reporting.	Yes.	
§ 63.8(d)–(e)	Quality Control Program and CMS Performance Evaluation.	No	Subpart NNNN does not require the use of Performance continuous emissions monitoring systems.
§ 63.8(f)(1)–(5)	Use of an Alternative Monitoring Method	Yes.	
§ 63.8(f)(6)	Alternative to Relative Accuracy Test	No	Subpart NNNN does not require the use of continuous emissions monitoring systems.
§ 63.8(g)(1)–(5)	Data Reduction	No	Sections 63.4163 and 63.4168 specify monitoring data reduction.
§ 63.9(a)–(d)	Notification Requirements	Yes.	
§ 63.9(e)	Notification of Performance Test	Yes	Applies only to capture system and control device performance tests at sources using these to comply with the standard.
§ 63.9(f)	Notification of Visible Emissions/Opacity Test.	No	Subpart NNNN does not have opacity or visible standards.
§ 63.9(g)(1)–(3)	Additional Notifications When Using CMS.	No	Subpart NNNN does not require the use of continuous emissions monitoring systems.
§ 63.9(h)	Notification of compliance Status	Yes	Section 63.4110 specifies the dates for submitting the notification of compliance status.
§ 63.9(i)	Adjustment of Submittal Deadlines	Yes.	
§ 63.9(j)	Change in Previous Information	Yes.	
§ 63.10(a)	Recordkeeping/Reporting—Applicability and General Information.	Yes.	
§ 63.10(b)(1)	General Recordkeeping Requirements ...	Yes	Additional requirements are specified in §§ 63.4130 and 63.4131.
§ 63.10(b)(2)(i)–(v)	Recordkeeping Relevant to Startup, Shutdown, and Malfunction Periods and CMS.	Yes	Requirements for Startup, Shutdown, and Malfunction records only apply to add-on control devices used to comply with the standard.
§ 63.10(b)(2)(vi)–(xi)		Yes.	
§ 63.10(b)(2)(xii)	Records	Yes.	
§ 63.10(b)(2)(xiii)		No	Subpart NNNN does not require the use of continuous emissions monitoring systems.
§ 63.10(b)(2)(xiv)		Yes.	
§ 63.10(b)(3)	Recordkeeping Requirements for Applicability Determinations.	Yes.	
§ 63.10(c)(1)–(6)	Additional Recordkeeping Requirements for Sources with CMS.	Yes.	
§ 63.10(c)(7)–(8)		No	The same records are required in § 63.4120(a)(4).
§ 63.10(c)(9)–(15)		Yes.	
§ 63.10(d)(1)	General Reporting Requirements	Yes	Additional requirements are specified in § 63.4120.
§ 63.10(d)(2)	Report of Performance Test Results	Yes	Additional requirements are specified in § 63.4120(h).
§ 63.10(d)(3)	Reporting Opacity or Visible Emissions Observations.	No	Subpart NNNN does not require opacity or visible emissions observations.
§ 63.10(d)(4)	Progress Reports for Sources with Compliance Extensions.	Yes.	

TABLE 2 TO SUBPART NNNN.—APPLICABILITY OF GENERAL PROVISIONS TO SUBPART NNNN—Continued

Citation	Subject	Applicable to subpart NNNN	Explanation
§ 63.10(d)(5)	Startup, Shutdown, and Malfunction Reports.	Yes	Applies only to add-on control devices at sources using these to comply with the standard.
§ 63.10(e)(1)–(2)	Additional CMS Reports	No	Subpart NNNN does not require the use of continuous emissions monitoring systems.
§ 63.10(e)(3)	Excess Emissions/CMS Performance Reports.	No	Section 63.4120(g) specifies the contents of periodic compliance reports.
§ 63.10(e)(4)	COMS Data Reports	No	Subpart NNNN does not specify requirements for opacity or COMS.
§ 63.10(f)	Recordkeeping/Reporting Waiver	Yes.	Subpart NNNN does not specify use of flares for Flares compliance.
§ 63.11	Control Device Requirements Flares	No	
§ 63.12	State Authority and Delegations	Yes.	
§ 63.13	Addresses	Yes.	
§ 63.14	Incorporation by Reference	Yes.	
§ 63.15	Availability of Information/Confidentiality	Yes.	

TABLE 3 TO SUBPART NNNN. ORGANIC HAP CONTENT OF SOLVENTS AND SOLVENT BLENDS

Solvent/solvent blend	CAS. No.	Average organic HAP mass fraction	Typical organic HAP, percent by mass
(1) Toluene	108–88–3	1.0	Toluene.
(2) Xylene(s)	1330–20–7	1.0	Xylenes, ethylbenzene.
(3) Hexane	110–54–3	0.5	n–hexane.
(4) n–Hexane	110–54–3	1.0	n–hexane
(5) Ethylbenzene	100–41–4	1.0	Ethylbenzene.
(6) Aliphatic 140		0	None
(7) Aromatic 100		0.02	1% xylene, 1% cumene
(8) Aromatic 150		0.09	Naphthalene
(9) Aromatic naphtha	64742–95–6	0.02	1% xylene, 1% cumene
(10) Aromatic solvent	64742–94–5	0.1	Naphthalene
(11) Exempt mineral spirits	8032–32–4	0	None
(12) Lignines (VM & P)	8032–32–4	0	None
(13) Lactol spirits	64742–89–6	0.15	Toluene
(14) Low aromatic white spirit	64742–82–1	0	None
(15) Mineral spirits	64742–88–7	0.01	Xylenes
(16) Hydrotreated naphtha	64742–48–9	0	None
(17) Hydrotreated light distillate	64742–47–8	0.001	Toluene
(18) Stoddard solvent	8052–41–3	0.01	Xylenes
(19) Super high-flash naphtha	64742–95–6	0.05	Xylenes
(20) Varsol® solvent	8052–49–3	0.01	0.5% xylenes, 0.5% ethyl benzene.
(21) VM & P naphtha	64742–89–8	0.06	3% toluene, 3% xylene.
(22) Petroleum distillate mixture	68477–31–6	0.08	4% naphthalene, 4% biphenyl.

TABLE 4 TO SUBPART NNNN. ORGANIC HAP CONTENT OF PETROLEUM SOLVENT GROUPS

Solvent type	Average content organic HAP mass fraction	Typical organic HAP percent by mass
Aliphatic ¹	0.03	1% Xylene, 1% Toluene, and 1% Ethylbenzene.
Aromatic ²	0.06	4% Xylene, 1% Toluene, and 1% Ethylbenzene.

¹Mineral Spirits 135, Mineral Spirits 150 EC, Naphtha, Mixed Hydrocarbon, Aliphatic Hydrocarbon, Aliphatic Naphtha, Naphthol Spirits, Petroleum Spirits, Petroleum Oil, Petroleum Naphtha, Solvent Naphtha, Solvent Blend.

²Medium-flash Naphtha, High-flash Naphtha, Aromatic Naphtha, Light Aromatic Naphtha, Light Aromatic Hydrocarbons, Aromatic Hydrocarbons, Light Aromatic Solvent.



Federal Register

**Friday,
December 22, 2000**

Part V

Department of Commerce

**National Oceanic and Atmospheric
Administration**

15 CFR Part 922

**Boundary Changes in the Flower Garden
Banks National Marine Sanctuary;
Addition of Stetson Bank and Technical
Corrections; Final Rule**

DEPARTMENT OF COMMERCE**NATIONAL OCEANIC AND
ATMOSPHERIC ADMINISTRATION****15 CFR Part 922**

[Docket No. 000328088-0088-01]

RIN 0648-XA50

**Boundary Changes in the Flower
Garden Banks National Marine
Sanctuary; Addition of Stetson Bank
and Technical Corrections**

AGENCY: Marine Sanctuaries Division (MSD), Office of Ocean and Coastal Resource Management (OCRM), National Ocean Service (NOS), National Oceanic and Atmospheric Administration (NOAA), Department of Commerce (DOC).

ACTION: Final rule.

SUMMARY: The National Oceanic and Atmospheric Administration (NOAA) is amending the regulations implementing the designation of the Flower Garden Banks National Marine Sanctuary (FGBNMS or Sanctuary) and its Management Plan (MP) to apply to a new area, popularly known as known as Stetson Bank, which was added to the Sanctuary by Section 8 of the National Marine Sanctuaries Act (NMSA). NOAA is also slightly adjusting the boundary of the new area to improve administrative efficiency, correcting an error in a boundary coordinate in the West Flower Garden Bank area of the Sanctuary, and increasing the precision of all boundary coordinates based on new positioning technology.

DATES: This rule is effective January 22, 2001.

ADDRESSES: Questions concerning the regulations for the Flower Garden Banks National Marine Sanctuary may be addressed to G.P. Schmahl, Manager, Flower Garden Banks National Marine Sanctuary, 216 W. 26th Street, Suite 104, Bryan, Texas, 77803.

FOR FURTHER INFORMATION CONTACT: Chris Ostrom, (301)713-3137, Extension 129.

SUPPLEMENTARY INFORMATION:**I. Background**

In response to requests from the sport diving industry and sport scuba divers from all over the United States to provide protection for a popular sport diving spot in the northwestern Gulf of Mexico Congress enacted Section 8 of the NMSA (P.L. 104-283), to include Stetson Bank in the boundaries of the FGBNMS.

The new area included within the Sanctuary boundaries is generally

defined in Section 8 as the area within the 52 meter isobath surrounding Stetson Bank. Section 8 authorizes the Secretary of Commerce to make minor adjustments to the statutory boundary as necessary to protect living coral resources or to simplify administration of the Flower Garden Banks National Marine Sanctuary, and to establish precisely the geographic boundaries of Stetson Bank. Section 8 states that such adjustments shall not significantly enlarge or otherwise alter the size of the new area, and shall not result in the restriction of oil and gas activities otherwise permitted outside of the no activity zone designated by the Minerals Management Service (MMS) of the Department of the Interior (DOI), for Stetson Bank (i.e., outside of the 52 meter isobath) as that zone is depicted on the MMS map entitled "Final Notice of Sale 161, Western Gulf Mexico, Biological Stipulation Map Package."

Section 8 also states that the new area shall be part of the FGBNMS and shall be managed and regulated as though it had been designated by the Secretary of Commerce under the National Marine Sanctuaries Act. Finally, Section 8 states that the regulations applicable to the Sanctuary prior to the incorporation of the new area within the Sanctuary boundary shall be applicable to the new area unless modified by the Secretary, and that the regulations shall apply to the area no later than November 25, 1996.

Section 8 further directed the Secretary of Commerce to prepare a chart depicting the boundaries of the Sanctuary as modified by the addition of the new area. In 1998, high resolution bathymetric data for the area around Stetson Bank was made available by the U.S. Geological Survey (USGS), of the Department of the Interior. The 52 meter isobath surrounding Stetson Bank has been determined using this USGS data. A chart depicting the 52 meter isobath, and the Sanctuary boundary around Stetson Bank, was provided to the House Resources Committee and the Senate Committee on Commerce, Science and Transportation in July of 1999.

A major activity in the area of Stetson Bank is offshore oil and gas leasing, development and production, which is regulated by the MMS of DOI. MMS has developed a grid system that subdivides the sea floor into 3 mile by 3 mile squares, called lease blocks, for the purpose of selling and managing oil and gas leases. For management purposes, the MMS subdivides lease blocks into 64 equal squares, known as "64ths", under a system known as the "1/4 1/4

1/4" system. "64ths" may be used, for example, to delineate no-activity zones around areas protected by biological stipulations imposed by MMS. The 52 meter isobath surrounding Stetson Bank, overlaid with the "64ths" grid system, is shown in Figure 1.

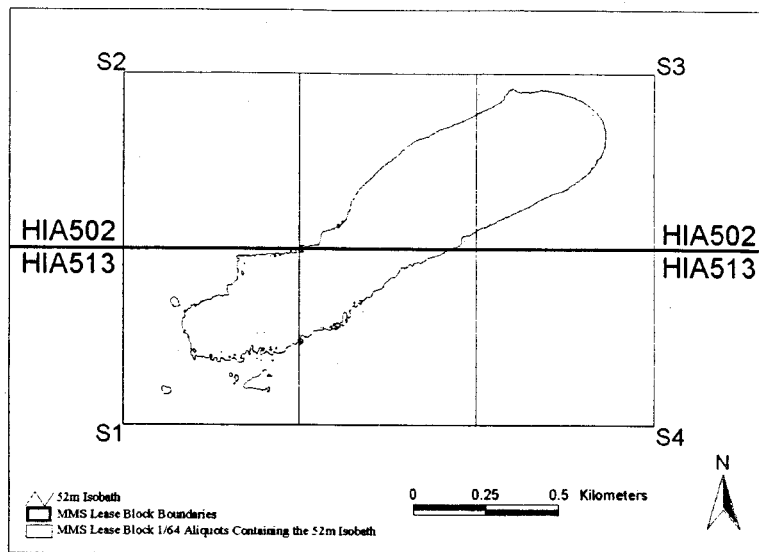
NOAA by this final rule is adjusting the area set forth in Section 8 of the NMSPA to consist of the six "64ths" squares that overlay the 52 meter isobath surrounding Stetson Bank (labeled as points S-1, S-2, S-3 and S-4 in Figure 1). Each of these "64ths" includes an area of 0.364 square kilometers, thus making the total area of the Stetson Bank addition 2.184 square kilometers. The exact coordinates of the boundary of this area are shown in Appendix A.

The use of "64ths" to determine the area and its corresponding boundary is convenient for MMS in managing oil and gas activities near the Sanctuary because the boundary lines of the Sanctuary correspond directly to lines used in MMS's grid system, and the area within the Sanctuary corresponds to a whole number of MMS grid units. The six "64ths" selected to be within the boundary create a rectangular shape which will be easier to distinguish than an irregular shape on the navigational charts produced by the NOS of NOAA. The rectangular shape, and the fact that the rectangle is closely aligned with the latitude and longitude lines on navigation charts, makes it easier for vessel navigators to know whether they are within the Sanctuary boundary.

Since the passage of the NMSPA, which references MMS maps and lease sale stipulations for OCS Lease Sale 161, MMS has conducted OCS Lease Sale 171 which has more accurate maps and lease stipulations for the Stetson Bank area. Therefore, the regulations refer to Lease Sale 171 (instead of Lease Sale 161 as directed in P.L. 104-283) for the geographic description of Stetson Bank and the lease stipulations that apply to Stetson Bank.

In reviewing the coordinates MMS used to delineate the boundaries of the East and West Flower Garden Banks, an error in one of the West Bank coordinates was discovered (at point W-10 in Appendix A). In addition, MMS has provided more accurate coordinate readings for each point in the boundary. This rule corrects and refines the boundaries of the East and West Flower Garden Banks using the more accurate coordinate readings, and sets forth the boundary coordinates for the Stetson Bank area of the Sanctuary.

Figure 1



Points S1, S2, S3, to S4 represent the area including Stetson Bank to be added to the Flower Garden Banks National Marine Sanctuary pursuant to P.L. 104-283.

Area Surrounding Stetson Bank To Be Added To The Flower Garden
Banks National Marine Sanctuary

(NAD 27)

Point	Latitude (N)	Longitude (W)
S-1.....	28 deg. 09'30.06738"	94 deg.18'31.34461"
S-2.....	28 deg.10'09.24374"	94 deg.18'29.57042"
S-3.....	28 deg.10'06.88036"	94 deg.17'23.26201"
S-4.....	28 deg. 09'27.70425"	94 deg.17'25.04315"

(NAD 83)

Point	Latitude (N)	Longitude (W)
S-1.....	28 deg. 09' 31.02671"	94 deg. 18' 31.98164"
S-2.....	28 deg. 10' 10.20196"	94 deg. 18' 30.20776"
S-3.....	28 deg. 10' 07.83821"	94 deg. 17' 23.89688"
S-4.....	28 deg. 09' 28.66320"	94 deg. 17' 25.67770"

II. Miscellaneous Rulemaking Requirements

National Marine Sanctuaries Act

Section 304(a)(4) of the National Marine Sanctuaries Act, 16 U.S.C. 1434(a)(4), provides that the terms of a designation may be modified only by the same procedures by which the original designation was made.

Designations of National Marine Sanctuaries are governed by sections 303 and 304 of the NMSA, 16 U.S.C. 1433, 1434. Section 8 of the NMSPA waives these requirements.

National Environmental Policy Act

NOAA has concluded that this regulatory action will not have a significant effect, individually or

cumulatively, on the human environment. Further, the action is categorically excluded from the requirement to prepare an environmental assessment or environmental impact statement in accordance with Section 6.05b.2 of NOAA Administrative Order 216-6. Specifically, this action is not likely to

result in significant impacts as defined in 40 CFR 1508.27.

The Stetson Bank area is already incorporated into the FGBNMS by law; this action is only to adjust the boundary to simplify the administration of the Sanctuary, and to establish precise geographic boundaries of Stetson Bank.

The Stetson Bank area added to the Sanctuary by Section 8 of the NMSPA (*i.e.*, the 52 meter isobath surrounding Stetson Bank) is small, as is the area after the boundary adjustment. The simple rectangular shape of the adjusted boundary fits the MMS grid system for managing oil and gas leasing and production activities, and it is relatively easy for navigators to know when their vessel is within the boundary. All the boundary alternatives considered are very small, thus there is no environmentally significant difference between them.

The new boundary is acceptable to NOAA, MMS, representatives of the sport diving and oil and gas industries that were involved in the Stetson Bank addition to FGBNMS, and was submitted to the House Resources Committee and Senate Commerce Committee several months prior to publication here and has received no negative response prior to publication in the **Federal Register**.

Executive Order 12866: Regulatory Impact

This action has been determined to be not significant for the purpose of Executive Order 12866.

Regulatory Flexibility Act

Because prior notice and opportunity for public comment are not required to be provided for this rule by 5 U.S.C. 553, or any other law, the analytical requirements of the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.* are inapplicable.

Administrative Procedures Act

The Assistant Administrator for Ocean Services and Coastal Zone Management, NOAA, has determined that under 5 U.S.C. 553(b)(B), there is good cause to waive the requirement for prior notice and public comment because public comment would serve no useful purpose and is therefore unnecessary. NOAA has held meetings with the MMS and reached agreement with MMS on the boundary of the Stetson Bank area of the FGBNMS. NOAA has also consulted affected stakeholders such as the oils and gas industry, commercial and sport fishing

industries, and sport diving industry, who also have no objection to the boundary adjustment.

Paperwork Reduction Act

This rule does not contain any collection of information requirements subject to the Paperwork Reduction Act.

List of Subjects in 15 CFR Part 922

Administrative practice and procedure, Coastal zone, Education, Environmental protection, Marine resources, Natural resources, Penalties, Recreation and recreation areas, Reporting and recordkeeping requirements, Research.

(Federal Domestic Assistance Catalog Number 11.429 Marine Sanctuary Program)

Dated: December 15, 2000.

Ted Lillestolen,

Deputy Assistant Administrator for Ocean Services and Coastal Zone Management.

Accordingly, for the reasons set forth above, 15 CFR Part 922 is amended as follows:

PART 922—[AMENDED]

1. The authority citation for Part 922 continues to read as follows:

Authority: 16 U.S.C. 1431 *et seq.*

Subpart L—Flower Garden Banks National Marine Sanctuary

2. Section 922.120, Boundary, is revised to read as follows:

§ 922.120 Boundary.

The Flower Garden Banks National Marine Sanctuary (the Sanctuary) consists of three separate areas of ocean waters over and surrounding the East and West Flower Garden Banks and Stetson Bank, and the submerged lands thereunder including the Banks, in the northwestern Gulf of Mexico. The area designated at the East Bank is located approximately 120 nautical miles (nmi) south-southwest of Cameron, Louisiana, and encompasses 19.20 nmi². The area designated at the West Bank is located approximately 110 nmi southeast of Galveston, Texas, and encompasses 22.50 nmi². The area designated at Stetson Bank is located approximately 70 nmi southeast of Galveston, Texas, and encompasses 0.64 nmi². The three areas encompass a total of 42.34 nmi² (145.09 square kilometers). The boundary coordinates for each area are listed in appendix A to this subpart.

3. Section 922.121, Definitions, is revised to read as follows:

§ 922.121 Definitions.

In addition to those definitions found at § 922.3, the following definition applies to this subpart:

No-activity zone means the two geographic areas delineated by the Department of the Interior in stipulations for OCS lease sale 112 over and surrounding the East and West Flower Garden Banks, and the geographic area delineated by the Department of the Interior in stipulations for OCS lease sale 171 over and surrounding Stetson Bank, as areas in which activities associated with exploration for, development of, or production of hydrocarbons are prohibited. The precise aliquot part description of these areas around the East and West Flower Garden Banks are provided in appendix B of this subpart; the no-activity zone around Stetson Bank is defined as the 52 meter isobath. These particular aliquot part descriptions for the East and West Flower Garden Banks, and the 52 meter isobath around Stetson Bank, define the geographic scope of the “no-activity zones” for purposes of the regulations in this subpart. The descriptions for the East and West Flower Garden Banks no-activity zones are based on the “ $\frac{1}{4}$ $\frac{1}{4}$ ” system formerly used by the Department of the Interior, a method that delineates a specific portion of a block rather than the actual underlying isobath.

4. Section 922.123, Permit procedures and criteria, is amended by revising paragraph (b) as follows:

§ 922.123 Permit procedures and criteria.

(b) Applications for such permits should be addressed to the Director, Office of Ocean and Coastal Resource Management; ATTN: Manager, Flower Garden Banks National Marine Sanctuary, 216 West 26th Street, Suite 104, Bryan, TX 77803.

5. Appendix A to subpart L of part 922, Flower Garden Banks National Marine Sanctuary Boundary Coordinates, is revised to read as follows:

Appendix A to Subpart L of Part 922—Flower Garden Banks National Marine Sanctuary Boundary Coordinates

This appendix contains a second set of boundary coordinates using the geographic positions of the North American Datum of 1983 (NAD 83). FGBNMS coordinates are now provided in both North American Datum of 1927 (NAD 27) and NAD 83.

Point	Latitude (N)	Longitude (W)
East Flower Garden Bank: (NAD 27)		
E-1	27 deg. 52' 53.82718"	93 deg. 37' 41.30310"
E-2	27 deg. 53' 34.83434"	93 deg. 38' 23.35445"
E-3	27 deg. 55' 13.64286"	93 deg. 38' 40.34368"
E-4	27 deg. 57' 30.71927"	93 deg. 38' 33.26982"
E-5	27 deg. 58' 27.66896"	93 deg. 37' 46.12447"
E-6	27 deg. 59' 01.41554"	93 deg. 35' 31.74954"
E-7	27 deg. 59' 00.50888"	93 deg. 35' 09.69198"
E-8	27 deg. 55' 22.38258"	93 deg. 34' 14.79162"
E-9	27 deg. 54' 04.05605"	93 deg. 34' 18.88720"
E-10	27 deg. 53' 26.70972"	93 deg. 35' 05.00978"
E-11	27 deg. 52' 52.06998"	93 deg. 36' 57.23078"
West Flower Garden Bank: (NAD 27)		
W-1	27 deg. 49' 10.16324"	93 deg. 50' 45.27154"
W-2	27 deg. 50' 12.35976"	93 deg. 52' 10.47158"
W-3	27 deg. 51' 12.82777"	93 deg. 52' 51.63488"
W-4	27 deg. 51' 32.41145"	93 deg. 52' 50.66983"
W-5	27 deg. 52' 49.88791"	93 deg. 52' 24.77053"
W-6	27 deg. 55' 00.93450"	93 deg. 49' 43.68090"
W-7	27 deg. 54' 58.33040"	93 deg. 48' 37.54501"
W-8	27 deg. 54' 35.26067"	93 deg. 47' 10.34866"
W-9	27 deg. 54' 14.80334"	93 deg. 46' 49.28963"
W-10	27 deg. 53' 35.63704"	93 deg. 46' 51.25825"
W-11	27 deg. 52' 57.34474"	93 deg. 47' 15.26428"
W-12	27 deg. 50' 40.26361"	93 deg. 47' 22.14179"
W-13	27 deg. 49' 10.89894"	93 deg. 48' 42.72307"
Stetson Bank: (NAD 27)		
S-1	28 deg. 09' 30.06738"	94 deg. 18' 31.34461"
S-2	28 deg. 10' 09.24374"	94 deg. 18' 29.57042"
S-3	28 deg. 10' 06.88036"	94 deg. 17' 23.26201"
S-4	28 deg. 09' 27.70425"	94 deg. 17' 25.04315"
East Flower Garden Bank: (NAD 83)		
E-1	27 deg. 52' 54.84288"	93 deg. 37' 41.84187"
E-2	27 deg. 53' 35.80428"	93 deg. 38' 23.89520"
E-3	27 deg. 55' 14.61048"	93 deg. 38' 40.88638"
E-4	27 deg. 57' 31.68349"	93 deg. 38' 33.81421"
E-5	27 deg. 58' 28.63153"	93 deg. 37' 46.66809"
E-6	27 deg. 59' 02.37658"	93 deg. 35' 32.28918"
E-7	27 deg. 59' 01.46983"	93 deg. 35' 10.23088"
E-8	27 deg. 55' 23.34849"	93 deg. 34' 15.32560"
E-9	27 deg. 54' 05.02387"	93 deg. 34' 19.42020"
E-10	27 deg. 53' 27.67871"	93 deg. 35' 05.54379"
E-11	27 deg. 52' 53.04047"	93 deg. 36' 57.76805"
West Flower Garden Bank: (NAD 83)		
W-1	27 deg. 49' 11.14452"	93 deg. 50' 45.83401"
W-2	27 deg. 50' 13.34001"	93 deg. 52' 11.03791"
W-3	27 deg. 51' 13.80672"	93 deg. 52' 52.20349"
W-4	27 deg. 51' 33.38988"	93 deg. 52' 51.23867"
W-5	27 deg. 52' 50.86415"	93 deg. 52' 25.33954"
W-6	27 deg. 55' 01.90633"	93 deg. 49' 44.24605"
W-7	27 deg. 54' 59.30189"	93 deg. 48' 38.10780"
W-8	27 deg. 54' 36.23221"	93 deg. 47' 10.90806"
W-9	27 deg. 54' 15.77527"	93 deg. 46' 49.84801"
W-10	27 deg. 53' 36.60997"	93 deg. 46' 51.81616"
W-11	27 deg. 52' 58.31880"	93 deg. 47' 15.82251"
W-12	27 deg. 50' 41.24120"	93 deg. 47' 22.69837"
W-13	27 deg. 49' 11.87936"	93 deg. 48' 43.28125"
Stetson Bank: (NAD 83)		
S-1	28 deg. 09' 31.02671"	94 deg. 18' 31.98164"
S-2	28 deg. 10' 10.20196"	94 deg. 18' 30.20776"
S-3	28 deg. 10' 07.83821"	94 deg. 17' 23.89688"

Point	Latitude (N)	Longitude (W)
S-4	28 deg. 09' 28.66320"	94 deg. 17' 25.67770"

6. Appendix B to subpart L of part 922, Coordinates for the Department of the Interior Topographic Lease Stipulations for OCS Lease Sale 171, is revised to read as follows:

**Appendix B to Subpart L of Part 922—
Coordinates for the Department of the
Interior Topographic Lease Stipulations
for OCS Lease Sale 171**

**Aliquot Part Description of Biological
Stipulation Area East Garden Bank**

*Block A-366 Texas Leasing Map No. 7C
(High Island Area East Addition South
Extension)*

SE¹/₄, SW¹/₄; S¹/₂, NE¹/₄, SE¹/₄; SE¹/₄, NW¹/₄,
SE¹/₄; S¹/₂, SE¹/₄.

Block A-376

W¹/₂, NW¹/₄, SW¹/₄; SW¹/₄, SW¹/₄, SW¹/₄.

Block A-374

W¹/₂, NW¹/₄, NW¹/₄; W¹/₂, SW¹/₄, NW¹/₄; SE¹/₄,
SW¹/₄, NW¹/₄; SW¹/₄,
NE¹/₄, SW¹/₄, W¹/₂, SW¹/₄; W¹/₂, SE¹/₄, SW¹/₄;
SE¹/₄, SE¹/₄, SW¹/₄.

Block A-375

E¹/₂; E¹/₂, NW¹/₄; E¹/₂, NW¹/₄, NW¹/₄; SW¹/₄,
NW¹/₄, NW¹/₄; E¹/₂,
SW¹/₄, NW¹/₄; NW¹/₄, SW¹/₄, NW¹/₄; SW¹/₄.

Block A-388

NE¹/₄; E¹/₂, NW¹/₄; E¹/₂, NW¹/₄, NW¹/₄; NE¹/₄,
SW¹/₄, NW¹/₄; E¹/₂,
NE¹/₄, SW¹/₄; NW¹/₄, NE¹/₄, SW¹/₄; NE¹/₄,
NW¹/₄, SW¹/₄; NE¹/₄,
SE¹/₄, SW¹/₄, NE¹/₄; NE¹/₄, NE¹/₄, SE¹/₄; W¹/₂,
NE¹/₄, SE¹/₄; NW¹/₄,

Block A-389

NE¹/₄, NW¹/₄; NW¹/₄, NW¹/₄; SW¹/₄, NW¹/₄;
NE¹/₄, SE¹/₄, NW¹/₄; W¹/₂,
SE¹/₄, NW¹/₄; N¹/₂, NW¹/₄, SW¹/₄.

**Aliquot Part Description of Biological
Stipulation Area West Garden Bank**

*Block A-383 Texas Leasing Map No. 7C
(High Island Area East Addition South
Extension)*

E¹/₂, SE¹/₄, SE¹/₄; SW¹/₄, SE¹/₄, SE¹/₄.

Block A-384

W¹/₂, SW¹/₄, NE¹/₄; SE¹/₄, SW¹/₄, NE¹/₄; S¹/₂,
SE¹/₄, NE¹/₄;
SE¹/₄, NW¹/₄; E¹/₂, SW¹/₄; E¹/₂, NW¹/₄, SW¹/₄,
SW¹/₄, NW¹/₄,
SW¹/₄; SW¹/₄, SW¹/₄; SE¹/₄.

Block A-385

SW¹/₄, SW¹/₄, NW¹/₄; NW¹/₄, SW¹/₄; NW¹/₄,
SW¹/₄, SW¹/₄.

Block A-397

W¹/₂, W¹/₂, NW¹/₄; W¹/₂, NW¹/₄, SW¹/₄; NW¹/₄;
SW¹/₄, SW¹/₄.

Block A-398

Entire block.

Block A-399

E¹/₂, SE¹/₄, NE¹/₄, NW¹/₄; E¹/₂, SE¹/₄, NW¹/₄;
E¹/₂, NE¹/₄, SW¹/₄;
SW¹/₄, NE¹/₄, SW¹/₄; NE¹/₄, SE¹/₄, SW¹/₄.

Block A-401

NE¹/₄, NE¹/₄; N¹/₂, NW¹/₄, NE¹/₄; NE¹/₄, SE¹/₄,
NE¹/₄.

*Block 134 Official Protraction Diagram
NG15-02 (Garden Banks)*

That portion of the block north of a line connecting a point on the east boundary of Block 134, X=1,378,080.00', Y=10,096,183.00', with a point on the west boundary of Block 134, X=1,367,079,385', Y=10,096,183.000', defined under the Universal Transverse Mercator grid system.

*Block 135 Official Protraction Diagram
NG15-02 (Garden Banks)*

That portion of the block northwest of a line connecting the southeast corner of Texas Leasing Map No. 7C, Block A-398, X=1,383,293.840', Y=10,103,281.930', with a point on the west boundary of Official Protraction Diagram NG15-02, Block 135, X=1,378,080.000', Y=10,096,183.000', defined under the Universal Transverse Mercator grid system.

[FR Doc. 00-32390 Filed 12-18-00; 2:55 pm]

BILLING CODE 3510-08-P



Federal Register

**Friday,
December 22, 2000**

Part VI

Department of the Interior

Fish and Wildlife Service

50 CFR Part 17

**Endangered and Threatened Wildlife and
Plants; Final Designation of Critical
Habitat for the Plant *Lesquerella*
Thamnophila (Zapata Bladderpod); Final
Rule**

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

RIN 1018-AG24

Endangered and Threatened Wildlife and Plants; Final Designation of Critical Habitat for the Plant *Lesquerella thamnophila* (Zapata Bladderpod)**AGENCY:** Fish and Wildlife Service, Interior.**ACTION:** Final rule.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), designate critical habitat pursuant to the Endangered Species Act of 1973, as amended (Act), for the plant *Lesquerella thamnophila* (Rollins & Shaw) (Zapata bladderpod). Critical habitat includes seven sites on 2,088 hectares (ha) (5,158 acres (ac)) of Lower Rio Grande Valley National Wildlife Refuge property in Starr County, Texas, and a privately owned 0.55 ha (1.36 ac) site also located in Starr County, Texas. Section 7 of the Act requires Federal agencies to ensure that actions they authorize, fund, or carry out are not likely to destroy or adversely modify designated critical habitat. As required by section 4 of the Act, we considered economic and other relevant impacts prior to making a final decision on what areas to designate as critical habitat.

DATES: The effective date of this rule is January 22, 2001.

ADDRESSES: You may inspect the complete file for this rule, by appointment, during normal business hours at the U.S. Fish and Wildlife Service, Ecological Services Field Office, c/o TAMUCC, Box 338, 6300 Ocean Drive, Corpus Christi, Texas, 78412.

FOR FURTHER INFORMATION CONTACT: Allan Strand, Field Supervisor of the Ecological Services Field Office in Corpus Christi, Texas (Telephone 361/994-9005; facsimile 361/994-8262).

SUPPLEMENTARY INFORMATION:**Background**

Lesquerella thamnophila, a member of the Brassicaceae (= Cruciferae or Mustard) family, was first collected by Neally in Starr County during his collections between 1882 and 1894. The first type specimen was collected in Zapata County, Texas, by R. C. Rollins in 1959. The species was named *L. thamnophila* in 1973 by R. C. Rollins and E. A. Shaw in their work on the genus *Lesquerella* (Rollins and Shaw

1973). Most of the collected specimens of *L. thamnophila* have come from Starr and Zapata Counties in Southern Texas. One specimen has been identified from Tamaulipas, Mexico.

Lesquerella thamnophila is a pubescent (overlaid with short hairs), somewhat silvery-green, herbaceous perennial plant, with sprawling stems 43 to 85 centimeters (cm) (17 to 34 inches (in)) long. It possesses narrow basal leaves, 4 to 12 cm (1.5 to 4.8 in) long, and 7 to 15 millimeters (mm) (0.3 to 0.6 in) wide, with entire-to-wavy or slightly-toothed margins. Stem leaves are 3 to 4 cm (1 to 1.5 in) long and 2 to 8 mm (0.1 to 0.3 in) wide, with margins similar to basal leaves. The inflorescence (arrangement of flowers on a single stalk) is a loose raceme of bright yellow-petaled flowers. The flowers appear at different seasons of the year depending upon timing of rainfall, and are arranged along an axis with the lower flowers maturing first. Fruits are round and 4.5 to 6.5 mm (0.2 to 0.8 in) in diameter on short, downward curving pedicels (slender stalks) (Poole 1989). Little is known of the population genetics, structure, or dynamics of the species.

All known populations of *Lesquerella thamnophila* in the United States occur in Starr and Zapata Counties, Texas, within approximately 3.2 kilometers (km) (2 miles (mi)) of the Rio Grande. Populations of *L. thamnophila* typically occur in upland sites that have not had extensive previous soil disruption. Soil types at known population sites suggest that the species is not closely tied to a specific soil texture; while many of the known populations occur on soils with moderate alkalinity, soil textures range from clay (Catarina soils) to fine sandy loam (Copita soils).

Lesquerella thamnophila can occur on graveled to sandy-loam upland terraces above the Rio Grande flood plain. The known populations are associated with three Eocene-age geologic formations—Jackson, Laredo, and Yegua—which have yielded fossiliferous (containing fossils) and highly calcareous (comprised of calcium carbonate) sandstones and clays.

Known Starr County populations occur within the Jimenez-Quemado soil association and on Catarina Series soils. Jimenez-Quemado soils are well-drained, shallow, and gravelly-to-sandy loam underlain by caliche (a hard soil layer cemented by calcium carbonate). This soil association is broad, dissected, and irregularly shaped, and occurs on huge terraces 5 to 6 meters (m) (20 to 50 feet (ft)) above the flood plain of the Rio Grande. In most areas, the Jimenez soils occupy the slope breaks extending from

the tops of ridges to the bottoms of the slopes, and the narrow valleys between them. Quemado soils occur as narrow areas on ridge tops, where the slope range is 3 to 20 percent. Steep escarpments can be present with rocky outcrops adjacent to the river flood plain.

Catarina Series soils consist of clayey, saline upland soils developed from calcareous, gypsiferous (containing gypsum), and/or saline clays that usually contain many drainage and erosional features. The underlying material of the soils contain calcareous concretions (rounded masses of mineral matter), gypsum crystals, and marine shell fragments (Thompson et. al. 1972).

Zapata bladderpod populations in Zapata County occur within the Zapata-Maverick soil association. Zapata soils are shallow, loamy or mixed, hyperthermic (high temperature), well-drained, and nearly level with undulating slopes ranging from 0 to 18 percent, primarily on uplands occurring over caliche. The upper portion of the soil horizon ranges 5 to 25 cm (2 to 10 in) in thickness, with chert gravel and coarse fragments consisting of a few to 25 percent of angular caliche 2.5 to 20 cm (1 to 8 in) long.

Maverick soils consist of upland clayey soils occurring over caliche with underlying calcareous material containing shale and gypsum crystals (Thompson et al. 1972). The upper zone consists of well-drained, moderately deep soft shale bedrock, sloping 1–10 percent and forming clayey sediments. Ancient deposition of rock material from the Rio Grande can be found in portions of these soils, and rock and Indian artifact collection has become a pastime for residents and visitors in the area.

Lesquerella thamnophila grows opportunistically; that is, the density of *L. thamnophila* plants and the size of populations fluctuate in response to availability of rainfall during the time of year with adequate temperatures for plant growth. Populations can respond dramatically to rainfall events, going from barely detectable to a substantial assemblage of thousands of individuals.

Lesquerella thamnophila occurs as an herbaceous component of an open *Leucophyllum frutescens* (cenizo) shrub community that grades into an *Acacia rigidula* (blackbrush) shrub community. Both plant communities dominate upland habitats on shallow soils near the Rio Grande (Diamond 1990). These shrub lands are sparsely vegetated due to the shallow, fast-draining, highly erosional soils and semi-arid climate (Poole 1989). Other related plant species in the cenizo and blackbrush

communities include *Acacia berlandieri* (guajillo), *Prosopis* sp. (mesquite), *Celtis pallida* (granjeno), *Yucca treculeana* (Spanish dagger), *Zizyphus obtusifolia* (lotebush), and *Guaiaacum angustifolium* (guayacan). The coverage of an aggressively invasive, nonnative grass, *Cenchrus ciliaris* (buffelgrass), is extensive at some of the sites. *Dichanthium annulatum* (Kleberg bluestem grass), which is used for erosion control on roadways, has also begun to invade natural areas and is present at all *L. thamnophila* sites, although not as extensively as buffelgrass.

Biologists have located and described a total of 10 populations of *Lesquerella thamnophila*, including the type locality discovered by R. C. Rollins in Zapata County in 1959. Six of the ten populations were found in Starr County and four in Zapata County. Of these ten populations, four are still known to support plants in varying numbers. Service personnel have visited populations at the locations where access is available. Following substantial rainfall in October 2000, Service biologists documented Zapata bladderpod plants at the Lower Rio Grande Valley National Wildlife Refuge's Cuellar Tract in Starr County, and at the Siesta Shores subdivision (5–10 plants) and the U.S. Highway 83 ROW site adjacent to the Siesta Shores subdivision (5–10 plants) in Zapata County. The October 2000 site visit failed to find the population on the U.S. 83 ROW near the Tigre Chiquito Bridge in Zapata County, where we proposed critical habitat. Other earlier attempts to relocate this population have also been unsuccessful and it is likely that this population has been extirpated due to vehicle disturbance and the encroachment of buffelgrass, despite a management agreement between the Texas Department of Transportation (TxDOT) and the Texas Parks and Wildlife Department (TPWD) designed to protect the site by excluding grass mowing during the plant's active growing season, and use of a six-inch mowing height to avoid damage to late-flowering or early-growing plants. The fourth Zapata County site, Falcon Heights West Subdivision (private land), is the type locality discovered in 1959 by Rollins and Shaw, and is also believed to be extirpated due to construction activity and invasion of buffelgrass.

In Starr County, biologists verified extant populations at two of the six sites previously known to have plants; the Lower Rio Grande Valley National Wildlife Refuge's Cuellar Tract and a private ranch near Roma/Los Saenz-

West. Service biologists visited the private ranch site in July 2000 and documented bladderpod plants. The four remaining Starr County sites are located on private land where access is limited or the exact location is unknown, making it difficult to survey for the plants.

Lesquerella thamnophila likely occurs in other areas in south Texas, in addition to these documented population sites. However, while the extent of potentially occupied habitat can be estimated from mapped soils, access to most of the land where *L. thamnophila* may occur is in private ownership, with limited access for survey efforts.

Previous Federal Action

Federal action involving this species began with section 12 of the Act (16 U.S.C. 1531 *et seq.*), which directed the Secretary of the Smithsonian Institution to prepare a report on plants considered to be endangered, threatened, or extinct. The report, designated as House Document No. 94–51, was presented to Congress on January 9, 1975. On July 1, 1975, we published a notice in the **Federal Register** (40 FR 27823) accepting the Smithsonian report as a petition within the context of section 4(c)(2) of the Act, now section 4(b)(3)(A), and announcing that we would initiate a review of the status of those plants. *Lesquerella thamnophila* was included as threatened in the Smithsonian report and in our notice.

On June 16, 1976 (41 FR 24523), we published a proposed rule to determine approximately 1,700 species of vascular plants as endangered, including *Lesquerella thamnophila*. However, the 1978 amendments to the Act required the withdrawal of all proposals over 2 years old (although a 1-year grace period was allowed for those proposals already over 2 years old). On December 10, 1979 (44 FR 70796), we published a notice withdrawing that portion of the June 16, 1976, proposal that had not been made final, which included *L. thamnophila*.

On December 15, 1980 (45 FR 82823), we published a list of plants under review for listing as threatened or endangered, which included *Lesquerella thamnophila* as a category 2 candidate. "Category 2 candidates" were those species for which available information indicated that listing as threatened or endangered may have been appropriate, but for which substantial data were not available to support preparation of a proposed rule.

Section 4(b)(3)(B) of the Act requires that we make findings on petitions within 12 months of their receipt. Section 2(b)(1) of the 1982 amendments

to the Act required that all petitions pending as of October 13, 1982, be treated as having been submitted on that date. We accepted the 1975 Smithsonian report as a petition, and we treated all the plants noted within the report, including *Lesquerella thamnophila*, as being newly petitioned on October 13, 1982. In each subsequent year from 1983 to 1993, we determined that listing *L. thamnophila* was warranted, but precluded by other listing actions of higher priority, and that additional data on vulnerability and threats were still being compiled.

A status report on *Lesquerella thamnophila* was completed on August 8, 1989 (Poole 1989). That report provided sufficient information on biological vulnerability and threats to warrant designating the species as a category 1 candidate and to support preparation of a proposed rule to list *L. thamnophila* as endangered. "Category 1 candidates" were those species for which we had substantial information indicating that listing under the Act was warranted.

We published notices revising the 1980 list of plants under review for listing as endangered or threatened in the **Federal Register** on September 27, 1985 (50 FR 39626), February 21, 1990 (55 FR 6184), and September 30, 1993 (58 FR 51171). We included *Lesquerella thamnophila* in the September 30, 1993, notice as a category 1 candidate.

Upon publication of the February 28, 1996, Notice of Review (61 FR 7605), we ceased using category designations for candidate species and included *Lesquerella thamnophila* simply as a candidate species. Candidate species are those for which we have on file sufficient information on biological vulnerability and threats to support proposals to list them as threatened or endangered species. We retained *L. thamnophila* as a candidate species in the September 19, 1997, Review of Plant and Animal Taxa (62 FR 49398).

On January 22, 1998, we published a proposed rule to list *Lesquerella thamnophila* as endangered, without critical habitat (63 FR 3301), and invited the public and State and Federal agencies to comment on the proposed listing. Section 4(a)(3) of the Act requires that, to the maximum extent prudent and determinable, we designate critical habitat at the time we determine a species to be endangered or threatened. Regulations at 50 CFR 424.12 state that critical habitat designation is not prudent when one or both of the following situations exist:

(i) The species is threatened by taking or other human activity, and identification of critical habitat can be

expected to increase the degree of such threat to the species, or

(ii) Such designation of critical habitat would not be beneficial to the species.

In the proposed rule, we indicated that designation of critical habitat was not prudent for *Lesquerella thamnophila* because of a concern that publication of precise maps and descriptions of critical habitat in the **Federal Register** could increase the vulnerability of this species to incidents of collection and vandalism. We also indicated that designation of critical habitat was not prudent because we believed it would not provide any additional benefit beyond that provided through listing as endangered. However, after consideration of recent court decisions overturning "not prudent" determinations for other species, we reconsidered the issue. We published a final rule listing *L. thamnophila* as endangered on November 22, 1999 (64 FR 63745), and stated that, based on limited funding for our listing program, we would defer critical habitat designation until other higher-priority listing actions were completed.

Subsequent to the final rule listing the species as endangered, the Southwest Center for Biological Diversity filed suit to compel us to designate critical habitat for several species, including *Lesquerella thamnophila* (*Southwest Center for Biological Diversity et al. v. Babbitt—Civil No. 99-D-1118*). We entered into settlement negotiations with the plaintiff and agreed to propose critical habitat with a final determination to be made no later than December 15, 2000. We proposed critical habitat for the species on July 19, 2000 (65 FR 44717).

Summary of Comments and Recommendations

In the proposed rule to designate critical habitat, we requested all interested parties to submit factual reports or information that might contribute to the development of a final rule. In addition, we prepared an Environmental Assessment of this action pursuant to the National Environmental Policy Act. We made the draft Environmental Assessment available for public review and comment. We also contacted appropriate Federal and State agencies, county governments, scientific organizations, and other interested parties and requested their comments before the closing date of September 18, 2000. We published newspaper notices in the Rio Grande Herald and the Zapata News on August 13, 2000, inviting general public comment. We posted approximately 200 letters soliciting

comments on the proposed rule, announcing the public hearing, and providing information on the Zapata bladderpod. One Texas State agency representative reviewed the proposal and provided valuable biological and habitat information and commented on the selection of critical habitat areas.

On August 24, 2000, we held an informal meeting and formal public hearing at Fort Ringgold in Rio Grande City to discuss the proposal and accept formal comments from the public. Fifteen individuals attended the meeting and hearing. One State representative provided formal comments at the public hearing.

Section 4 of the Act requires us to consider economic and other relevant impacts of specifying any particular area as critical habitat. An analysis of the economic effects of Zapata bladderpod critical habitat designation was prepared (Industrial Economics, Incorporated, 2000) and made available for public review and comment on October 3, 2000 (65 FR 58981). In that notice we solicited data and comments from the public on all aspects of the proposal, including data on economic impacts and other impacts of the designation. We also reopened the comment period, extending it until November 2, 2000.

We addressed written comments and oral statements presented at the public hearing and received during the comment periods in the following summary. The issues and our response to each issue is discussed below. Comments that we incorporated into this final rule are discussed in the Changes Between Proposed and Final Rules portion of this document.

Issue 1: Private land should not be included in critical habitat designation without the acknowledgment and consent of the owner.

Service Response: We made several attempts to contact the owner(s) of the private land site proposed as critical habitat. While a landowner's permission is not required to designate an area as critical habitat, it is our practice to contact landowners to the extent practicable. In the near future, we hope to work with the landowner(s) to conserve the native habitat that supports Zapata bladderpod, as well as other endangered plant and rare animal species.

Issue 2: Comments from one reviewer indicated that in the final rule listing *Lesquerella thamnophila* as endangered, we identified a historical *L. thamnophila* locality along a roadside cut of Highway 83. The commenter questioned why that site was not proposed as critical habitat.

Service Response: We have not found *Lesquerella thamnophila* plants at this site in a number of years, nor have we heard from other agencies that the plant has been relocated at this location. We believe the species to be extirpated from this site and therefore, do not consider this essential to the conservation of the species.

Issue 3: Critical habitat designation will do little to benefit *Lesquerella thamnophila*. The areas proposed on State and private land are extremely small, probably too small to support viable populations. While the amount of acreage on Federal land is certainly adequate, the occupied habitat should already receive adequate protection. The areas of unoccupied habitat on Federal land are best guesses at what might provide suitable habitat for reintroduction.

Service Response: We agree that lands within the geographic range occupied by *Lesquerella thamnophila* already receive protection through section 7 of the Act for activities that a Federal agency carries out, funds, or permits; however, critical habitat may provide additional benefits by focusing conservation activities in areas determined to be essential for recovery of *L. thamnophila*. Although some of the areas are small, they still support the bladderpod and the small number of known populations of this species makes protection of those sites essential. We selected the refuge sites that are of unknown occupancy as critical habitat, on the basis of soil surveys and vegetation studies by refuge biologists and botanists familiar with the tract sites. Additionally, results of a habitat suitability modeling study, contracted by TxDOT and designed to predict habitat for rare plant species along the southern portion of the Rio Grande, indicates that the refuge sites are favorable for recovery efforts (Wu & Smeins 1999). Since there is still much that needs to be learned about the biology, distribution, and habitat of the species, we chose as critical habitat the sites most likely to either yield as-yet discovered populations or be most suitable for translocation of the bladderpod, if this becomes necessary for the species recovery.

Issue 4: The Texas Transportation Commission approved U.S. Highway 83 as part of the Priority One Texas Trunk System by Minute Order 107484. This type of highway would be built to a minimum of a four-lane divided highway to connect cities with populations of 20,000 or more. A completed feasibility study has determined that a future freeway would be possible along this route. The costs

for compensatory mitigation, biological assessments, and alternative analysis are anticipated to be extremely high and may cause construction delays on the expansion of U.S. 83 in the area of the Tigre Chiquito proposed critical habitat site.

Service Response: No Zapata bladderpod plants have been found at the Tigre Chiquito site since 1997. Biologists surveyed the site in March and October 2000 after significant rainfall in the area. Buffelgrass is now the dominant cover in the area of the ROW where the Zapata bladderpod plants historically grew, and the population appears to be extirpated. We removed the Tigre Chiquito site from the final critical habitat designation since it does not have the features and habitat characteristics that are necessary to sustain the species. We do not consider this area to be essential habitat for the conservation of the species.

Issue 5: The Environmental Protection Agency (EPA) indicated that we should evaluate Executive Order 12898, Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations, in our economic analysis.

Service Response: Executive Order 12898 requires that each Federal agency make achieving environmental justice part of its mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of its programs, policies, and activities on minorities and low-income populations. We do not believe that the designation of critical habitat for endangered and threatened species results in any changes to human health or environmental effects on surrounding human populations, regardless of their socioeconomic characterization. As such, we do not believe that Executive Order 12898 applies to critical habitat designations.

Issue 6: The EPA provided detailed comments on additional information that they felt should be included in the economic analysis to better characterize the economic effects on the refuge and the local economy, including the addition of figures and tables showing economic and population growth, an evaluation of historical patterns and current information describing section 7 consultations, including time and costs, and an evaluation of refuge visitation statistics.

Service Response: We attempted to estimate economic impacts that are reasonably certain to result from designation of critical habitat. We did this by considering what specific activities are likely to occur on the

refuge, TxDOT, and private lands included in the proposed designation. We identified whether these activities are likely to involve a Federal nexus, whether such a nexus will result in a section 7 consultation and, in turn, whether the consultation will result in modifications to projects. We do not feel it necessary to include the additional information described above in this economic analysis. We feel that the methodology used is adequately designed to distill the salient and relevant aspects of any potential economic impacts of designation. We also do not believe that the designation of critical habitat will affect refuge visitation, as the designation only affects Federal activities that are likely to destroy or adversely modify the area of critical habitat.

Issue 7: The EPA felt that the economic analysis should rely on established sources of information and not only the opinions of Fish and Wildlife staff.

Service Response: In addition to contacting Fish and Wildlife staff, personal communications were made with the TxDOT and attempts were also made to contact the private landowner(s) (see Issue 1). Unfortunately, since comments and information on land uses and the effects of the designation were not available from the private landowner, Fish and Wildlife staff could only speculate as to activities likely to occur on the private land. In this particular designation, we also note that the majority of land proposed for critical habitat is part of the Lower Rio Grande Valley National Wildlife Refuge; therefore, it was appropriate to contact Fish and Wildlife Refuge staff as the primary source of information on specific activities that would likely take place on the refuge, and the possible effect of the designation on these activities.

Issue 8: The EPA commented that the economic analysis does not adequately address potential benefits associated with the critical habitat designation.

Service Response: The primary purpose of critical habitat designation is to protect areas that are needed to conserve endangered and threatened species. However, we expect the benefits associated with this designation to be limited. We conclude this because the designation is unlikely to have any significant effect on both current and planned economic activities within the designated areas. For reasons previously stated, Federal agencies are already required to consult with us on activities that may affect the Zapata bladderpod. While critical habitat designation for the Zapata bladderpod may have some

benefit by focusing conservation activities in areas considered essential for recovery of the bladderpod, we expect the benefit to be minimal due to the fact that Federal agencies are already aware of the importance of these areas.

Issue 9: EPA commented that the U.S. Geological Survey or similar agency should be contacted to determine whether locations of oil and gas reserves or leases/claims exist for the critical habitat areas.

Service Response: According to Fish and Wildlife refuge staff there are mineral right claims in the critical habitat areas. However, the refuge already requires any party seeking to use National Wildlife Refuge land to perform surveys and environmental assessments, and the refuge manager must make a written determination of compatibility with the refuge purposes and the mission of the National Wildlife Refuge System, regardless of whether the proposed project will take place in critical habitat. A project can take place on the Refuge only if the Service deems that the project does not materially detract from the fulfillment of the refuge purpose or System mission. Therefore, we believe that any costs associated with project modifications or administrative effort would be due to the refuge's requirement to comply with the National Wildlife Refuge System Administration Act, not due to the designation of critical habitat. We appreciate the comment and have incorporated the information on mineral rights into the final economic analysis.

Peer Review

In accordance with our peer review policy of July 1, 1994 (59 FR 34270), we sent the proposed rule to four knowledgeable biologists and/or botanists who are familiar with the Zapata bladderpod. Only one of the peer reviewers provided comments on the proposed designation. Those comments included clarifications on the status of known populations and additional biological information that we incorporated into this final rule, and also discussed in the "Summary of Comments" section (above).

Changes Between Proposed and Final Rules

Locations of extant populations. The TPWD provided information clarifying the locations and status of some *Lesquerella thamnophila* populations. Although the proposed rule discussed population locations and status based on information in our files which came from various sources over time, drought conditions and inaccessibility to most private lands have hampered efforts to

survey for the species. Surveys of known populations following rain events even as recently as October 2000 have confirmed the plant's presence at three of the four sites.

Agreement between TxDOT and TPWD. In the proposed rule we stated that the agreement between these two agencies was to exclude mowing practices at the two highway ROW sites. The final rule clarifies that the agreement was for TxDOT to mow only between June and January, thus avoiding what was considered to be the active growing season. Also, a recommended six-inch mowing height is specified in the agreement to avoid damaging any late-flowering or early-growing plants.

Mapping errors. The TPWD pointed out two corrections to map 2: The TxDOT site in the vicinity of Lopeno is south rather than north of Lopeno, and the Cuellar's tract shape was incorrect. We appreciate the corrected information and applied it to the final rule, although we determined that the TxDOT sites will not be included in the final critical habitat designation.

Removal of Proposed Sites. Based on the results of the October 2000 and earlier surveys, we removed the two TxDOT Highway 83 ROW sites from this final critical habitat designation since we determined that these sites are no longer considered essential for the conservation of the species. No *Lesquerella thamnophila* plants have been found at the Tigre Chiquito site since 1997. Since buffelgrass is now the dominant cover in the area of the ROW where *Lesquerella thamnophila* plants historically grew, and biologist found no plants during surveys of the site in March and October 2000 after significant rainfall in the area, we believe it is highly likely the population is extirpated. The U.S. Highway 83 ROW site adjacent to the Siesta Shores subdivision does not appear to be a viable population due to the low number of plants (approximately 5 plants). In addition to the low number of plants, the site is located on a high bluff that is eroding away and the area is invaded by buffelgrass. Since the proposal, the site has continued to degrade and we no longer consider it essential for the conservation of the species. We removed these two sites from this final critical habitat designation since the areas do not have, and are unlikely to develop, the features and habitat characteristics that are necessary to sustain the species; we do not consider these areas to be essential for the conservation of the species.

Critical Habitat

Critical habitat is defined in section 3 of the Act as—(i) the specific areas within the geographic area occupied by a species, at the time it is listed in accordance with the Act, on which are found those physical or biological features (I) essential to the conservation of the species and (II) that may require special management considerations or protection; and (ii) specific areas outside the geographic area occupied by a species at the time it is listed, upon a determination that such areas are essential for the conservation of the species. "Conservation" means the use of all methods and procedures that are necessary to bring an endangered species or a threatened species to the point at which listing under the Act is no longer necessary. We have designated critical habitat sites based on the regulatory, educational, and informational benefits that may further protect the species and its associated habitats. Designation of critical habitat can help focus conservation activities for a listed species by identifying areas, both within and outside the geographical range occupied by the species, which contains one or more of the essential habitat features (primary constituent elements) described below in the critical habitat units section, and that are essential for the conservation of a listed species. Designation of critical habitat alerts the public as well as land-managing agencies to the importance of these areas.

Section 4(a)(3) of the Act, as amended, and implementing regulations (50 CFR 424.12), require that, to the maximum extent prudent and determinable, the Secretary designate critical habitat at the time the species is determined to be endangered or threatened. We selected critical habitat areas to provide for the conservation of *Lesquerella thamnophila* within a large portion of its geographic range in the United States. One segment of critical habitat contains the largest known population of the species. Another area is known to support a smaller extant population. The additional segments provide the necessary primary constituent elements and are believed capable of supporting the species. It is unknown whether the plant occurs on these sites, since Service biologists have not been able to survey at a time when the plants presence would likely be evident (*i.e.*, following significant rainfall). These areas are within the historical range of the species, contain habitats that are protected from disturbance, and support the ecological

requirements of *Lesquerella thamnophila*.

The critical habitat areas described below constitute our best assessment of the areas needed for the species' conservation. Because of this species' precarious status, mere stabilization of *Lesquerella thamnophila* populations at their present levels will not achieve conservation. Maintenance and enhancement of the two larger extant populations, plus translocation of the plant in suitable areas of historical range, are necessary for the species' survival and recovery. One of the most important conservation actions will be establishment of secure, self-reproducing populations in suitable habitats. Thus, we find that it is essential for the conservation and recovery of the species that critical habitat for *Lesquerella thamnophila* include both areas that currently sustain the species, and areas of unknown occupancy that contain the primary constituent elements. We selected the following sites based on suitable soil types, as taken from survey maps and vegetation types similar to the plant communities in which the bladderpod currently exists. Additionally, selection of these sites is supported by the results of a habitat suitability modeling study which indicates these sites to be favorable for recovery efforts (Wu & Smeins 1999).

Seven Lower Rio Grande National Wildlife Refuge tracts in Starr County are designated as critical habitat, including the Cuellar, Chapeno, and Arroyo Morteros Tracts located south/southwest of the Falcon Heights subdivision; Las Ruinas, Los Negros, and Arroyo Ramirez tracts located west and northwest of the City of Roma; and the La Puerta Tract located southeast of Rio Grande City. These areas include both the largest known population of Zapata bladderpod as well as additional suitable habitat of uncertain occupancy, as described above. One private land site northeast of the town of Salineno has also been designated as critical habitat in Starr County. This site supports the largest known population of Zapata bladderpod outside the refuge.

Section 4(b)(8) of the Act requires us to describe in any proposed or final regulation that designates critical habitat those activities (public or private) which may destroy or adversely modify such habitat or be affected by such designation. Activities which may destroy or adversely modify critical habitat include those that alter the primary constituent elements to the extent that the value of critical habitat for both the survival and recovery of *Lesquerella thamnophila* is appreciably

reduced. We note that such activities may also jeopardize the continued existence of the species when areas currently occupied by the species are affected. Such activities may include those that appreciably degrade or destroy native Tamaulipan thornscrub communities. Activities such as road building, land clearing for oil/gas exploration, soil disturbance for pasture improvement, livestock overgrazing, introducing or encouraging the spread of nonnative species, and heavy recreational use may likely destroy or adversely modify critical habitat.

Designation of critical habitat on the National Wildlife Refuge tracts could affect the following actions and agencies. These effects may be direct, due to actions on the refuge tracts, or indirect effects from actions taken on surrounding lands. Actions include, but are not limited to, recreation management, road construction, granting of utility rights of way, and habitat restoration projects by the Fish and Wildlife Service; oil and gas exploration, extraction, and/or transportation permitted by the Bureau of Land Management and the Federal Energy Regulatory Commission; road construction and brush clearing by the Immigration and Naturalization Service; and range improvement projects, including establishment of non-native grasses, funded through or assisted by the U.S. Department of Agriculture's Natural Resource Conservation Service and Farm Service Agency.

Economic Analysis

Section 4(b)(2) of the Act requires us to designate critical habitat on the basis of the best scientific and commercial information available and to consider the economic and other relevant impacts of designating a particular area as critical habitat. We may exclude areas from critical habitat upon a determination that the benefits of such exclusions outweigh the benefits of specifying such areas as part of critical habitat. We cannot exclude such areas from critical habitat if such exclusion would result in the extinction of the species concerned.

Economic effects caused by listing the Zapata bladderpod as an endangered species and by other statutes are the baseline against which the effects of critical habitat designation are evaluated. The economic analysis must

then examine the incremental economic effects and benefits of the critical habitat designation. Economic effects are measured as changes in national income, regional jobs, and household income. We made the draft economic analysis available for public review and comment as described in the "Summary of Comments" section of this document. The final analysis, which reviewed and incorporated public comments as appropriate, concluded that no significant economic impacts are expected from critical habitat designation above and beyond that already imposed by the listing of the Zapata bladderpod under the Act and other statutes.

A copy of the final economic analysis is included in our administrative record and may be obtained by contacting our office (see ADDRESSES section).

Available Conservation Measures

Conservation measures provided to species listed as endangered or threatened under the Act include recognition, recovery actions, requirements for Federal protection, and prohibitions against certain practices. Recognition through designating critical habitat encourages and results in conservation actions by Federal, State, and private agencies, groups, and individuals. The Act provides for possible land acquisition and cooperation with the States and requires that recovery actions be carried out for all listed species. The protection required of Federal agencies and the prohibitions against certain activities involving listed species are discussed, in part, below.

Section 7(a) of the Act requires Federal agencies to evaluate their actions with respect to any species that is listed as endangered or threatened and with respect to its critical habitat. Regulations implementing this interagency cooperation provision of the Act are codified at 50 CFR part 402. Section 7(a)(4) requires Federal agencies to confer with us on any action that is likely to jeopardize the continued existence of a listed species or result in destruction or adverse modification of proposed critical habitat. If a species is listed or critical habitat is designated subsequently, section 7(a)(2) requires Federal agencies to ensure that activities they authorize, fund, or carry out are not likely to jeopardize the continued

existence of such a species or to destroy or adversely modify its critical habitat. If a Federal action may affect a listed species or its critical habitat, the responsible Federal agency must enter into consultation with us. Consequently, some Federal agencies may request reinitiation of consultation on actions for which consultation has been completed on effects to the species, but that did not consider the effects of the action on critical habitat.

Activities on Federal lands that may affect *Lesquerella thamnophila* or its critical habitat will require section 7 consultation. Activities on non-Federal lands requiring a permit or utilizing funding from a Federal agency, such as a permit from the U.S. Army Corps of Engineers under section 404 of the Clean Water Act or funding of a highway project by the Federal Highway Administration, would also be subject to the section 7 consultation process. Federal actions not affecting the species, as well as actions on non-federal lands that are not federally funded or permitted, would not require section 7 consultation.

Required Determinations

Regulatory Planning and Review

In accordance with Executive Order 12866, this rule is a significant regulatory action and has been reviewed by the Office of Management and Budget (OMB).

(a) This rule will not have an annual economic effect of \$100 million or more, or adversely affect an economic sector, productivity, jobs, the environment, or other units of government. We conducted an analysis of the economic impact of the designation prior to making this final determination.

(b) This rule will not create inconsistencies with other agencies' actions. Table 1 shows a comparison of the effects on Federal actions resulting from the species' listing versus those expected to result from critical habitat designation. Federal agencies have been required to ensure that their actions do not jeopardize the continued existence of *Lesquerella thamnophila* since the species was listed. We will continue to review proposed activities with other Federal agencies as afforded through section 7 interagency consultation per the Endangered Species Act regulations.

TABLE 1.—FEDERAL ACTIONS POTENTIALLY AFFECTED BY LISTING OF LESQUERELLA THAMNOPHILA AND ADDITIONAL EFFECTS THAT MAY RESULT FROM CRITICAL HABITAT DESIGNATION

Categories of activities	Activities potentially affected by species listing only ¹	Additional activities potentially affected by critical habitat designation ²
Federal Activities Potentially Affected ³ .	Activities which remove or destroy occupied habitat whether by mechanical, chemical, or other means (e.g. soil disturbance for purposes including pasture improvement, heavy recreational use, inappropriate application of herbicides, etc.); sale, exchange, or lease of Federal land that contains occupied habitat that is likely to result in the habitat being destroyed or appreciably degraded.	Same activities which appreciably degrade or destroy unoccupied critical habitat.
Private and other non-Federal Activities Potentially Affected ⁴ .	Activities which require a Federal action (permit, authorization, or funding) and which: (1) remove or destroy occupied habitat, whether by mechanical, chemical, or other means (e.g. road building and other construction projects, inappropriate application of herbicides, land clearing for purposes including oil and gas exploration, soil disturbance for purposes including pasture improvement, significant overgrazing, etc.); or (2) appreciably decrease habitat value or quality through indirect effects (e.g. introducing or encouraging the spread of nonnative species).	Same activities which appreciably degrade or destroy unoccupied critical habitat.

¹ This column represents the activities potentially affected by listing the Zapata bladderpod as an endangered species under the Endangered Species Act (November 22, 1999; 64 FR 224).

² This column represents the activities potentially affected by the critical habitat designation beyond the effects resulting from the species' listing.

³ Activities initiated by a Federal agency.

⁴ Activities initiated by a private or other non-Federal entity that may need Federal authorization or funding.

(c) This final rule will not significantly impact entitlements, grants, user fees, loan programs, or the rights and obligations of their recipients. Federal agencies are currently required to ensure that their activities do not jeopardize the continued existence of the species and we do not anticipate that the adverse modification prohibition (resulting from critical habitat designation) will have significant incremental effects.

(d) This rule will not raise novel legal or policy issues. This final rule follows the requirements for determining critical habitat contained in the Endangered Species Act.

Regulatory Flexibility Act (5 U.S.C. 601 et seq.)

In the economic analysis (under section 4 of the Act), we determined that the designation of critical habitat will have no significant effect on a substantial number of small entities. As discussed under Regulatory Planning and Review above, this rule is not expected to result in any significant restrictions in addition to those currently in existence.

Small Business Regulatory Enforcement Fairness Act (5 U.S.C. 804(2))

In the economic analysis, we determined that designation of critical habitat will not cause (a) any effect on the economy of \$100 million or more, (b) an increase in costs or prices for

consumers; individual industries; Federal, State, or local government agencies; or geographic regions, or (c) any significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises.

Takings

In accordance with Executive Order 12630, this rule does not have significant takings implications, and a takings implication assessment is not required. As discussed above, the designation of critical habitat affects only Federal agency actions. The rule will not increase or decrease the current restrictions on private property concerning take of *Lesquerella thamnophila*. Critical habitat designation does not preclude development of habitat conservation plans and issuance of incidental take permits. The private landowner whose property is included in the designated critical habitat will continue to have opportunity to utilize their property in ways consistent with the survival of *Lesquerella thamnophila*.

Government-to-Government Relationship With Tribes

In accordance with the Presidential Memorandum of April 29, 1994, "Government-to-Government Relations with Native American Tribal Governments" (59 FR 22951), we are

required to assess the effects of critical habitat designation on tribal lands and tribal trust resources. We are not designating any tribal lands as critical habitat, and we do not anticipate any effects on tribal trust resources.

Unfunded Mandates Reform Act (2 U.S.C. 1501 et seq.)

In accordance with the Unfunded Mandates Reform Act (2 U.S.C. 1501 et seq.):

a. This rule will not "significantly or uniquely" affect small governments. A Small Government Agency Plan is not required.

b. This rule will not produce a Federal mandate on State, local or tribal governments or the private sector of \$100 million or greater in any year, i.e., it is not a "significant regulatory action" under the Unfunded Mandates Reform Act. The designation of critical habitat imposes no obligations on State or local governments.

Federalism

In accordance with Executive Order 13132, the rule does not have significant Federalism effects. A Federalism assessment is not required. In keeping with Department of the Interior policy, we requested information from and coordinated development of this critical habitat designation with appropriate State resource agencies in Texas. We will continue to coordinate any future designation of critical habitat for *Lesquerella thamnophila* with the

appropriate State agencies. The designation of critical habitat will impose few additional restrictions beyond those currently in place and, therefore, has little incremental impact on State and local governments and their activities. The designation may have some benefit to these governments in that the areas essential to the conservation of the species are more clearly defined, and the primary constituent elements of the habitat necessary to the survival of the species are specifically identified.

Civil Justice Reform

In accordance with Executive Order 12988, the Department of the Interior's Office of the Solicitor determined that this rule does not unduly burden the judicial system and meets the requirements of sections 3(a) and 3(b)(2) of the Order. The Office of the Solicitor reviewed this final determination. We made every effort to ensure that this final determination contains no drafting errors, provides clear standards, simplifies procedures, reduces burden, and is clearly written such that litigation risk is minimized.

National Environmental Policy Act

It is our position that, outside these areas covered by the U.S. Tenth Circuit Court, we do not need to prepare an environmental analysis as defined by the National Environmental Policy Act (NEPA) in connection with designating critical habitat. We published a notice outlining our reasons for this determination in the **Federal Register** on October 25, 1983 (48 FR 49244). This assertion was upheld in the courts of the Ninth Circuit (*Douglas County v.*

Babbitt), 48 F.3d 1495 (Ninth Circuit Oregon 1995), *cert. denied* 116 S. Ct. 698 (1996). However, when critical habitat involves states within the Tenth Circuit, pursuant to the ruling in *Catron County Board of Commissioners v. U.S. Fish and Wildlife Service*, 75 F.3d 1429 (10th Circuit 1996), we undertake a NEPA analysis for critical habitat designation. Although *Lesquerella thamnophila* does not occur in any 10th Circuit states, this designation is subject to 10th Circuit review because the case compelling the settlement agreement was filed in New Mexico. Thus, we prepared an Environmental Assessment and a Finding of No Significant Impact for this action.

Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.)

This rule does not contain any information collection requirements for which Office of Management and Budget approval under the Paperwork Reduction Act is required. This rule references incidental take permits which contain information collection activity. The Fish and Wildlife Service has OMB approval for the collection under OMB Control Number 1018-0094. The Service may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

References Cited

- Diamond, D. 1990. Plant Communities of Texas (series level). Texas Parks and Wildlife Department. Austin, Texas.
Poole, J. 1989. Status Report on *Lesquerella thamnophila*. U. S. Fish and Wildlife Service, Albuquerque, New Mexico.

- Rollins, R. C. and E. A. Shaw. 1973. The Genus *Lesquerella*. Harvard University Press, Cambridge, Massachusetts.
Thompson, C.M., R.R. Sanders, and D. Williams. 1972. Soil Survey of Starr County, Texas. U.S. Department of Agriculture. Soil Conservation Service, Temple, Texas.
Wu, Ben X., and Fred E. Smeins. 1999. Multiple-Scale Habitat Models of Rare Plants: Model Development and Evaluation. TxDOT (Pharr District-Environmental Affairs Division).

Author

The author of this final determination is Loretta Pressly (see **ADDRESSES** section).

List of Subjects in 50 CFR Part 17

Endangered and threatened species, Exports, Imports, Reporting and record-keeping requirements, Transportation.

Regulation Promulgation

Accordingly, we amend part 17, subchapter B of chapter I, title 50 of the Code of Federal Regulations as set forth below:

PART 17—[AMENDED]

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

Authority: 16 U.S.C. 1361–1407; 16 U.S.C. 1531–1544; 16 U.S.C. 4201–4245; Pub. L. 99–625, 100 Stat. 3500; unless otherwise noted.

2. In § 17.12(h) revise the entry for “*Lesquerella thamnophila*” under “FLOWERING PLANTS” to read as follows:

§ 17.12 Endangered and threatened plants.

* * * * *
(h) * * *

Species		Historic range	Family	Status	When listed	Critical habitat	Special rules
Scientific name	Common name						
FLOWERING PLANTS							
*	*	*	*	*	*		*
<i>Lesquerella</i>	Zapata	U.S.A.	Brassicaceae	E	671	17.96(a)	N/A
<i>thamnophila</i>	bladderpod	(TX).					
.....		Mexico.					
*	*	*	*	*	*		*

3. In § 17.96 add critical habitat for *Lesquerella thamnophila*, Zapata bladderpod, in alphabetical order by scientific name under Family Brassicaceae to read as follows:

* * * * *

§ 17.96 Critical habitat-plants.

(a) Flowering plants.

* * * * *

Family Brassicaceae: *Lesquerella thamnophila* (Zapata bladderpod)

1. Critical habitat units are depicted for Starr County, Texas, on the maps below. Critical habitat includes National

Wildlife Refuge tracts and one private land site. Maps are for general informational purposes only; the legal descriptions precisely define critical habitat boundaries.

2. Within these areas, the primary constituent elements include:

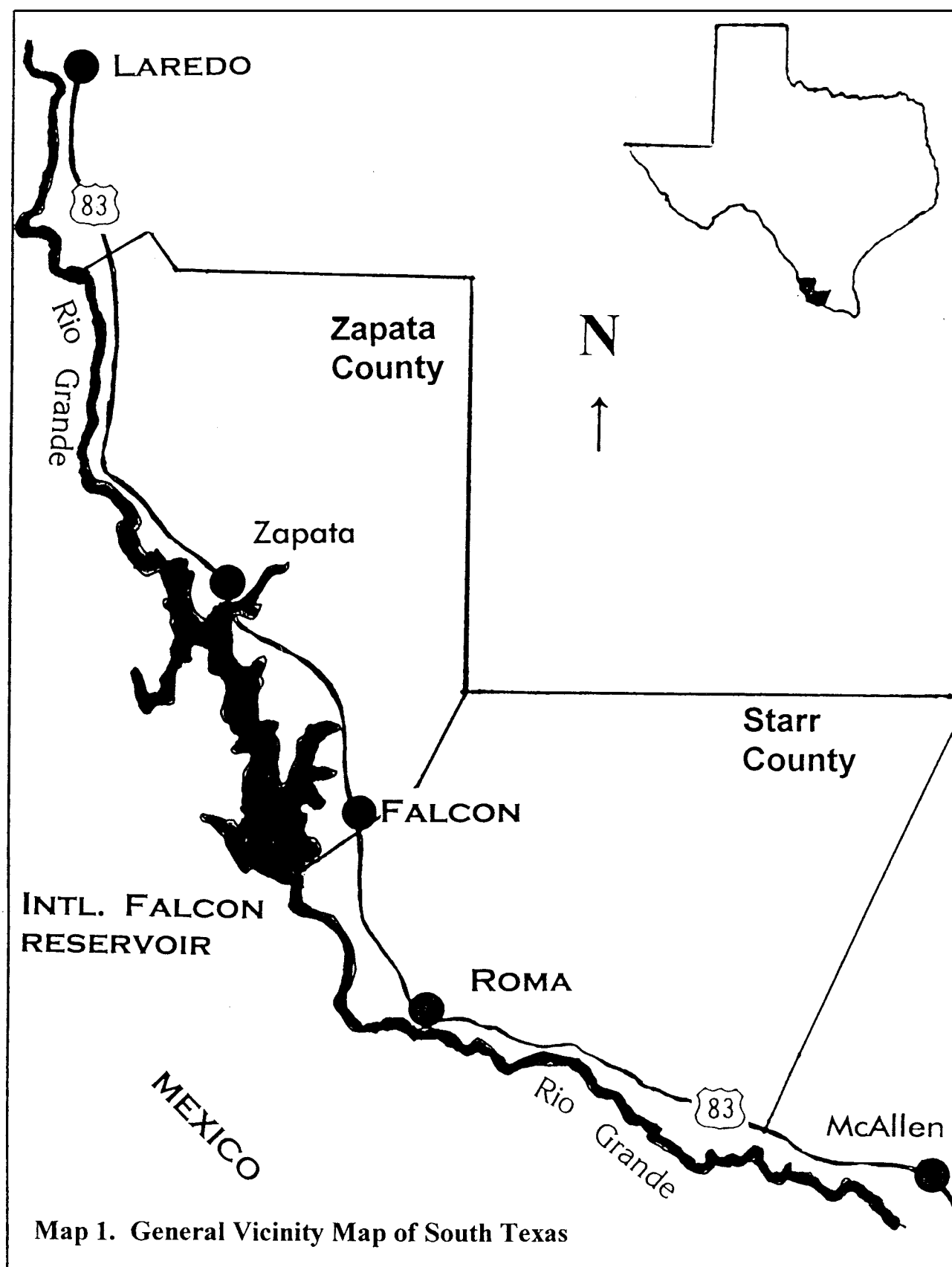
(a) Arid upland habitats of various soil types, including highly calcareous

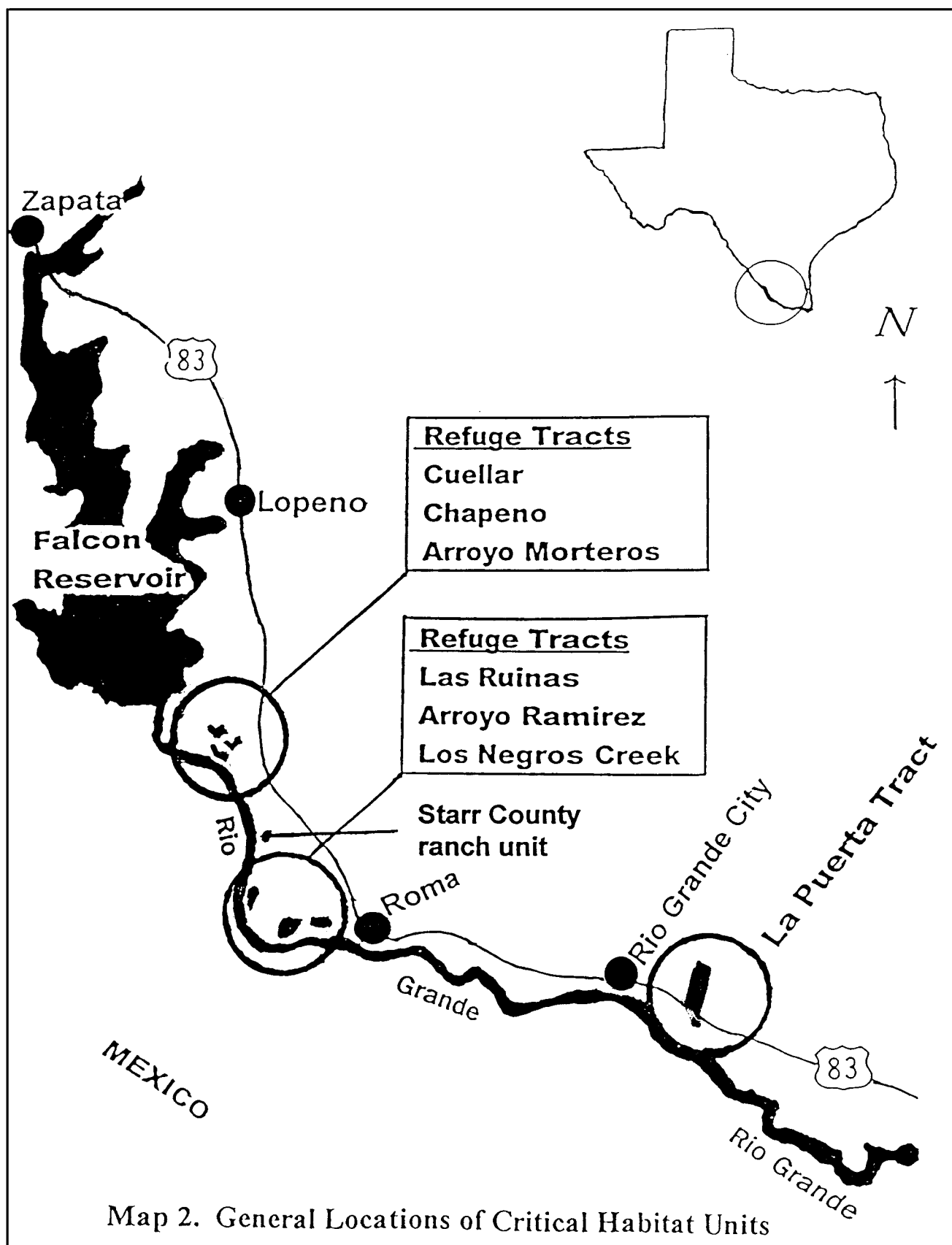
sandy loam to loamy sand, with low to moderate salinity levels on low sloping hills;

(b) Absence of substantial previous soil disturbance and seeding or sodding of exotic grasses; and

(c) A sparse overstory of shrub species typical of the Tamaulipan biotic province, but lacking a complete canopy as might be provided by a continuous overstory dominated by mesquite (*Prosopis glandulosa*).

3. Existing features and structures, such as buildings, roads, railroads, urban development, and other features not containing primary constituent elements, are not considered critical habitat.





Critical Habitat on Lower Rio Grande Valley National Wildlife Refuge Tracts, Starr County, Texas (Area measurements are approximate.):

Unit 1, Cuellar Tract (18 hectares (ha); 45 acres (ac))—(Segment 669). Note: All bearings are based on the Texas State Plane Coordinate System, South Zone, as referenced by the National Geodetic Survey Triangulation Station “LABRA” (not found) having State plane coordinates of N = 331,881.065, E = 1,794,777.75. The scale factor used is 0.9999252, and the theta angle is $-00^{\circ} 37' 32''$. All areas and distances are true surface measurements. Beginning at a standard U.S. Fish and Wildlife Service (FWS) aluminum monument set for corner on the southeasterly line of Porcion No. 59 and the northeast corner of Share 35 and stamped “Tract 669, COR. No. 1, R.P.L.S. #4303” and having a State plane coordinate value of N = 320,083.51, E = 1,799,578.77, from which triangulation station “LABRA”, bears N $22^{\circ} 08' 38''$ W, 12,737.98 feet; thence, in a southwesterly direction along the common line of Porcion 59 and 60, S $54^{\circ} 32' 24''$ W, 2,290.19 feet, to a standard FWS aluminum monument set for corner, being the common corner of Shares 35 and 26 and stamped “Tract 669, COR. No. 2, R.P.L.S. No. 4303; thence, in a northwesterly direction along the common line of Share 35 with Shares 26 and 27, N $35^{\circ} 27' 36''$ W, 640.00 feet to a standard FWS aluminum monument set for corner, being the most southerly common corner of Shares 35 and 34 and stamped “Tract 669, COR. No. 3, R.P.L.S. No. 4303”; thence, in a northeasterly direction along the common line of Shares 35 and 34; N $54^{\circ} 32' 24''$ E, 2,290.19 feet to a standard FWS aluminum monument set for corner, being the most northerly common corner of shares 35 and 34 and stamped “Tract 669, COR. No. 4, R.P.L.S. No. 4303; thence, in a southeasterly direction along the common line of Shares 35 and 36 Parcel-A; S $35^{\circ} 27' 36''$ E, 640.00 feet to the point of beginning and containing 33.648 acres of land.

(Cuellar Tract—Segment 672). Note: All bearings are based on the Texas State Plane Coordinate System, South Zone, as referenced by U.S. Fish and Wildlife Service GPS Monument No. 105 having State plane coordinates (NAD 27) of N = 311,099.90, E = 1,799,824.45. The scale factor used is 0.9999252, and the theta angle is $-00^{\circ} 37' 32''$. All areas and distances are true surface measurements. Beginning at a standard FWS aluminum monument set for corner on the common line between

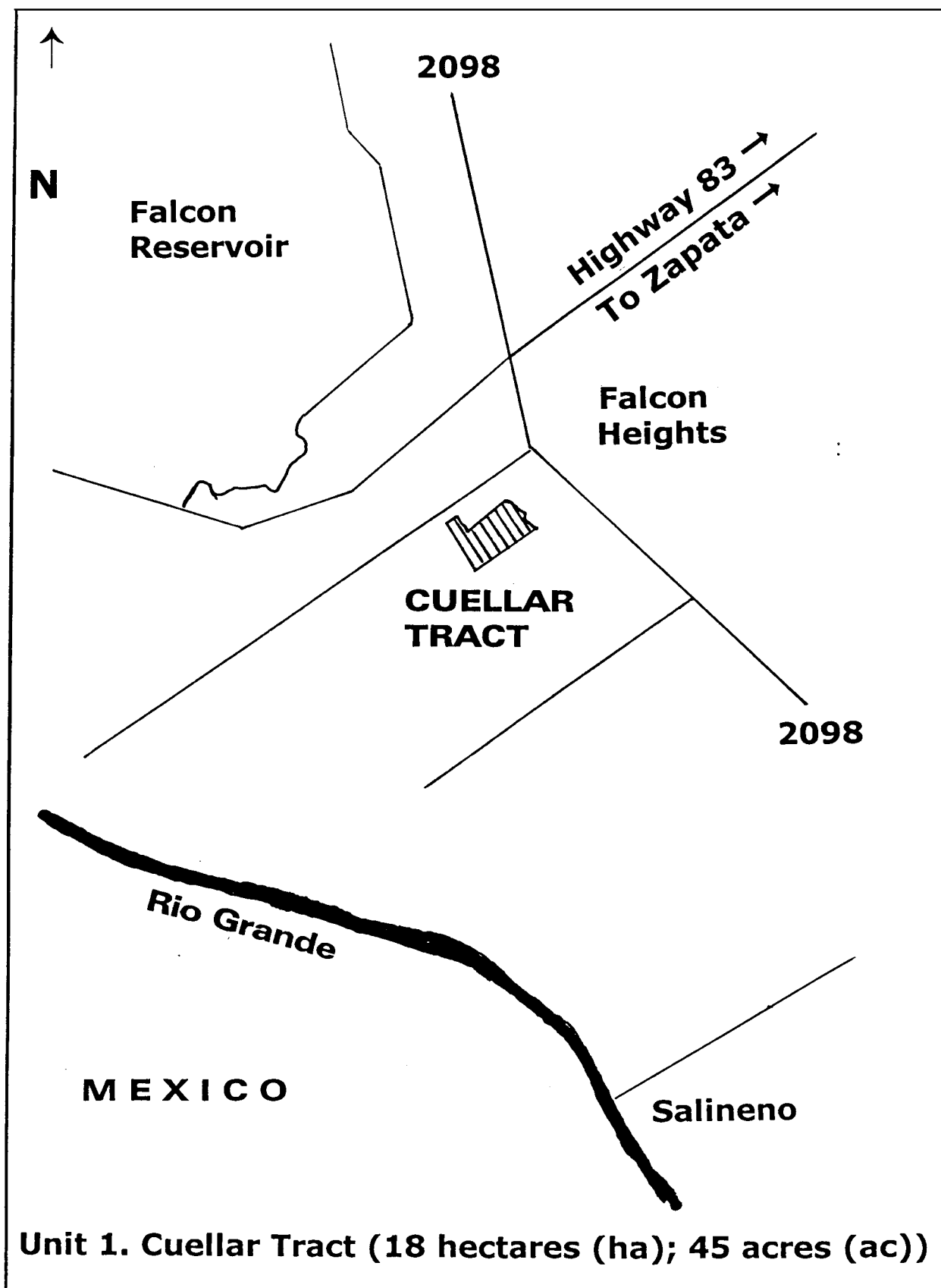
Porcions 59 and 60, and being the northeast corner of Share 26 and stamped “Tract 672, COR. No. 1, R.P.L.S. No. 3680” and having a State plane coordinate value of N = 318,737.64, E = 1,797,725.36, from which FWS GPS Monument No. 105 bears S $15^{\circ} 22' 02''$ E, 7,920.94 feet; thence, in a southeasterly direction along the common line of Porcion 59 and 60, S $54^{\circ} 27' 12''$ W, 806.50 feet to a standard FWS aluminum monument set for corner, being the southeast corner of said north one-half ($\frac{1}{2}$) of Share 26, same being the northeast corner of the south one-half ($\frac{1}{2}$) of Share 26 and stamped “Tract 672, COR. No. 2, R.P.L.S. No. 3680”; thence, in a northwesterly direction along the common line of said north and south one-half ($\frac{1}{2}$) of Share 26; N $35^{\circ} 27' 36''$ W, 463.31 feet to a standard FWS aluminum monument set for corner in the common line between Shares 26 and 27 and stamped “Tract 672, COR. No. 3, R.P.L.S. No. 3680”; thence, in a northeast direction along the common line of Shares 26 and 27; N $54^{\circ} 32' 24''$ E, 806.50 feet to a standard FWS aluminum monument set for corner, being the most northerly common corner of Shares 26 and 27 in the south line of Share 35 and stamped “Tract 672, COR. No. 4, R.P.L.S. No. 3680”; thence, in a southeasterly direction along the common line of Shares 35 and 26; S $35^{\circ} 27' 36''$ E, 462.09 feet to the point of beginning and containing 8.567 acres of land.

(Cuellar Tract—Segment 673). Note: All bearings are based on the Texas State Plane Coordinate System, South Zone, as referenced by FWS GPS Monument No. 105 having State plane coordinates (NAD 27) of N = 311,099.90, E = 1,799,824.45. The scale factor used is 0.9999252, and the theta angle is $-00^{\circ} 37' 32''$. All areas and distances are true surface measurements. Beginning at a standard FWS aluminum monument set for the common north corner of Shares 26 and 27, in the south line of Share 35 and stamped “Tract 672, COR. No. 4, R.P.L.S. No. 3680” and having a state plane coordinate value of N = 319,114.02, E = 1,797,457.29, from which FWS GPS Monument No. 105 bears S $16^{\circ} 27' 21''$ E, 8,356.40 feet; thence, in a southwesterly direction along the common line of Shares 26 and 27, S $54^{\circ} 32' 24''$ N, 806.50 feet to a standard FWS aluminum monument set for corner, being the southeast corner of said north one-half ($\frac{1}{2}$) of Share 27, same being the northeast corner of the south one-half ($\frac{1}{2}$) of Share 27 and stamped “Tract 672, COR. No. 3, R.P.L.S. No. 3680”; thence, in a

northwesterly direction along the common line of said north and south one-half ($\frac{1}{2}$) of Share 27; N $35^{\circ} 27' 36''$ W, 592.30 feet to a standard FWS aluminum monument set for corner in the common line between Shares 27 and 28 and stamped “Tract 674, COR. No. 3, R.P.L.S. No. 3680”; thence, in a northeasterly direction along the common line of Shares 27 and 28, N $54^{\circ} 32' 24''$ E, 806.50 feet to a standard FWS aluminum monument set for corner, being the most northerly common corner of Shares 27 and 28 in the south line of Share 34 and stamped “Tract 674, COR. No. 2, R.P.L.S. No. 3680”; thence, in a southeasterly direction along the common line of Shares 34 and 27, S $35^{\circ} 27' 36''$ E, 592.30 feet to the point of beginning and containing 10.966 acres of land.

(Cuellar Tract—Segment 672). Note: All bearings are based on the Texas State Plane Coordinate System, South Zone, as referenced by FWS GPS Monument No. 105 having State plane coordinates (NAD 27) of N = 311,099.90, E = 1,799,824.45. The scale factor used is 0.9999252, and the theta angle is $-00^{\circ} 37' 32''$. All areas and distances are true surface measurements. Beginning at a standard FWS aluminum monument set replacing a 1-inch iron pipe found for the common north corner of Shares 28 and 29, in the south line of Share 33 and stamped “Tract 674, COR. No. 1, R.P.L.S. No. 3680”; and having a state plane coordinate value of N = 320,078.90, E = 1,796,770.06, from which FWS GPS Monument No. 105 bears S $18^{\circ} 47' 11''$ E, 9,484.36 feet; thence, in a southeasterly direction along the common line of Share 28 and Shares 33 and 34, S $35^{\circ} 27' 36''$ E, 592.30 feet to a standard FWS aluminum monument set for corner, being the common northerly corner of Shares 28 and 27 and stamped “Tract 674, COR. No. 2, R.P.L.S. No. 3680”; thence, in a southwesterly direction along the common line of said Share 28 and 27; S $54^{\circ} 32' 24''$ W, 806.50 feet to a standard FWS aluminum monument set for the southeasterly corner of said north one-half ($\frac{1}{2}$) of Share 28, same being the northeasterly corner of the south one-half ($\frac{1}{2}$) of Share 28 and stamped “Tract 674, COR. No. 3, R.P.L.S. No. 3680”; thence, in a northwesterly direction along the common line of the north and south one-half ($\frac{1}{2}$) of Share 28, N $35^{\circ} 27' 36''$ W, 592.30 feet to a standard FWS aluminum monument set for corner in the common line between Shares 28 and 29 and stamped “Tract 674, COR. No. 4, R.P.S. No. 3680”; thence, in a northeasterly direction along the

common line of Shares 28 and 29; N 54° 32' 24" E, 806.50 feet to the point of beginning and containing 10.966 acres of land.



Unit 2, Chapeno Tract (28 ha; 69 ac)—(Chapeno Tract—Segment 660). Note: All bearings and distances are based on the International Boundary Commission Monuments as referenced by the U.S.C. & G.S. Triangulation Station “LABRA.” The scale factor used is 0.9999252, and the theta angle is $-00^{\circ} 37' 32''$ (NAD 1927). All areas shown are true ground areas. Commencing for reference at the U.S.C. & G.S. triangulation station “LABRA,” having coordinate values: $x = 1,794,777.75$, $y = 331,881.06$; thence, S $02^{\circ} 08' 43''$ W, a distance of 9,020.47 feet to the northwesterly boundary line of said 44.900-acre tract for the northernmost corner of said Share No. 17 and being corner No. 1 and the northernmost corner and place of beginning of the tract herein-described; thence, along the northeasterly boundary line of Share No. 17 and the southwesterly boundary line of a 35-foot perpetual easement, S $32^{\circ} 11' 36''$ E, 840.62 feet to the easternmost corner of said Share No. 17 and being corner No. 2 of this tract; thence, along the southeasterly boundary line of Share No. 17 and the northwesterly boundary line of Share No. 18, S $47^{\circ} 29' 30''$ W, 293.59 feet to a said point on a fence line along the southwesterly boundary line of said 44.900-acre tract for the southernmost corner of said Share No. 17 and being corner No. 3 of this tract; thence, following said fence line along the southwesterly boundary line of Share No. 17 and the southwesterly boundary line of said 44.900-acre tract, N $30^{\circ} 16' 28''$ W, 166.16 feet to a standard FWS aluminum monument stamped “Tract (660), R.P.S. No. 4731” set for a corner of said 44.900-acre tract and being corner No. 4 of this tract; thence, continuing along said fence line along the southwesterly boundary line of Share No. 17 and the southwesterly boundary line of said 44.900-acre tract, N $31^{\circ} 04' 59''$ W, 684.02 feet to a standard FWS aluminum monument stamped “Tract (660), R. P. S. No. 4731” set for the westernmost corner of said 44.900-acre tract and being corner No. 5 of this tract, thence, following a fence line along the northwesterly boundary line of Share No. 17 and the northwesterly boundary line of said 44.900-acre tract, N $48^{\circ} 42' 36''$ E, 273.46 feet to the place of beginning and containing 5.396 acres of land.

(Chapeno Tract—Segment 661). Note: All bearings and distances are based on the International Boundary Commission Monuments as referenced by the U.S.C. & G.S. triangulation station “LABRA.” The scale factor used is 0.9999252, and the theta angle is $-00^{\circ} 37' 32''$ (NAD 1927). All areas shown are true ground

areas. Commencing for reference at the U.S.C. & G.S. triangulation station “LABRA,” having coordinate values: $x = 1,794,777.75$, $y = 331,881.06$; thence, S $00^{\circ} 48' 20''$ E, a distance of 9,702.45 feet to the northernmost corner of said Share No. 18 and being corner No. 1 and the northernmost corner and place of beginning of the tract herein-described; thence, along the northeasterly boundary line of Share No. 18 and the southwesterly boundary line of Share No. 19, S $42^{\circ} 40' 05''$ E, 623.01 feet to a point on a fence line along the southeasterly boundary line of said 44.900-acre tract for the easternmost corner of said Share No. 18 and being corner No. 2 of this tract; thence, following said fence line along the southeasterly boundary line of Share No. 18 and the southeasterly boundary line of said 44.900-acre tract, S $54^{\circ} 58' 43''$ W, 14.82 feet to a standard FWS aluminum monument stamped “Tract (661), R. P. S. No. 4731” set for a corner of said 44.900-acre tract and being corner No. 3 of this tract; thence, continuing along said fence line along the southeasterly boundary line of Share No. 18 and the southeasterly boundary line of said 44.900-acre tract, S $54^{\circ} 17' 40''$ W, 442.61 feet to a standard FWS aluminum monument stamped “Tract (661), R. P. S. No. 4731” set for the southernmost corner of said 44.900-acre tract and being corner No. 4 of this tract; thence, following a fence line along the southwesterly boundary line of Share No. 18 and the southwesterly boundary line of said 44.900-acre tract, N $30^{\circ} 16' 28''$ W, 581.86 feet to a point for the westernmost corner of said Share No. 18 and being corner No. 5 of this tract; thence, along the southeasterly boundary line of Share No. 17 and the northwesterly boundary line of Share No. 18, N $47^{\circ} 29' 30''$ E, 329.16 feet to the place of beginning and containing 5.396 acres of land.

(Chapeno Tract—Segment 662). Note: All bearings and distances are based on the International Boundary Commission Monuments as referenced by the U.S.C. & G.S. triangulation station “LABRA.” The scale factor used is 0.9999252, and the theta angle is $-00^{\circ} 37' 32''$ (NAD 1927). All areas shown are true ground areas. Commencing for reference at the U.S.C. & G.S. triangulation station “LABRA,” having coordinate values: $x = 1,794,777.75$, $y = 331,881.06$; thence, S $00^{\circ} 53' 22''$ E, a distance of 9,308.09 feet to the northernmost corner of said Share No. 19 and being corner No. 1 and the northernmost corner and the place of beginning of the tract herein-described; thence, along the northeasterly boundary line of Share No. 19 and the

southwesterly boundary line of Share No. 20, S $41^{\circ} 14' 45''$ E, 941.54 feet to a point on a fence line along the southeasterly boundary line of said 44.900-acre tract for the easternmost corner of said Share No. 19 and being corner No. 2 of this tract; thence, following said fence line along the southeasterly boundary line of Share No. 19 and the southeasterly boundary line of said 44.900-acre tract, S $55^{\circ} 22' 51''$ W, 8.49 feet to a standard FWS aluminum monument stamped “Tract (662), R. P. S. No. 4731” set for a corner of said 44.900-acre tract and being corner No. 3 of this tract; thence, continuing along said fence line along the southeasterly boundary line of Share No. 19 and the southeasterly boundary line of said 44.900-acre tract, S $54^{\circ} 58' 43''$ W, 243.72 feet to the southernmost corner of Share No. 19 and being corner No. 4 of this tract; thence, along the northeasterly boundary line of Share No. 18 and the southwesterly boundary line of Share No. 19, N $42^{\circ} 40' 05''$ W, 623.01 feet to a corner of Share No. 19 and being corner No. 5 of this tract; thence, along the northeasterly boundary line of a 35-foot perpetual easement and the southwesterly boundary line of Share No. 19, N $32^{\circ} 08' 41''$ W, 293.64 feet to the westernmost corner of said Share No. 19 and being corner No. 6 of this tract; thence, along the southeasterly boundary line of a 35-ft. perpetual easement and the northwesterly boundary line of Share No. 19, N $48^{\circ} 23' 35''$ E, 219.73 feet to the place of beginning and containing 5.396 acres of land.

(Chapeno Tract—Segment 663). Note: All bearings and distances are based on the International Boundary Commission Monuments as referenced by the U.S.C. & G.S. triangulation station “LABRA.” The scale factor used is 0.9999252, and the theta angle is $-00^{\circ} 37' 32''$ (NAD 1927). All areas shown are true ground areas. Commencing for reference at the U. S. C. & G. S. triangulation station “LABRA,” having coordinate values: $x = 1,794,777.75$, $y = 331,881.06$; thence, S $01^{\circ} 55' 50''$ E, a distance of 9,166.26 feet to the northernmost corner of said share No 20, and being corner No. 1, and the northernmost corner and place of beginning of the tract herein-described; thence, along the northeasterly boundary line of Share No. 20 and the southwesterly boundary line of Share No. 21, S $44^{\circ} 17' 45''$ E, 975.87 feet to a point on a fence line along the southeasterly boundary line of said 44.900-acre tract for the easternmost corner of said Share No. 20 and being corner No. 2 of this tract; thence, following said fence line along the

southeasterly boundary line of Share No. 20 and the southeasterly boundary line of said 44.900-acre tract; S 55° 22' 51" W, 273.48 feet to the southernmost corner of Share No. 20 and being corner No. 3 of this tract; thence, along the northeasterly boundary line of Share No. 19 and the southwesterly boundary line of Share No. 20, N 41° 14' 45" W, 941.54 feet to the westernmost corner of Share No. 20 and being corner No. 4 of this tract; thence, along the southeasterly boundary line of a 35-ft. perpetual easement and the northwesterly boundary line of Share No. 20, N 48° 23' 35" E, 219.73 feet to the place of beginning and containing 5.396 acres of land.

(Chapeno Tract—Segment 664). Note: All bearings and distances are based on the International Boundary Commission Monuments as referenced by the U.S.C. & G.S. triangulation station "LABRA." The scale factor used is 00.9999252, and the theta angle is $-00^{\circ} 37' 32''$ (NAD 1927). All areas shown are true ground areas. Commencing for reference at the U.S.C. & G.S. triangulation station "LABRA," having coordinate values: $x = 1,794,777.75$, $y = 331,881.06$; thence, S 03° 00' 15" E, a distance of 9,027.56 feet to the northernmost corner of said Share No. 21 and being corner No. 1 and the northernmost corner and place of beginning of the tract herein-described; thence, along the northeasterly boundary line of Share No. 21 and the southwesterly boundary line of Share No. 22, S 46° 18' 57" E, 1,008.60 feet to a point on a fence line along the southeasterly boundary line of said 44.900-acre tract for the easternmost corner of Share No. 21 and being corner No. 2 of this tract; thence, following said fence line along the southeasterly boundary line of Share No. 21 and the southeasterly boundary line of said 44.900-acre tract, S 54° 17' 59" W, 56.04 feet to a standard FWS aluminum monument stamped "Tract (664), R. P. S. No. 4731" set for a corner of said 44.900-acre tract and being corner No. 3 of this tract; thence, continuing along said fence line along the southeasterly boundary line of Share No. 21 and the southeasterly boundary line of said 44.900-acre tract, S 55° 22' 51" W, 202.51 feet to the southernmost corner of Share No. 21 and being corner No. 4 of this tract; thence, along the northeasterly boundary line of Share No. 20 and the southwesterly boundary line of Share No. 21, N 44° 17' 45" W, 975.87 feet to the westernmost corner of Share No. 21 and being corner No. 5 of this tract; thence, along the southeasterly boundary line of a 35-foot perpetual easement and the

northwesterly boundary line of Share No. 21, N 48° 23' 35" E, 219.73 feet to the place of beginning and containing 5.396 acres of land.

(Chapeno Tract—Segment 665). Note: All bearings and distances are based on the International Boundary Commission Monuments as referenced by the U.S.C. & G.S. Triangulation station "LABRA." The scale factor used is 00.9999252, and the theta angle is $-00^{\circ} 37' 32''$ (NAD 1927). All areas shown are true ground areas. Commencing for reference at the U.S.C. & G.S. Triangulation station "LABRA," having coordinate values: $x = 1,794,777.75$, $y = 331,881.06$; thence, S 04° 06' 38" E, a distance of 8,892.12 feet to the northernmost corner of said Share No. 22 and being corner No. 1 and the northernmost corner and place of beginning of the tract herein-described; thence, following a fence line along the northeasterly boundary line of Share No. 22 and the southwesterly boundary line of Share No. 23, S 47° 33' 31" E, 1,036.06 feet to a point on a fence line along the southeasterly boundary line of said 44.900-acre tract for the easternmost corner of said Share No. 22 and being corner No. 2 of this tract; thence, following said fence line along the southeasterly boundary line of Share No. 22 and the southeasterly boundary line of said 44.900-acre tract, S 54° 17' 59" W, 245.67 feet to the southernmost corner of Share No. 22 and being corner No. 3 of this tract; thence, along the northeasterly boundary line of Share No. 21 and the southwesterly boundary line of Share No. 22, N 46° 18' 57" W, 1,008.60 feet to the westernmost corner of Share No. 22 and being corner No. 4 of this tract; thence, along the southeasterly boundary line of a 35-foot perpetual easement and the northwesterly boundary line of Share No. 22, N 48° 23' 35" E, 219.73 feet to the place of beginning and containing 5.396 acres of land.

(Chapeno Tract—Segment 666). Note: All bearings and distances are based on the International Boundary Commission Monuments as referenced by the U.S.C. & G.S. triangulation station "LABRA." The scale factor used is 00.9999252, and the theta angle is $-00^{\circ} 37' 32''$ (NAD 1927). All areas shown are true ground areas. Commencing for reference at the U.S.C. & G.S. Triangulation station "LABRA," having coordinate values: $x = 1,794,777.75$, $y = 331,881.06$; thence, S 05° 15' 03" E, a distance of 8,710.10 feet to the northernmost corner of said Share No. 23 and being corner No. 1 and the northernmost corner and place of beginning of the tract herein-described; thence, following a fence line along the northeasterly boundary line of Share No. 23 and the southwesterly boundary

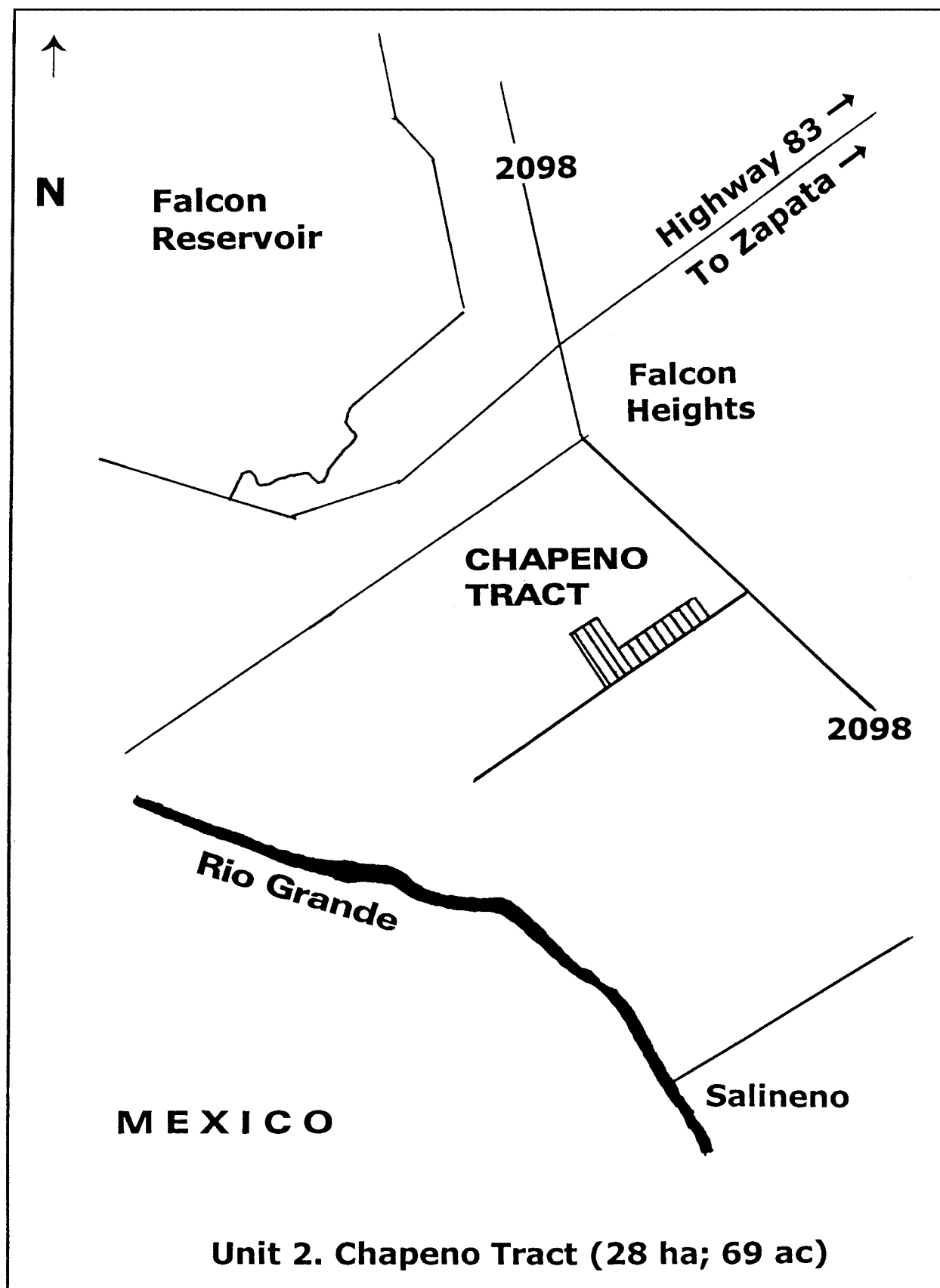
line of said Share No. 24, S 48° 10' 23" E, 1,061.62 feet to a point on a fence line along the southeasterly boundary line of said 44.900-acre tract for the easternmost corner of Share No. 23 and being corner No. 2 of this tract; thence, following said fence line along the southeasterly boundary line of Share No. 23 and the southeasterly boundary line of said 44.900-acre tract, S 54° 17' 59" W, 234.95 feet to the southernmost corner of Share No. 23 and being corner No. 3 of this tract; thence, along the northeasterly boundary line of Share No. 22 and the southwesterly boundary line of Share No. 23, N 47° 33' 31" W, 1,036.06 feet to the westernmost corner of Share No. 23 and being corner No. 4 of this tract; thence, along the southeasterly boundary line of a 35-ft. perpetual easement and the northwesterly boundary line of Share No. 23, N 48° 23' 35" E, 219.73 feet to the place of beginning and containing 5.396 acres of land.

(Chapeno Tract—Segment 667). Note: All bearings and distances are based on the International Boundary Commission Monuments as referenced by the U.S.C. & G.S. Triangulation station "LABRA." The scale factor used is 00.9999252, and the theta angle is $-00^{\circ} 37' 32''$ (NAD 1927). All areas shown are true ground areas. Commencing for reference at the U.S.C. & G.S. Triangulation station "LABRA," having coordinate values: $x = 1,794,777.75$, $y = 331,881.06$; thence, S 06° 25' 32" E, a distance of 8,631.65 feet to the northeasterly boundary line of said 44.900-acre tract for corner No. 1 and the place of beginning of the tract herein-described; thence, following a fence line along the northeasterly boundary line of share No. 24 and the northeasterly boundary line of said 44.900-acre tract, S 51° 42' 47" E, 679.97 feet to a standard FWS aluminum monument stamped "Tract (667), R. P. S. No. 4731" set for a corner of said 44.900-acre tract and being corner No. 2 of this tract; thence, continuing along the fence line along the northeasterly boundary line of Share No. 24 and the northeasterly boundary line of said 44.900-acre tract, S 01° 11' 48" E, 136.46 feet to a standard FWS aluminum monument stamped "Tract (667), R. P. S. No. 4731" set for a corner of said 44.900-acre tract and being corner No. 3 of this tract; thence, continuing along the fence line along the northeasterly boundary line of Share No. 24 and the northeasterly boundary line of said 44.900-acre tract, S 54° 15' 17" E, 309.21 feet to a standard FWS aluminum monument stamped "Tract (667), R. P. S. No. 4731" set on a fence line for the easternmost corner of Share No. 24 and

being on the southeasterly boundary line of said 44.900-acre tract and being corner No. 4 of this tract; thence, following said fence line along the southeasterly boundary line of share No. 24 and the southeasterly boundary line of said 44.900-acre tract, S 54° 17' 59" W, 197.94 feet to the southernmost

corner of Share No. 24 and being corner No. 5 of this tract; thence, following said fence line along the southwesterly boundary line of Share No. 24 and the northeasterly boundary line of Share No. 23, N 48° 10' 23" W, 1,061.62 feet to the westernmost corner of Share No. 24 and northernmost corner of Share

No. 23 and being corner No. 6 of this tract; thence, along the southeasterly boundary line of a 35-ft. perpetual easement and the northwesterly boundary line of Share No. 24, N 48° 23' 35" E, 219.73 feet to the place of beginning and containing 5.396 acres of land.



Unit 3, Arroyo Morteros Tract (41 ha; 102 ac)—Note: All bearings are based on the Texas State Plane Coordinate System, South Zone, (NAD 27), as

referenced by FWS GPS Monument No. 105 having State plane coordinates of N

= 311,099.90, E = 1,799,824.45. The scale factor used is 0.9999252, and the theta angle is $-00^{\circ} 37' 32''$. All areas and distances are true surface measurements. Beginning at a 1/2-inch iron rod found for corner No. 1 on the common line between Porcions 59 and 60, and being the northwest corner of that certain 127.71-acre tract and having a State plane coordinate value of N = 315,746.07, E = 1,793,538.58, from which FWS GPS monument No. 105 bears S $53^{\circ} 31' 49''$ E, 7,816.59 feet; thence, in a northeasterly direction along the common line of Porcion 59 and 60; N $54^{\circ} 27' 12''$ E, 510.43 feet to a standard FWS aluminum monument set for corner replacing a 1/2-inch iron rod found, being the northwest corner of the herein described tract and stamped "Tract 670, Cor. No. 2, R. P. L. S. No. 3680"; thence, in a easterly direction through the interior of said 536.485 acre tract; S $35^{\circ} 20' 27''$ E, 3,621.01 feet to a standard FWS aluminum monument set for corner replacing a 1/2-inch iron rod found, being the northeast corner of the herein-described tract and stamped "Tract 670, Cor. No. 3, R.P.L.S. No. 3680"; thence, in a southerly direction continuing through the interior of said 536.485 acre tract; S $61^{\circ} 18' 54''$ W, 219.24 feet to a fence corner post found for a northwesterly corner of that certain 17.408 acre tract and being corner No. 4; thence, in a easterly direction along the common line between said 17.408 acre tract and the herein described tract; S $88^{\circ} 47' 16''$ W, 110.41 feet to a fence post found for angle point and corner No. 5; thence, in a easterly direction continuing along said common line between a 17.408 acre tract and herein described tract; N $79^{\circ} 11' 33''$ W, 67.63 feet to a fence post found for angle point and corner No. 6; thence, in a easterly direction continuing along said common line between a 17.408 acre tract and herein described tract; S $71^{\circ} 49' 04''$ W, 50.57 feet to a fence post found for angle point and corner No. 7; thence, in a southerly direction continuing along said common line between a 17.408 acre tract and herein described tract; S $15^{\circ} 40' 49''$ W, 44.43 feet to a fence post found for angle point and corner No. 8; thence, in a southerly direction continuing along said common line between a 17.408 acre tract and herein described tract; S $00^{\circ} 18' 59''$ E, 253.83 feet to a fence post found for angle point and corner No. 9; thence, in a southerly direction continuing along said common line between a 17.408 acre tract and herein described tract; S $06^{\circ} 36' 21''$ W, 182.88 feet to a fence post found for angle point and corner No. 10; thence, in a southerly direction continuing

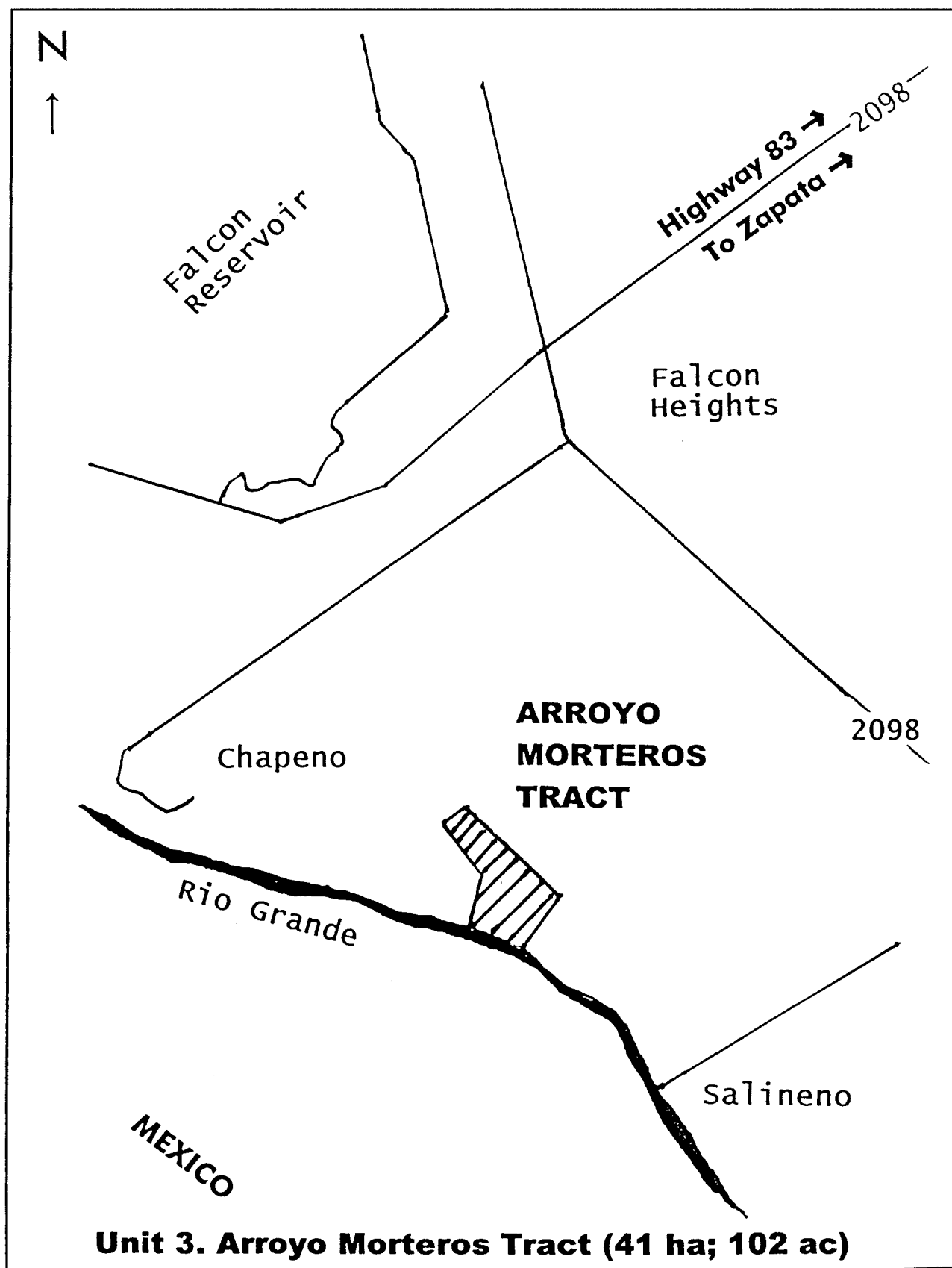
along said common line between a 17.408 acre tract and herein described tract; S $26^{\circ} 38' 19''$ W, 125.18 feet to a fence post found for angle point and corner No. 11; thence, in a southerly direction continuing along said common line between a 17.408 acre tract and herein described tract; S $67^{\circ} 33' 26''$ W, 129.76 feet to a fence post found for angle point and corner No. 12; thence, in a southerly direction continuing along said common line between a 17.408-acre tract and herein described tract; S $45^{\circ} 58' 19''$ W, 73.00 feet to a fence post found for angle point and corner No. 13; thence, in a southerly direction continuing along said common line between a 17.408 acre tract and herein described tract; S $35^{\circ} 10' 19''$ W, 113.60 feet to a fence post found for angle point and corner No. 14; thence, in a southerly direction continuing along said common line between a 17.408 acre tract and herein described tract; S $19^{\circ} 34' 19''$ W, 42.80 feet to a fence post found for angle point and corner No. 15; thence, in a southerly direction continuing along said common line between a 17.408-acre tract and herein described tract; S $15^{\circ} 23' 41''$ W, 28.84 feet to a 1/2-inch iron rod found on the apparent gradient boundary of the Rio Grande for the southeast corner hereof and corner No. 16; thence, in a westerly direction along said apparent gradient boundary of the Rio Grande; N $62^{\circ} 26' 09''$ W, 81.47 feet to a point on said apparent gradient boundary of the Rio Grande for corner No. 7; thence, in a northwesterly direction continuing along said apparent gradient boundary of the Rio Grande; N $36^{\circ} 34' 14''$ W, 122.63 feet to a point on said apparent gradient boundary of the Rio Grande for corner No. 18; thence, in a northerly direction continuing along said apparent gradient boundary of the Rio Grande; N $20^{\circ} 15' 10''$ W, 58.91 feet to a point on said apparent gradient boundary of the Rio Grande for corner No. 19; thence, in a northwesterly direction continuing along said apparent gradient boundary of the Rio Grande; N $34^{\circ} 02' 20''$ W, 118.95 feet to a point on said apparent gradient boundary of the Rio Grande for Corner No. 20; thence, in a westerly direction continuing along said apparent gradient boundary of the Rio Grande; S $73^{\circ} 36' 56''$ W, 17.73 feet to a point on said apparent gradient boundary of the Rio Grande for corner No. 21; thence, in a northwesterly direction continuing along said apparent gradient boundary of the Rio Grande; N $43^{\circ} 36' 30''$ W, 118.21 feet to a point on said apparent gradient boundary of the Rio Grande corner No. 22; thence, in a northerly

direction continuing along said apparent gradient boundary of the Rio Grande; N $28^{\circ} 12' 58''$ W, 168.21 feet to a point on said apparent gradient boundary of the Rio Grande for corner No. 23; thence, in a northwesterly direction continuing along said apparent gradient boundary of the Rio Grande; N $49^{\circ} 09' 29''$ W, 149.82 feet to a point on said apparent gradient boundary of the Rio Grande for corner No. 24; thence, in a westerly direction continuing along said apparent gradient boundary of the Rio Grande; N $66^{\circ} 23' 26''$ W, 123.27 feet to a point on said apparent gradient boundary of the Rio Grande for corner No. 25; thence, in a westerly direction continuing along said apparent gradient boundary of the Rio Grande; N $77^{\circ} 18' 49''$ W, 240.49 feet to a point on said apparent gradient boundary of the Rio Grande for corner No. 26; thence, in a westerly direction continuing along said apparent gradient boundary of the Rio Grande; S $80^{\circ} 06' 32''$ W, 129.98 feet to a point on said apparent gradient boundary of the Rio Grande for corner No. 27; thence, in a westerly direction continuing along said apparent gradient boundary of the Rio Grande; N $79^{\circ} 54' 48''$ W, 218.17 feet to a point on said apparent gradient boundary of the Rio Grande for corner No. 28; thence, in a westerly direction continuing along said apparent gradient boundary of the Rio Grande; S $81^{\circ} 13' 28''$ W, 136.03 feet to a 1/2-inch iron rod found on said apparent gradient boundary of the Rio Grande for the southeast corner of the aforementioned 127.71 acre tract, same being the southwest corner hereof and corner No. 29; thence, in a northerly direction along the common line between said 127.71-acre tract and the herein described tract; N $06^{\circ} 09' 33''$ W, 237.00 feet to a fence post found for angle point and corner No. 30; thence, in a northerly direction continuing along the common line between said 127.71-acre tract and the herein described tract; N $05^{\circ} 51' 34''$ W, 198.49 feet to a fence post found for angle point and corner No. 31; thence, in a Northerly direction continuing along the common line between said 127.71-acre tract and the herein described tract; N $07^{\circ} 49' 27''$ E, 161.97 feet to a fence post found for angle point and corner No. 32; thence, in a Northerly direction continuing along the common line between said 127.71-acre tract and the herein described tract; N $07^{\circ} 47' 00''$ E, 302.39 feet to a fence post found for angle point and corner No. 33; thence, in a northerly direction continuing along the common line between said 127.71 acre tract and the herein described tract; N $07^{\circ} 17' 37''$ E,

493.82 feet to a fence post found for angle point and corner No. 34; thence, in a northeasterly direction continuing along the common line between said 127.71-acre tract and the herein described tract, as fenced; N 46° 28' 41" E, 643.50 feet to a fence post found for

angle point and corner No. 35; thence, in a northwesterly direction continuing along the common line between said 127.71 acre tract and the herein described tract; N 47° 51' 47" W, 1,087.49 feet to a fence post found for angle point and corner No. 36; thence,

in a northerly direction continuing along the common line between said 127.71-acre tract and the herein described tract; N 21° 22' 25" W, 375.05 feet to the point of beginning and containing 89.90 acres of land.



Unit 4, Las Ruinas Tract (104 ha; 256 ac)—Note: All bearings are based on the

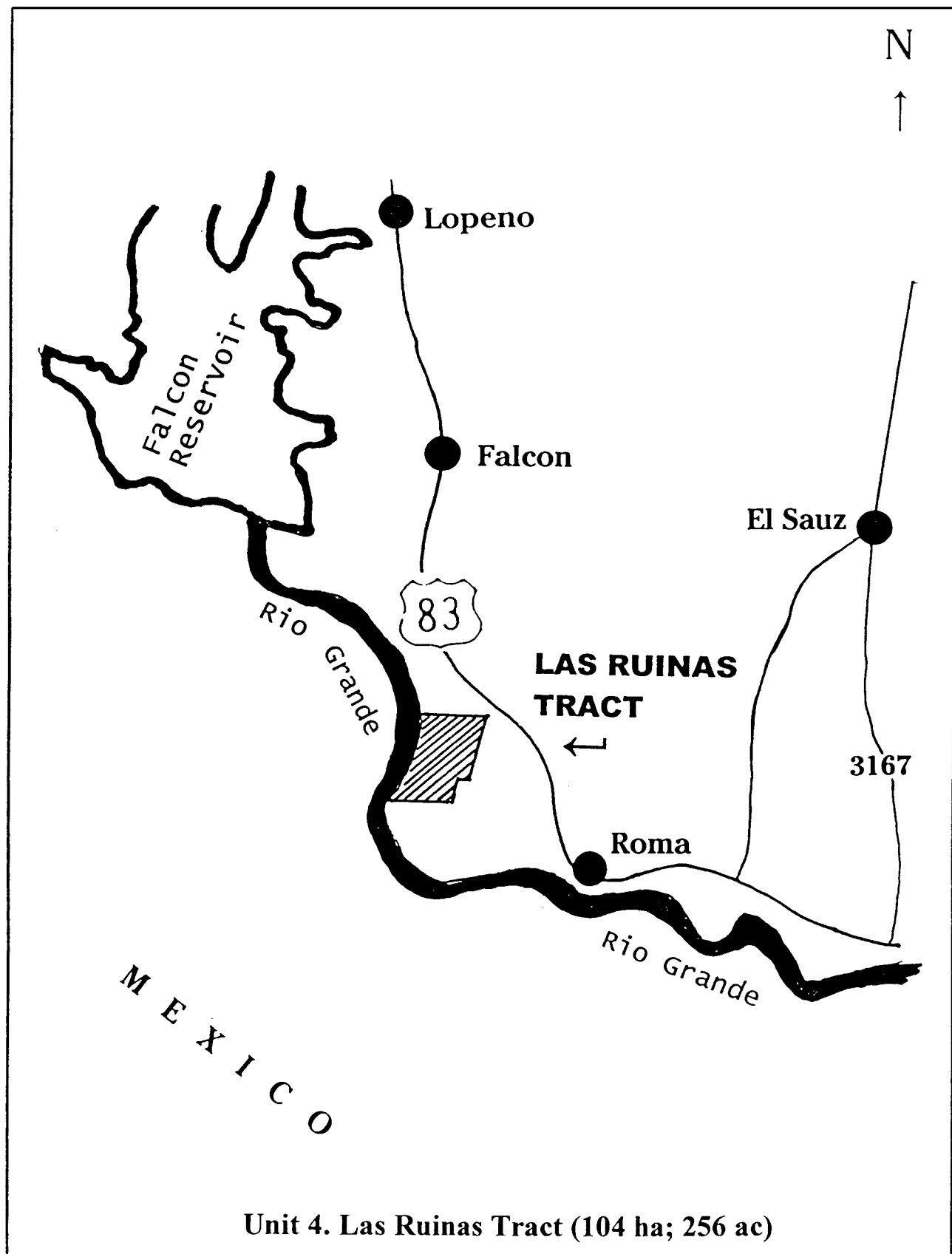
Texas State Plane Coordinate System, South Zone, as referenced by National

Geodetic Survey (NGS.) Triangulation Station "GORGORA" having State plane

coordinates (NAD 27) of N = 275,335.73, E = 1,833,217.01. The scale factor used is 0.9999421, and the theta angle is -00° 16' 22". All areas and distances are true surface measurements. Beginning at a 2-inch iron pipe having State plane coordinates of N = 280,488.40, E = 1,804,584.01 for the northerly southeast corner of the herein described tract, from which said triangulation station "GORGORA" bears S 79° 47' 55" E, a distance of 29,092.93 feet, same being the southwest corner of Share 96, of said Porcion 66, and the southwest corner of a 1455.52-acre tract of land as described, same being in the north line of Share 94, of said Porcion 66, same being in the north line of Tract "K", a 26.82-acre tract of land as described, for corner No. 1 and point of beginning of the herein described tract of land. Thence, westerly along the common line between said northerly line of tract "K" and the southerly line hereof N 80° 30' 29" W, 871.09 feet to a 6" iron pipe found for corner No. 2, same being the northwest corner of said Tract "K"; thence, southerly along the common line between the westerly line of said Tract "K" and the easterly line hereof S 09° 22' 35" W, 837.18 feet, to a 1 3/4" iron pipe found for the southwest corner of said tract "K" and the northwest corner of a 23.5131-acre tract of land at corner No. 3, thence, southerly along the common line between said 23.5131-acre tract and the most southerly easterly line hereof, S 09° 22' 35" W, 540.00 feet to a standard FWS aluminum monument set, said monument being in the north line of a 56.82-acre tract of land as described for corner No. 4 and stamped "Tract 630, Ref. No. 4, RPLS 3680"; thence, westerly along the common northerly line between said 56.82 acre tract and the southerly line hereof, N 80° 31' 16" W, 3295.18 feet to the apparent gradient boundary of the Rio Grande, and passing a standard FWS aluminum monument set for reference at a distance of 3,210.08 feet and stamped "Tract 630, Ref. No. 5, RPLS 3680"; thence, northerly along the apparent gradient boundary of the Rio Grande N 63° 00' 17" E, 192.97 feet to a point on the apparent gradient boundary of the Rio Grande for Corner No. 6; thence, northerly continuing along said apparent gradient boundary of the Rio Grande N 62° 39' 49" E, 398.99 feet to a point on the apparent gradient boundary of the Rio Grande for Corner No. 7; thence, northerly continuing along said apparent gradient boundary of the Rio Grande N 60° 14' 39" E, 722.34 feet to a point on the apparent gradient boundary of the Rio Grande for corner No. 8; thence,

northerly continuing along said apparent gradient boundary of the Rio Grande N 57° 28' 43" E, 416.75 feet to a point on the apparent gradient boundary of the Rio Grande for corner No. 9; thence, northerly continuing along said apparent gradient boundary of the Rio Grande N 57° 55' 40" E, 171.44 feet to a point on the apparent gradient boundary of the Rio Grande for corner No. 10; thence, northerly continuing along said apparent gradient boundary of the Rio Grande N 47° 49' 48" E, 287.44 feet to a point on the apparent gradient boundary of the Rio Grande for corner No. 11; thence, northerly continuing along said apparent gradient boundary of the Rio Grande N 43° 00' 00" E, 246.79 feet to a point on the apparent gradient boundary of the Rio Grande for corner No. 12; thence, northerly continuing along said apparent gradient boundary of the Rio Grande N 39° 40' 14" E, 295.08 feet to a point on the apparent gradient boundary of the Rio Grande for corner No. 13; thence, northerly continuing along said apparent gradient boundary of the Rio Grande N 35° 41' 43" E, 380.79 feet to a point on the apparent gradient boundary of the Rio Grande for corner No. 14; thence, northerly continuing along said apparent gradient boundary of the Rio Grande N 31° 28' 24" E, 370.58 feet to a point on the apparent gradient boundary of the Rio Grande for corner No. 15; thence, northerly continuing along said apparent gradient boundary of the Rio Grande N 33° 19' 15" E, 293.00 feet to a point on the apparent gradient boundary of the Rio Grande for corner No. 16; thence, northerly continuing along said apparent gradient boundary of the Rio Grande N 13° 43' 08" E, 146.31 feet to a point on the apparent gradient boundary of the Rio Grande for corner No. 17; thence, northerly continuing along said apparent gradient boundary of the Rio Grande N 11° 00' 57" E, 189.14 feet to a point on the apparent gradient boundary of the Rio Grande for corner No. 18; thence, northerly continuing along said apparent gradient boundary of the Rio Grande N 02° 10' 54" W, 305.51 feet to a point on the apparent gradient boundary of the Rio Grande for corner No. 19; thence, northerly continuing along said apparent gradient boundary of the Rio Grande N 01° 31' 51" W, 416.25 feet to a point on the apparent gradient boundary of the Rio Grande for corner No. 20; thence, northerly continuing along said apparent gradient boundary of the Rio Grande N 00° 01' 29" W, 441.45 feet to a point on the apparent gradient

boundary of the Rio Grande for corner No. 21; thence, northerly continuing along said apparent gradient boundary of the Rio Grande N 03° 29' 26" E, 405.03 feet to a point on the apparent gradient boundary of the Rio Grande for corner No. 22; thence, northerly continuing along said apparent gradient boundary of the Rio Grande N 08° 08' 02" E, 308.09 feet to a point on the apparent gradient boundary of the Rio Grande for corner No. 23; thence, northerly continuing along said apparent gradient boundary of the Rio Grande N 39° 03' 01" E, 218.95 feet to a point on the apparent gradient boundary line of the Rio Grande, for corner No. 24 and northwest corner of this tract, same being the southwest corner of a 60.77-acre tract of land; thence, easterly along the common line between the south line of said 60.77-acre tract and the northerly line hereof S 80° 31' 16" E, 1942.92 feet to a standard FWS aluminum monument set and stamped "Tract 630, Ref. No. 25, RPLS 3680" for corner No. 25, same being the southeast corner of said 60.77-acre tract, same being in the west line of Share 339 of said Porcion 66, same being in the west line of said 1,455.52-acre tract of land, and passing a standard FWS aluminum monument set for Reference at a distance of 38.95 feet and stamped "Tract 630, Ref. No. 24, RPLS 3680"; thence, southerly along the common line between the west line of said Share 339, Share 319, Share 227, Share 231, Share 230, Share 229, Share 518, Share 226, Share 225, Share 224, and said Share 96, same being the west line of said 1,455.52-acre tract and the east line hereof S 09° 28' 44" W, 3,845.12 feet and passing a 2-inch iron pipe found for the southwest corner of Share 339, same being the northwest corner of Share 319 at a distance of 315.48 feet, and being 0.46 feet easterly of and perpendicular to this line, and also passing a 1-1/2 inch iron pipe found for the southwest corner of Share 319, same being the northwest corner of Share 227 at a distance of 711.48 feet, and being 0.39 feet easterly of and perpendicular to this line, and also passing a 2-inch iron pipe found for the southwest corner of Share 231, same being the northwest corner of Share 230 at a distance of 1,320.71 feet, and being 0.09 feet easterly of and perpendicular to this line, to the point of beginning of the herein described tract and containing 254.42 acres of land.

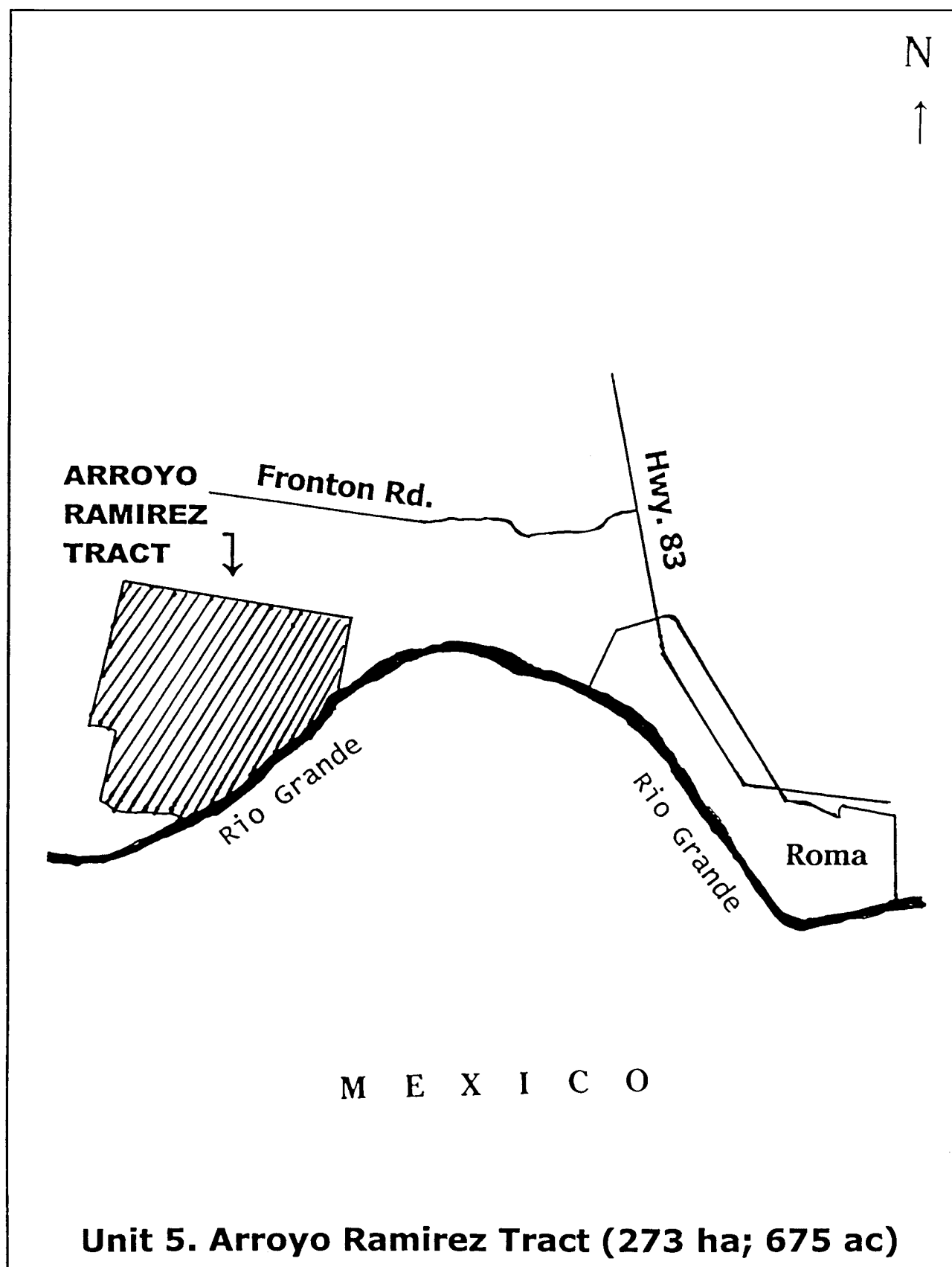


Unit 5, Arroyo Ramirez Tract (273 ha; 675 ac)—Formal surveying of the tract

has not been performed. Described as, "All of Share 79, Porcion 68, Abstract

191, Former Jurisdiction of Mier, Mexico, now Starr County, Texas, and

all of Share 166, Porcion 69, Abstract No. 160, Former Jurisdiction of Mier, Mexico, now Starr County, Texas. Description by approximated latitude/longitude coordinates (attached maps): Beginning at Latitude/Longitude 26° 24	00.9"N/099° 03' 23.9"W, westward to Latitude/Longitude 026° 24' 04.7"N/099° 03' 46.5"W, northward to Lat/Long 026° 24' 25.2"N/099° 03' 43.3" W, westward to Lat/Long 026° 24' 26.0" N/099° 03' 49.8" W, northward to Lat/Long	026° 25' 05.5" N/099° 03' 42.6" W, eastward to Lat/Long 026° 24' 56.6" N/099° 02' 40.3" W to the apparent gradient boundary of the Rio Grande River.



Unit 6, Los Negros Creek Tract (47 ha; 116 ac)—The following described tract

of land is located in Starr County, Texas, about 1 mile northwest of the

town of Roma, being 111.67 acres out of Share 13, Porcion 70, and being more

particularly described as follows:
Beginning at Cor. No. 1, an iron pin set for the northeast corner of Share No. 13 of Porcion No. 70 ; thence, along an old fence line and the dividing line between Share Nos. 13, 1-B and 12-A, S 09° 15' W, 2,694.00 feet to Cor. No. 2 an iron pin set on the Old High Bank of the Rio Grande and the southeast corner of this tract; thence leaving said fence line and along said Old High Bank with the

following two courses, N 63° 17' 27" W, 1,161.54 feet to Cor. No. 3 and N 87° 10' 00" W, 612.00 feet to Cor. No. 4, a set iron pin and the southwest corner of this tract; thence leaving said Old High Bank and along the dividing line of Tract 2 and 3 of said Share 13 and an old fence line with the following three courses, N 09° 15' E, 841.30 feet to Cor. No. 5, a set iron pin; N 80° 45' W, 397.50 feet to Cor. No. 6, a set iron pin; and N

09° 15' E, 1,572.60 feet to Cor. No. 7 & iron pin set for the northwest corner of this tract; thence leaving said dividing line and along the north line of this tract and an old fence line, S 80° 45' E, 2,113.70 feet to Cor. No. 1 and the true place of beginning, containing 111.67 acres of land bounded on the West, North, and East by lands of unknown owner and on the South by the Rio Grande.



Unit 7, La Puerta Tract (1,577 ha; 3,895 ac) (Segment 590). Note: All

bearings and distances are based on the Texas State Plane Coordinate System,

South Zone, as referenced by National Geodetic Survey (NGS) triangulation

station "Fordyce 2" and NGS triangulation station "Monument". Scale factor used was 0.99993949; theta angle used was $-00^{\circ} 06' 15''$. All areas are true ground measured areas. Beginning at corner No. 1, a standard U.S. Fish and Wildlife Service (FWS) aluminum monument stamped "TR 590 COR 1" set in the west boundary of Porcion 86, said point being at the southwest corner of the aforementioned 8,061-acre tract, and also being the northeast corner of a 160-acre tract recorded in volume 60, pages 47-48, Deed Records, Starr County, Texas, from which NGS triangulation station "Monument" bears N. $68^{\circ} 59' 27''$ W, 8,477.20 feet; thence, from corner No. 1, along the western boundary line of said 8,061-acre tract and Porcion 86, N $09^{\circ} 02' 27''$ E, 25,125.17 feet to corner No. 2, a standard FWS aluminum monument stamped "TR 590 COR 2", set at a fence corner from which NGS triangulation station "Monument" bears S $28^{\circ} 34' 49''$ W, 24,795.18 feet; said corner No. 2 also being the northwest corner of the herein described tract, thence, from corner No. 2, departing said western boundary line, with fence, S. $78^{\circ} 52' 36''$ E, 1,889.04 feet, to corner No. 3, a standard FWS aluminum monument stamped "TR 590 COR 3" set at fence corner; thence, from corner No. 3, continuing with fence, N $06^{\circ} 16' 07''$ E, 1,007.99 feet to corner No. 4, a standard FWS aluminum monument stamped "TR 590 COR 4" set at fence corner; thence, from corner No. 4, continuing with fence, S $78^{\circ} 42' 12''$ E, 2,691.33 feet to corner No. 5, a standard FWS aluminum monument stamped "TR 590 COR 5" set for angle; thence from corner No. 5, continuing with fence, S $72^{\circ} 35' 38''$ E, 2,000.57 feet to corner No. 6, a standard FWS aluminum monument stamped "TR 590 COR 6" set at fence corner, said point being a perpendicular distance of 20.20 feet from the eastern boundary line of Porcion 87, said point also being the Northeast corner of the herein described tract; thence, from corner No. 6, continuing with fence, S $09^{\circ} 01' 08''$ W, 10,831.38 feet to corner No. 7, a standard FWS aluminum monument stamped "TR 590 COR 7" set for angle adjacent to a found $\frac{5}{8}$ -inch iron pin; thence, from corner No. 7, continuing with fence, S $08^{\circ} 56' 57''$ W, 10,030.04 feet, to corner No. 8, a standard FWS aluminum monument stamped "TR 590 COR 8" set for angle point, said point being at the intersection of said fence with the east boundary line of Porcion 87; thence, from corner No. 8, departing said fence, along the east boundary line of Porcion 87, S $09^{\circ} 02' 27''$ W, 4,824.69

feet to corner No. 9, a standard FWS aluminum monument stamped "TR 590 COR 9" set for corner; thence, from corner No. 9, departing said east line, N $80^{\circ} 47' 09''$ W, 6,527.80 feet to the place of beginning and containing 3,844.674 acres.

(La Puerta 590a). Note: All bearings and distances are based on the Texas State Plane Coordinate System, South Zone, (NAD 27), as referenced by the National Geodetic Survey (NGS) Triangulation Station "Monument" having a coordinate value of N = 250,167.56; E = 1,912,489.81. Scale factor applied equals 0.99993949; theta angle equals $-00^{\circ} 06' 15''$. All areas are based on true ground measurements. Beginning at corner No. 1, a standard FWS aluminum monument stamped "TR 590A COR 1" set over a 2-inch iron pipe found in the west boundary line of Porcion 87, east boundary line of Porcion 86, at the northwest corner of said Lot 22, also being the northeast corner of a 2.83-acre tract as described by deed recorded in Volume 516, Page 62, Official Records, Starr County, Texas and being in the south boundary line of USA Tract (590) as described by deed recorded in Volume 608, Page 309, Official Records, Starr County, Texas said point having a coordinate value of N = 246,550.96; E = 1,923,962.74 and bearing S $72^{\circ} 30' 13''$ E, 12,029.47 feet from NGS Triangulation Station "Monument"; thence from corner No. 1, with south boundary line of said USA Tract (590), the north boundary line of said Lot 22, S $80^{\circ} 47' 09''$ E, 2,922.00 feet to corner No. 2, a standard FWS aluminum monument stamped "TR 590 COR 9" found at the southeast corner of said USA Tract (590), also being the northeast corner of said Lot 21, and being in the east boundary line of Porcion 87, west boundary line of Porcion 88 for the northeast corner of the herein-described tract of land; thence, from Corner No. 2, with the said east boundary line of Porcion 87, west boundary line of Porcion 88, and also being the east boundary line of said Lot 21, S $08^{\circ} 18' 30''$ W, 1,130.60 feet to corner No. 3, a standard FWS aluminum monument stamped "TR 590A COR 3" set in the existing north right-of-way line of U.S. Highway 83 with the intersection of said east boundary line of Porcion 87, west boundary line of Porcion 88 for the southeast corner of the herein described tract of land; thence, from corner No. 3, with and along the said existing north right-of-way line of U.S. Highway 83, N $66^{\circ} 14' 23''$ W, 18.20 feet to corner No. 4, a standard FWS aluminum monument stamped "TR 590A COR 4" set for an

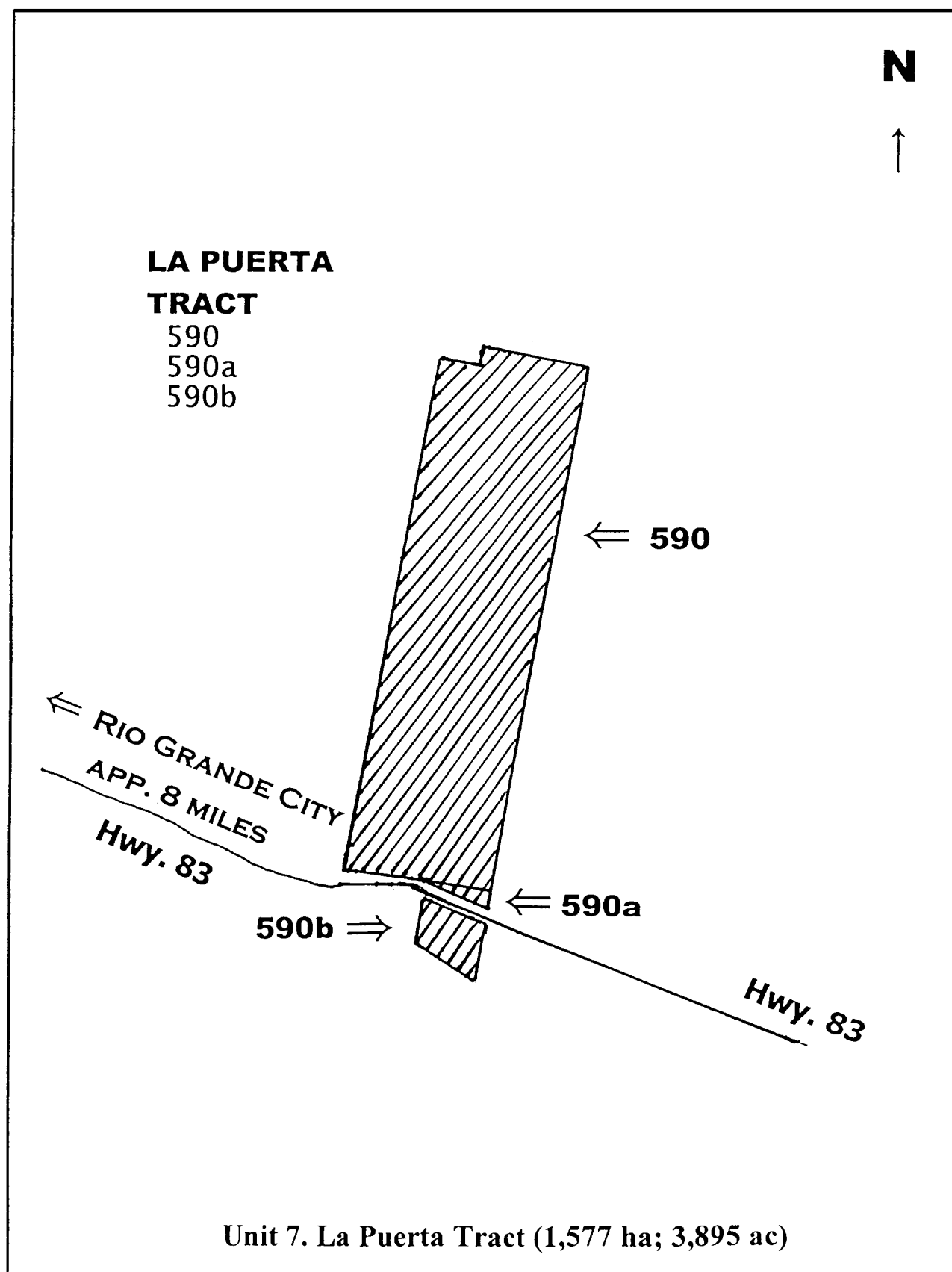
angle point; thence, from corner No. 4, continuing along said existing north right-of-way line, N $60^{\circ} 31' 23''$ W, 100.39 feet to corner No. 5, a standard FWS aluminum monument stamped "TR 590A COR 5" set for an angle point; thence, from corner 5, continuing along said existing north right-of-way line, N $66^{\circ} 14' 23''$ W, 499.97 feet to corner No. 6, a standard FWS aluminum monument stamped "TR 590A COR 6" set for an angle point; thence, from corner No. 6, continuing along said existing north right-of-way line, N $71^{\circ} 57' 23''$ W, 100.39 feet to a corner No. 7, a standard FWS aluminum monument stamped "TR 590A COR 7" set for an angle point; thence, from corner No. 7, continuing along said existing north right-of-way line, N $66^{\circ} 14' 14''$ W, 1,084.94 feet to corner No. 8, a $\frac{5}{8}$ -inch iron rod found at the intersection of the said existing north right-of-way line with the proposed north right-of-way line of U.S. Highway 83; thence, from corner No. 8, departing said existing north right-of-way line with and along the proposed north right-of-way line of U.S. Highway 83, N $60^{\circ} 43' 04''$ W, 200.90 feet to corner No. 9, a $\frac{5}{8}$ -inch iron rod found for an angle point; thence, from corner No. 9, continuing along said proposed north right-of-way line, N $69^{\circ} 54' 31''$ W, 300.83 feet to corner No. 10, a $\frac{5}{8}$ -inch iron rod found at the intersection of said proposed north right-of-way line with the existing north right-of-way line of U.S. Highway 83; thence, from corner No. 10, with the said existing north right-of-way line of U.S. Highway 83, N $66^{\circ} 16' 51''$ W, 399.70 feet to corner No. 11, a standard FWS aluminum monument stamped "TR 590A COR 11" set over a $\frac{1}{2}$ -inch iron rod found for an angle point; thence, from corner No. 11, continuing along said existing North right-of-way line, N $64^{\circ} 31' 54''$ W, 335.45 feet to corner No. 12, a standard FWS aluminum monument stamped "TR 590A COR 12" set at the intersection of said existing north right-of-way line with the west boundary line of Porcion 87, east boundary line of Porcion 86; thence, from corner No. 12, departing said existing north right-of-way line with the said west boundary line of Porcion 87, east boundary line of Porcion 86, N $08^{\circ} 56' 59''$ E, 357.90 feet to corner No. 1, the point of beginning and containing 50.033 acres of land.

(La Puerta Tract—Segment 590b). Note: All bearings and distances are based on the Texas State Plane Coordinate System, South Zone, (NAD 27), as referenced by the National Geodetic Survey (NGS) Triangulation Station "Monument" having a

coordinate value of N = 250,167.56' E = 1,912,489.81. Scale factor applied equals 0.00003040; theta angle equals $-00^{\circ} 06' 15''$. All areas are based on true ground measurements. Beginning at corner No. 1, a $\frac{5}{8}$ -inch iron rod found at the intersection of the west boundary line of Porcion 87, east boundary line of Porcion 86 with the proposed south right-of-way line of U.S. Highway 83, said point bears S $08^{\circ} 57' 33''$ W, 139.55 feet from a $\frac{5}{8}$ -inch iron rod found in the existing south right-of-way line of U.S. Highway 83, said point having a coordinate value of N = 245,880.85, E = 1,923,857.21 and bearing S $69^{\circ} 20' 18''$ E, 12,148.81 feet from NGS Triangulation Station "Monument"; thence, from corner No. 1, with the said proposed south right-of-way line, S $66^{\circ} 14' 23''$ E, 3,043.33 feet to corner No. 2,

a $\frac{5}{8}$ -inch iron rod found at the intersection of the east boundary line of Porcion 87, the west boundary line of Porcion 88 and the said proposed south right-of-way line, thence, from corner No. 2, with the said east boundary line of Porcion 87, west boundary line of Porcion 88, S $08^{\circ} 59' 29''$ W, 2,925.70 feet to corner No. 3, a standard FWS aluminum monument stamped "TR 590B COR 3" set over a $\frac{1}{2}$ -inch iron rod found at the intersection of said east boundary line of Porcion 87, west boundary line of Porcion 88 with the north right-of-way line of the Missouri-Pacific Railroad; thence, from corner No. 3, with the said north right-of-way line of the Missouri-Pacific Railroad, N $52^{\circ} 58' 07''$ W, 3,333.49 feet to corner No. 4, a standard FWS aluminum monument stamped "TR 590B COR 4"

set over a $\frac{3}{8}$ -inch iron rod found at the intersection of the said north right-of-way line with the said west boundary line of Porcion 87, the east boundary line of Porcion 86, said point also being the southeast corner of a 39.492-acre tract, thence from corner No. 4, with the said west boundary line of Porcion 87, east boundary line of Porcion 86, N $08^{\circ} 56' 13''$ E, 1,715.55 feet to corner No. 5, a standard FWS aluminum monument stamped "TR 590B COR 5" set over a $\frac{1}{2}$ -inch iron rod found at the southeast corner of a 2.0-acre tract, thence, from corner No. 5, continuing along said west boundary line of Porcion 87, east boundary line of Porcion 86, N $09^{\circ} 08' 05''$ E, 418.93 feet to corner No. 1, the point of beginning and containing 170.950 acres of land.



Unit 8-Private ranch site comprises 0.552 hectares (1.36 acres) within the

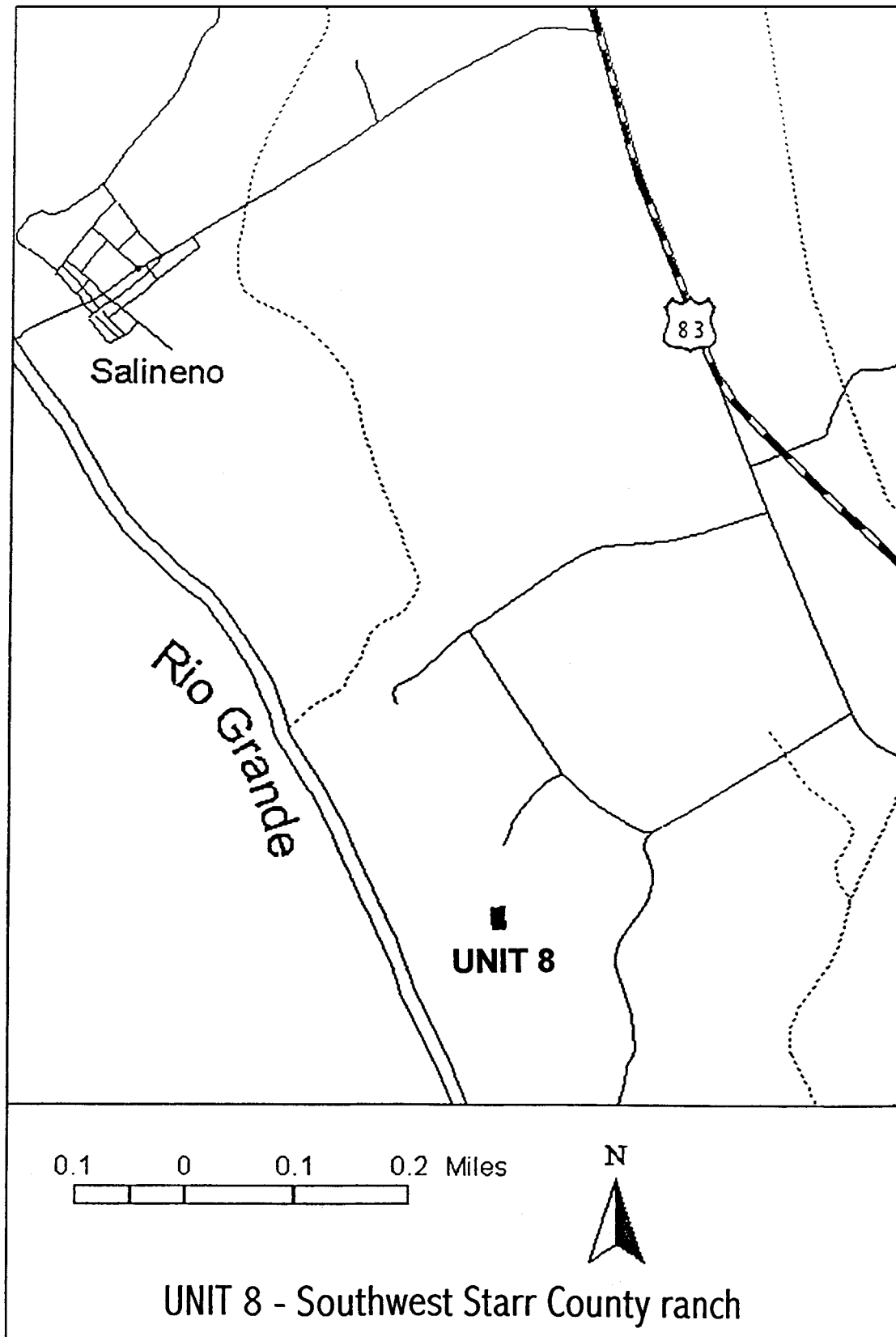
Universal Transverse Mercator, Zone 14 and begins at UTM 490706 E, 2929709

N; thence to 490729 E, 2929706 N; to 490748 E, 2929720 N; to 490762 E,

2929722 N; to 490767 E, 2929704 N; to
490767 E, 2929679 N; to 490769 E,
2929654 N; to 490770 E, 2929637 N; to

490770 E, 2929629 N; to 490760 E,
2929619 N; to 490743 E, 2929614 N; to
490732 E, 2929612 N; to 490720 E,

2929614 N; to 490709 E, 2929670 N; and
thence to point of beginning.



* * * * *

Dated: December 14, 2000.

Kenneth L. Smith,

*Acting Assistant Secretary for Fish and
Wildlife and Parks.*

[FR Doc. 00-32465 Filed 12-21-00; 8:45 am]

BILLING CODE 4310-55-C



Federal Register

**Friday,
December 22, 2000**

Part VII

Department of Housing and Urban Development

24 CFR Part 903

**Rule to Deconcentrate Poverty and
Promote Integration in Public Housing;
Final Rule**

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT**24 CFR Part 903**

[Docket No. FR-4420-F-10]

RIN 2577-AB89

Rule to Deconcentrate Poverty and Promote Integration in Public Housing

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

ACTION: Final rule.

SUMMARY: This final rule amends HUD's Public Housing Agency Plan regulations to fully reflect the importance of deconcentration by income and affirmatively furthering fair housing in a PHA's admission policy, consistent with the directive to achieve "One America," and to provide further direction to PHAs on the implementation of deconcentration and affirmatively furthering fair housing. This final rule follows publication of an April 17, 2000 proposed rule and takes into consideration public comment received on the proposed rule. The amendments made by this final rule concerning the deconcentration component of a PHA's admission policy are applicable to PHAs with fiscal years commencing on and after July 1, 2001.

DATES: January 22, 2001.

FOR FURTHER INFORMATION CONTACT: Rod Solomon, Deputy Assistant Secretary, Office of Policy, Program and Legislative Initiatives, Office of Public and Indian Housing, Department of Housing and Urban Development, 451 Seventh Street, SW, Room 4116, Washington, DC 20410; telephone (202) 708-0713 (this is not a toll-free number). Persons with hearing or speech impairments may access that number via TTY by calling the Federal Information Relay Service at (800) 877-8339.

SUPPLEMENTARY INFORMATION:**I. Background—April 17, 2000 Proposed Rule**

On April 17, 2000 (65 FR 20686), HUD published a rule that proposed to amend the deconcentration provisions of HUD's October 21, 1999 Public Housing Agency Plan final rule to achieve two purposes: (1) to assure that PHAs know what they must do to deconcentrate poverty in the public housing program; and (2) to assure that PHAs know what they must do to affirmatively further fair housing, as it relates to admissions to public housing.

The approach to deconcentrate property provided in HUD's April 17,

2000 proposed rule generally would have required public housing agencies (PHAs) to determine an overall average income for tenants in their family developments; characterize each building as higher income or lower income based on whether the average income in the building is above or below the overall average; and require that lower income families be admitted to higher income buildings and higher income families be admitted to lower income buildings.

II. Changes Made at the Final Rule Stage

As will be discussed in more detail below in Section IV of this preamble, HUD received many good suggestions and recommendations on modification of HUD's April 17, 2000 proposal and on alternative strategies and methods that could be utilized by PHAs to deconcentrate poverty in public housing. After careful consideration of all comments, this final rule adopts a deconcentration of poverty approach similar to that provided in the proposed rule, an approach that focuses on a determination of average income, but with some significant changes that increase flexibility for PHAs in addressing concentration of poverty specific to their communities.

The approach adopted at this final rule stage is as follows:

*Deconcentration of Poverty in Public Housing***Public Housing Developments Exempt from Deconcentration and Income Mixing Requirements**

After further consideration of how the deconcentration and income mixing provisions would apply to various types of public housing developments, HUD determined that certain developments should be exempt from the requirement to deconcentrate poverty because of the development's resident population, type or types of units, or number of units. Public housing developments that are exempt from application of the requirement to deconcentrate poverty and mix incomes are the following:

- Public housing developments operated by a PHA with fewer than 100 public housing units;
- Public housing developments operated by a PHA which house only elderly persons or persons with disabilities, or both;
- Public housing developments operated by a PHA that operates only one general occupancy, family public housing development;
- Public housing developments approved for demolition or for

conversion to tenant-based assistance; and

- Public housing developments which include public housing units operated in accordance with a HUD-approved mixed-finance plan using HOPE VI or public housing funds awarded before the effective date of this rule, provided that the PHA certifies (and includes reasons for the certification) as part of its PHA Plan (which may be accomplished either in the annual Plan submission or as a significant amendment to its PHA Plan) that exemption from the regulation is necessary to honor an existing contractual agreement or be consistent with a mixed finance plan, including provisions regarding the incomes of public housing residents to be admitted to that development, which has been developed in consultation with residents with rights to live at the affected development and other interested persons.

Analyzing Concentration of Poverty as Part of PHA Annual Planning Process.

The final rule clarifies that as part of a PHA's annual planning process, a PHA must submit with its Annual Plan an admissions policy designed to provide for deconcentration of poverty and income-mixing by bringing higher income tenants into lower income developments and lower income tenants into higher income developments. To comply with this statutory requirement, the rule provides that a PHA must conduct an analysis of the incomes of the families residing in public housing developments that are subject to the requirement to deconcentrate poverty. Public housing developments that are subject to the requirement to deconcentrate poverty are general occupancy, family public housing developments, excluding those developments, identified earlier in this preamble, as being exempt from the requirement, and are referred to as "covered developments."

Promoting Deconcentration of Poverty and Income Mixing in Developments with Concentration of Poverty. To meet the statutory requirement to develop an admissions policy designed to provide for deconcentration of poverty and income mixing in covered developments identified to have a concentration of poverty, the rule provides for a PHA to undertake the following steps.

Step 1—Determine Average Income of All Families Residing in All Covered Developments. For Step 1, a PHA shall determine the average income of all families residing in all covered developments. A PHA may use median incomes, instead of average income,

provided that the PHA includes a written explanation in its PHA Annual Plan justifying use of median incomes in the PHA's Annual Plan.

Step 2—Determine Average Income of Families in Each Covered Development. For Step 2, a PHA shall determine the average income of all families residing in each covered development. In determining average income for each development, a PHA has the option of adjusting its income analysis for unit size in accordance with procedures prescribed by HUD. The range of incomes calculated by a PHA using this method is referred to as the Established Income Range.

Step 3—Determining Which Developments Are Outside the Established Income Range. For Step 3, a PHA shall determine whether each of its covered developments falls above, within or below the Established Income Range, which is defined as those covered developments where the average income is between 85 percent and 115 percent (inclusive of those percentages) of the PHA-wide average for covered developments.

Step 4—Option to Provide Reasons Developments Are Outside of the Established Income Range. For Step 4, a PHA which has covered housing developments with average incomes outside the Established Income Range may explain or justify the development income profile for these developments as being consistent with and furthering both the goals of deconcentration as specified by the statute (bringing higher income tenants into lower income developments and vice versa) and the local goals and strategies contained in the PHA Annual Plan. Elements of explanations or justifications that may satisfy these requirements may include, but shall not be limited to the following:

(1) The covered development or developments are subject to consent decrees or other resident selection and admission plans mandated by court action;

(2) The covered development or developments are part of the PHA's programs, strategies or activities specifically authorized by statute, such as mixed-income or mixed-finance developments, homeownership programs, self-sufficiency strategies, or other strategies designed to deconcentrate poverty, promote income mixing in public housing, or increase the incomes of public housing residents, or the income mix is otherwise subject to individual review and approval by HUD;

(3) The covered development's or developments' size, location and/or configuration promote income

deconcentration, such as scattered site or small developments;

(4) The income characteristics of the covered development or developments are explained by other circumstances.

Step 5—Policy for Deconcentrating Poverty and Income Mixing in Developments Outside the Established Income Range. Where the income profile for a covered development is not sufficiently explained or justified in the PHA Annual Plan submission, the PHA shall include in its admissions policy specific strategies to promote deconcentration of poverty and income mixing in such covered development. Compliance with the statutory deconcentration requirement is not intended to impair or adversely affect the PHA's ability to exercise the authority to institute or implement other provisions in the statute such as local preferences or site-based waiting lists. Depending on local circumstances, a PHA's deconcentration strategy, included as part of the PHA's admissions policy (which may be undertaken in conjunction with other efforts such as efforts to increase self-sufficiency or current residents), may include but is not limited to one or more of the following:

(1) Providing incentives designed to encourage families with incomes below the Established Income Range to accept units in developments with incomes above the Established Income Range or the reverse situation—to encourage families with incomes above the Established Income Range to accept units in developments with incomes below the Established Income Range. Incentives include rent incentives, affirmative marketing plans, or added amenities;

(2) Targeting investment and capital improvements toward developments with an average income below the Established Income Range to encourage applicant families whose income is above the Established Income Range to accept units in those developments;

(3) A preference for admission of working families in developments below the Established Income Range;

(4) PHAs may skip a family on the waiting list to reach another family in an effort to further the goals of the PHA's deconcentration policy. Skipping to promote deconcentration shall not be considered an adverse action;

(5) Other strategies as permitted by statute and determined by the PHA in consultation with the residents and the community, through the PHA Annual Plan process, to be responsive to the local context and the PHA's strategic objectives.

Consistent with the Public Housing Reform Act, a PHA's admissions policy and any specific deconcentration strategies that are part of the admissions policy may not impose or require any specific income or racial quotas for any developments.

Determining Compliance with Deconcentration and Income Mixing Requirements. HUD shall consider a PHA to be in compliance with the deconcentration requirements if:

(1) The PHA's income analysis shows that the PHA has no general occupancy family developments to which the deconcentration requirements apply—that is the average incomes of the covered development are within the Established Income Range;

(2) The PHA has covered developments with average incomes above or below the Established Income Range and the PHA provides a sufficient explanation in its Annual Plan that supports that (1) the income mix is consistent with the requirements for deconcentration of poverty and income mixing, despite the categorization of the covered developments as above and below the Established Income Range, and (ii) the income mix of such development or developments is consistent with and furthers the locally determined goals of the PHA's Annual and Five Year Plans; or

(3) The PHA incorporates in its admissions policy, specific strategies the PHA will take that can be expected to promote deconcentration of poverty and income mixing in developments with average incomes outside of the Established Income Range and implements this admissions policy.

Fair Housing Regional Approaches and Voucher Housing Search Assistance

The final rule does not contain any changes from the proposed rule with respect to fair housing requirements. HUD, nevertheless, is taking this opportunity to emphasize the potential importance of regional approaches as PHAs pursue their responsibilities to affirmatively further fair housing, pursue deconcentration of poverty and attempt to offer their families maximum housing choices. In many urban areas, the limited jurisdictions of individual PHAs and these PHAs' individual waiting lists, forms and rules may limit to the extent to which families move across PHA lines even when there are work or school-related reasons to do so. PHAs can and should address these issues through measures such as providing lists of other public housing agencies and federally assisted housing in the metropolitan area and participating in regional counseling and

mobility efforts to assist voucher holders.

With respect to voucher holders, housing counseling and transportation assistance may help accomplish these goals and contribute to voucher holders' success. Such expenses are eligible voucher administrative fee expenses. In addition, HUD may allow PHAs to convert voucher program funds to administrative fees for this purpose where the PHA shows that these expenditures will not reduce the number of families that otherwise would receive and successfully use vouchers in that fiscal year. HUD will issue further guidance on this matter by January 15, 2001.

III. Implementation of Amended Deconcentration and Income Mixing Requirements

The amendments made by this final rule concerning the deconcentration component of a PHA's admission policy are applicable to PHAs with fiscal years commencing on and after July 1, 2001.

IV. Public Comments on the April 17, 2000 Proposed Rule

The public comment period for the April 17, 2000 proposed rule, closed on June 1, 2000, and at the end of the comment period, HUD received 193 public comments. In this section of the preamble, HUD provides a summary of the public comments and HUD's responses to issues or questions raised by the commenters. The heading "Comment" states the comment made by a commenter or commenters and the heading "Response" presents HUD's response to the issue or issues raised by the commenter or commenters.

Comment: The final rule should provide an exemption for high performing PHAs and certain standard performing PHAs. By exempting high performing and certain standard performing PHAs, HUD will be following the statutory and regulatory scheme of rewarding high performing and standard performing PHAs for managing all aspects of their programs, including deconcentration goals, in an effective manner.

Response. HUD's Public Housing Assessment System, the system by which PHAs are determined to be high performing, standard or troubled agencies, does not assess the concentration of poverty in PHA developments. Since this factor is not assessed as part of a PHA's management of a development, an exemption on this basis would not be appropriate.

Comment: The rule should focus on neighborhoods not just developments. HUD should concentrate on assisting

localities to improve their housing stock (housing production and neighborhood improvement) in entire neighborhoods, as incentives to attract higher-income people. The rule should not just focus on developments within a neighborhood.

Response. The Public Housing Reform Act, in amending the U.S. Housing Act of 1937, requires HUD to focus on income concentration in buildings and developments. Paragraph (3)(B)(i) of section 16 of the U.S. Housing Act of 1937, captioned "Prohibition of Concentration of Low-Income Families" provides in relevant part as follows:

A public housing agency shall submit with its annual public housing agency plan under section 5A an admissions policy designed to provide for deconcentration of poverty and income-mixing by bringing higher income tenants into lower income projects and lower income tenants into higher income projects. Although the Public Housing Reform Act requires a focus on income

concentration in public housing developments, HUD recognizes that efforts directed solely to the income makeup of a housing development may not succeed in achieving deconcentration. Under its HOPE VI Program, HUD has been successful in transforming entire neighborhoods, including the physical structures of public housing. Under HUD's mixed-finance programs, PHAs can leverage private capital with HUD funding and create mixed-income communities. Recently, HUD published its interim rule implementing a new Fair Market Rents policy that HUD anticipates will also assist in promoting deconcentration of poverty. HUD is working with its PHA partners to confront the problem of concentration of poverty through several approaches.

Comment: The goal of deconcentration is best achieved by emphasizing economic development activities. Rather than the approach advocated by the proposed rule, deconcentration is best achieved by emphasizing such approaches as mobility counseling, incentives for the development of regional strategies and the general support of economic development activities. Promoting integration regionally can help alleviate economic disparities among cities and their suburban counterparts.

Response: As noted in the response to the earlier comment, HUD agrees that concentration of poverty should be addressed through several approaches. With respect to the approaches recommended by the commenter, HUD has been working with its PHA partners to provide mobility counseling to applicants, landlord outreach and other

steps to increase housing choice in the voucher program and promote racial and economic deconcentration.

Comment: HUD's proposed rule contradicts the intent of the Public Housing Reform Act which is to deregulate public housing and give PHAs more flexibility. The intent of the Public Housing Reform Act is to give PHAs the flexibility to fashion independent and localized economic development strategies. HUD's April 17, 2000 proposed rule is in direct conflict with statutory intent by mandating a certain approach to deconcentration of poverty. Congress gave PHAs, not HUD, the discretion to adopt deconcentration strategies.

HUD Response. HUD has provided increased flexibility for PHAs to develop more localized strategies to deconcentrate poverty.

Comment: A deconcentration of poverty approach that focuses on buildings, not developments, conflicts with the statute, causes significant administrative difficulties, and adversely affects use of site-based waiting lists. The proposed rule conflicts with the statute because the proposed rule requires deconcentration on a building-by-building basis, while the statute requires deconcentration on a "project" basis. A building-by-building approach creates significant administrative difficulties. Managing individual waiting lists for each building will require PHAs to hire additional staff to track income information by building.

Response. HUD believes that in including an income analysis of buildings, HUD's April 17, 2000 proposed rule was not in conflict with the statute. The statute speaks in terms of buildings and developments. However, as discussed in Section II of this preamble, the rule was revised at the final rule stage to address only developments.

Comment: The deconcentration of income requirement appears to be in conflict with the income targeting requirement. There will most likely be conflicts in some situations between the income targeting requirement and the deconcentration requirement because income targeting dictates that a PHA target 40 percent of new admissions at the 30 percent or less area median income level, and the deconcentration policy may dictate that a higher income household be placed in a vacant unit. At the final rule stage, HUD must clarify how a PHA is to comply with both the deconcentration of income requirement and the income targeting requirement.

HUD Response. These two requirements were established to work

in support of one another. Congress established the deconcentration requirement to assure that the extremely low-income families targeted by PHAs under the income targeting requirement or otherwise admitted to public housing are not concentrated in one or more developments.

Comment: Skipping over lower income families to offer units to higher income families is unfair and would harm those persons that badly need affordable housing. Skipping may adversely affect applicants who have been on the waiting list a long time and desperately need affordable housing. Skipping will either have the effect of denying these longterm applicants housing or significantly delaying their admission to housing. Skipping may also have the effect of denying very low-income applicants the opportunities to participate in self-sufficiency programs offered by PHAs. Skipping should only be used where there is a significant difference in incomes among residents, which is not the case in the majority of public housing developments.

HUD Response. HUD understands the concerns about skipping but also recognizes that skipping may be needed by a PHA to achieve the objectives of deconcentration without adversely affecting the family or families skipped. Any local preference system involves skipping from the order otherwise required by a waiting list organized by date of application. In that respect, skipping to achieve deconcentration goals is the same.

Comment: HUD's proposed rule exceeds statutory authority by using race and income as measures of compliance with the deconcentration requirement. The provisions in the proposed rule regarding deconcentration of income are the only provisions derived from the Public Housing Reform Act. References in HUD's proposed rule to racial concentrations in public housing are subject to the provisions of the Fair Housing Act and various civil rights laws, not the Public Housing Reform Act. In view of the statute's permissive language regarding the measures a PHA may utilize to achieve deconcentration, as well as the specific statutory prohibition against income or racial quotas in the implementation of deconcentration policies, HUD's proposed rule, by including provisions to address racial concentration, is not consistent with the clear intent of the Public Housing Reform Act.

HUD Response. The provisions in the rule that address compliance with the deconcentration of poverty requirement of the Public Housing Reform Act are

limited to a discussion of income deconcentration. There is no discussion of racial concentration in these provisions. However, in the proposed rule and this final rule, HUD does remind PHAs of their responsibilities under the Fair Housing Act, and their responsibilities to affirmatively further fair housing, and provides guidance on how this obligation to affirmatively further fair housing may be carried out.

Implementation of the deconcentration of poverty requirement of the Public Housing Reform Act does not preclude HUD from including in this rule provisions or references to requirements imposed on PHAs by other statutes or regulations. Further, section 511(d)(15) of the Public Housing Reform Act (section 5A(d)(15) of the U.S. Housing Act), which establishes the PHA Plan, requires a PHA to certify that it will carry out its PHA Plan in conformity with the Fair Housing Act and other nondiscrimination statutes and that it will affirmatively further fair housing. This is the first time the PHAs have been required explicitly by statute to comply with the affirmatively further fair housing requirement. Part of the PHA's Annual Plan is the PHA's admissions policy. HUD's rule properly addresses compliance with the statutory deconcentration requirement and the statutory nondiscrimination requirements.

Comment: HUD should clarify that the provisions in the rule concerning affirmatively further fair housing are applicable to admissions. In the preamble to the proposed rule, HUD clearly states that the rule is issued to fully reflect the importance of deconcentration by income as well as the importance of affirmatively furthering fair housing in a PHA's admission policy. The "purpose" section of the rule, § 903.1, however, inadvertently omits reference to affirmatively furthering fair housing "in admissions." This section simply refers to a PHA's responsibility to affirmatively further fair housing. Because this section is directed towards a PHA's admissions policy, which includes a deconcentration policy, the phrase "in admissions" must follow the phrase "to affirmatively further fair housing" for clarity purposes.

HUD Response. HUD agrees with the commenter and has added this language to § 903.1.

Comment: The final rule should require specific deconcentration steps to affirmatively further fair housing. A PHA should be required to certify that it will use deconcentration steps that the PHA has specifically identified and other actions as appropriate in order to

meet its obligation to affirmatively further fair housing. The final rule should include specific performance criteria that will measure a PHA's progress toward achieving deconcentration and desegregation goals.

HUD Response. HUD believes that its provisions in the rule, which are unchanged from the proposed rule stage, strike the appropriate balance of clarifying a PHA's obligation to affirmatively further fair housing and providing guidance on how such obligation may be carried out by PHAs.

Comment: HUD oversteps its authority with the affirmatively furthering fair housing requirement imposed on PHAs in this rule. HUD's affirmatively furthering fair housing requirement seeks to create a new fair housing enforcement mechanism whereby HUD may challenge a PHA's civil rights certification if HUD believes that the PHA is not achieving the desired outcomes of its deconcentration policy. PHAs are committed to ensuring against discrimination in housing and guaranteeing equal opportunity and meaningful choice in carrying out their mission. PHAs have no legal duty to take undefined steps to affirmatively furthering fair housing.

HUD Response. As noted in an earlier response, the Public Housing Reform Act requires a PHA to include with its Annual Plan a certification that the PHA will carry out its PHA plan in conformity with certain nondiscrimination statutes, including the Fair Housing Act, and will affirmatively further fair housing. In view of this certification, which can be challenged, HUD has an obligation to provide PHAs with guidance on the types of actions that will be recognized as actions to affirmatively further fair housing.

Comment: PHAs should not be penalized if racial concentration in their developments mirror that of the surrounding community. PHAs should not be found to have discriminated on the basis of race if the racial and ethnic characteristics of the PHA's development mirror that of the surrounding community. Before HUD challenges a civil rights certification, HUD should have documented evidence that a PHA is not in compliance with its certification and representations to HUD.

HUD Response. To determine if PHAs are complying with their obligation to affirmatively further fair housing, HUD does not assess a PHA on the racial makeup of its developments. A PHA is assessed by the actions taken to offer housing choice or incentives that make

a particular development more attractive, or to engage in marketing efforts that are designed to reduce racial concentration, to name a few examples from the rule. A HUD challenge to a civil rights certification will be based on documented evidence that a PHA is not affirmatively furthering fair housing or the PHA is not in compliance with civil rights statutes, contrary to what the PHA has certified.

Comment: HUD should not implement any deconcentration requirement until the Multifamily Tenants Characteristics System (MTCS) can provide accurate information on average tenant income for each family development. Using MTCS data to compare each PHA development with the corresponding authority-wide average would assist in the determination of a standard income deviation from the overall norm. Developments within the standard deviation would not be subject to deconcentration efforts. However, using current MTCS data to determine poverty concentrations would not work because MTCS does not separate data when a PHA has, for instance, an elderly high-rise and a townhouse development under the same HUD project number. MTCS does not aggregate data if, for instance, townhouses have three different HUD project numbers because they were built under three different development budgets. There is also a problem with MTCS in that income amounts shown on MTCS reports reflect only income used in rent calculations, exclusive of income disregard as new earned income, non-reportable income or earnings excluded under Jobs-Plus.

HUD Response. The analysis to be done by PHAs to be in compliance with the statutory requirement to deconcentrate poverty is not dependent upon the MTCS data system, but HUD recognizes that this system would facilitate the PHA's analysis. HUD has worked to correct problems with MTCS and is continuing to work with PHAs to increase the level of reporting.

Comment: HUD's proposal to deconcentrate poverty without modifications will not achieve the desired result. There are other approaches to deconcentration that can be implemented more simply and successfully than HUD's approach. The comments that HUD received on its proposal to deconcentrate poverty ranged from a request to withdraw the entire proposal to proceeding with the proposal as is. The majority of the comments, however, stated that HUD's proposal was complicated and would not achieve deconcentration of poverty in concentrated areas. Many

commenters offered suggestions on how HUD's proposal could be improved and recommended certain modifications to the proposal. Other commenters suggested alternative methods to deconcentrate poverty. All the suggestions and recommendations were carefully considered and Section II of this preamble reflects the recommendations that were adopted at this final rule stage.

In this preamble, HUD does not provide the details of all recommendations for changes to its own proposal or the details of all the alternative deconcentration methods that were suggested, but the following provides an overview of the comments and critiques of HUD's proposal to deconcentrate poverty, as provided in the April 17, 2000 proposed rule, as well as an overview of alternative deconcentration approaches (HUD recognizes that there is overlap in these two categories).

Overview of comments on HUD's proposal to deconcentrate poverty. The deconcentration of poverty approach proposed by HUD is complex and will be difficult to administer. HUD's proposal does not include self-sufficiency strategies which are crucial to improving the income of residents and thereby helping to promote deconcentration. HUD's proposal is too vague and imprecise to achieve the objectives of deconcentration, and may in fact cause a higher concentration of poverty. HUD's proposal will result in longer waiting lists for housing. HUD's proposal does not take into account that some housing authorities do not have large waiting lists from which to select tenants. HUD's proposal does not focus sufficiently on incentives; the statute encourages incentives to achieve deconcentration. HUD's proposal prevents PHAs from fully implementing local preferences as provided by the Public Housing Reform Act. HUD's proposal has the effect of reinstituting Federal preferences that were eliminated by the Public Housing Reform Act. HUD's proposal exceeds statutory authority by requiring PHAs to use "skipping" for the purpose of deconcentration while the Public Housing Reform Act allows, but does not require, PHAs to use skipping. HUD's proposal will have the effect of creating income and racial quotas, which is prohibited by the Public Housing Reform Act. HUD's proposal will adversely affect PHAs' Family Self-Sufficiency programs where certain developments have been designated for occupancy by FSS families only. HUD's proposal will undermine HOPE VI programs because most of all the HOPE

VI buildings would be classified as above income and therefore target only below-average income families. HUD's proposal will only result in the labeling of developments and income steering that HUD has worked so hard in the past to eliminate. HUD's proposal provides no guidance concerning the length of time that deconcentration procedures must be followed; in other words, the proposal does not specify how many offers to higher income families must be made before a unit can be offered to a lower income family. Without clear direction in the rule, units could remain vacant for months. Additionally, the delays in filling units could negatively affect a PHA's PHAS score. HUD's deconcentration approach does not address the issue of the proximity of buildings in public housing developments; deconcentration will not be achieved if the buildings are in close proximity to one another. HUD's deconcentration approach does not address the issue of buildings that are located in concentrated poverty neighborhoods. HUD's definition of "building" as one or more contiguous structures containing at least 8 public housing units is not clear and requires further elaboration (e.g., what is meant by contiguous; does building mean 8 units in total or 8 units in each structure). HUD's deconcentration approach does not take into consideration the impact on elderly persons or persons with disabilities. HUD's definition of building presents too small a structure for deconcentration and would create an administrative burden for PHAs. How does a PHA address deconcentration in the context of a situation where the majority of the PHA's residents are low income elderly persons or persons with disabilities. Generally, elderly persons, as a result of social security income, are higher income tenants, buildings occupied predominately by the elderly will be classified as higher income, and elderly persons on the waiting list may be skipped over for units in an elderly building. HUD's deconcentration approach is costly. The delay in filling vacancies which will result if this approach is implemented will adversely affect a PHA's revenues. HUD needs to clarify what it means by higher income families. HUD's proposal will have a detrimental impact on PHA's voluntary transfer policies. HUD's proposal does not take into account the source of a family's income. The rule should distinguish between earned income and assistance. HUD's proposal conflicts with the policy goals of HOPE VI and mixed finance developments.

Overview of comments proposing alternative approaches to deconcentrate poverty. HUD should adhere to the deconcentration approach that was in the final PHA Plan rule published on October 21, 1999. The October 21, 1999 final rule provided a reasonable approach and adequate guidance concerning deconcentration and income mixing by PHAs. The appropriate deconcentration approach is a PHA specific approach where each PHA establishes its own goals and specific plans to reach those goals. It is virtually impossible for HUD to develop a deconcentration policy that will address all of the variables found in all PHAs' jurisdictions. A deconcentration policy must be left to the PHAs to develop locally. Deconcentration methods should include incentives such as flat rents and ceiling rents, lowering the percentage of adjusted income that goes for rent from 30 percent to 25 percent and income deductions (e.g., for transportation, uniforms, etc.) for working families. A suitable deconcentration approach would be one that provides for PHAs to set separate goals for three categories of developments: (1) developments in poverty areas; (2) developments well outside of poverty areas, and (3) developments that fall in between. The deconcentration approach that HUD noted in its April 17, 2000 proposed rule was an approach that HUD considered but did not adopt, is preferable to the approach that HUD proposed in the April 17, 2000 rule. The second approach (not adopted) allows PHAs to concentrate limited resources on areas with the greatest need of deconcentration. The final rule should offer an option of deconcentration methods from which PHAs may choose and also allow PHAs to design their own method. Any deconcentration approach should exempt tenant assignment and selection plans that are required by court order. Deconcentration should be implemented through a "metropolitan" directive issued to PHAs and that focuses on creating affordable rental housing opportunities in entire metropolitan areas. Properties located in high poverty neighborhoods that have yet to undergo revitalization should be exempted from the requirement to deconcentrate pending a site or neighborhood redevelopment plan. Deconcentration methods should focus on strategies to improve the incomes of current tenants, such as targeted workforce development programs or more vigorous implementation of

section 3.¹ Any deconcentration approach should exempt developments that are occupied by elderly persons or persons with disabilities. To include special populations as part of a deconcentration strategy will negatively affect the ability of a PHA to implement a designated housing plan. An effective deconcentration approach is one that encourages and promotes the development of public housing in non-concentrated areas. Small and medium-sized developments should be exempt from the deconcentration requirement. Small PHAs (PHAs with less than 250 units) should be exempt from the deconcentration requirement; the purpose of deconcentration is to address the poverty concentration problems of large urban housing authorities. PHAs with small scattered sites (less than 50 units per development) should be exempt from the deconcentration requirement. All scattered site developments should be exempt from the deconcentration requirement because the very nature of a scattered site program is to achieve deconcentration. PHAs with one development and one building should be exempt from the deconcentration requirement. For developments located in Empowerment Zones or in census tracts that qualify for Empowerment Zone status, a PHA should be allowed to skip over lower income applicants to reach higher income applicants at any and all complexes located in these areas. Moving to Work and the Jobs Plus demonstration programs should be exempt from the requirement to deconcentrate poverty because these programs are already designed to promote increased diversity of income among residents. The term "general occupancy public housing development" and "general occupancy development building" when used in reference to the determination of average income, should be defined to include buildings or developments with family units and should exclude buildings or developments that are serving exclusively the elderly, persons with disabilities or a combination of the elderly and persons with disabilities. An effective deconcentration approach should address adjustments in average income by family size and number of bedrooms. Families residing in

¹ Section 3 refers to section 3 of the Housing and Urban Development Act of 1968 which requires, among other things, recipients of certain HUD assistance, including public housing assistance, to ensure that, to the greatest extent feasible, training, employment and other economic opportunities will be directed to low- and very low-income persons, particularly those who are recipients of government assistance for housing.

developments approved for demolition or conversion for tenant-based assistance should be excluded from the average-income calculation. A deconcentration approach should not be dependent solely upon an analysis of average incomes, but rather PHAs should be allowed to use median incomes, census tract incomes, average incomes with standard deviations or other income analyses. An effective deconcentration approach should be based on thresholds that are a certain percentage of median income and significantly different from a PHA's average income (e.g., 25 percent or 50 percent) so that income mixing can actually be achieved. Average income should be determined by site, not by development or building. There needs to be a middle tier of buildings that are neither higher nor lower income to which a deconcentration policy would not apply. A PHA's deconcentration policy should consist of a certification by the PHA that it has complied with the 40 percent/30 percent income targeting requirement.

HUD Response. Again, HUD appreciates all the suggestions and recommendations on how deconcentration of poverty may be achieved in public housing. Section II of this preamble, which describes the changes made at the final rule stage reflects the suggestions and recommendations offered by the commenters that HUD has adopted.

HUD is retaining the requirement that the PHAs determine the average incomes of all families residing the public housing developments that are not exempt and subject to the deconcentration of poverty requirement (the covered developments). To design a policy, as required by the Public Housing Reform Act, that requires bringing higher income tenants in to lower income developments and lower income tenants into higher income developments, necessitates an analysis by the PHAs of the income characteristics of their developments. The final rule, however, provides for exempted middle tiers of developments and for various other exceptions. The final rule also allows PHAs more flexibility in developing specific actions for covered developments that the PHA believes will achieve deconcentration of poverty for those developments.

Comment: Skipping over families on the waiting list appears to violate Fair Housing Act requirements. Because of the correlation between income and race in most of the country's developments, the impact of this rule would be felt disproportionately by minority households which will be denied

housing for no other reason than that the available units are in lower income buildings.

HUD Response. Skipping is permitted by both the Public Housing Reform Act and this rule; skipping is not in violation of Fair Housing Act requirements provided it is uniformly applied by the PHA. If skipping is not applied in an objective and uniform manner by a PHA, then the PHA may be vulnerable to a charge of violation of Fair Housing Act requirements. The circumstances under which a PHA will skip a family to achieve deconcentration of poverty should be specified in the PHA's deconcentration policy. Skipping is permitted but not required and will occur less frequently because of the additional flexibility in the final rule.

Comment: Deconcentration can be achieved by HUD identifying problem developments and requiring corrective action. MTCS data contains all relevant information for HUD to comply with the statutory requirement that the Secretary review the income and occupancy characteristics of public housing developments. Once it is determined that there are violations then the Secretary has the authority to require appropriate corrective action. This is the best strategy to address the perceived income concentration problem.

HUD Response. The statutory requirement to deconcentrate poverty does not impose an obligation only on HUD to review the income and occupancy characteristics of public housing developments. The statute requires a PHA to include as part of the PHA's Annual Plan submission an admissions policy designed to provide for deconcentration of poverty and income-mixing by bringing higher income tenants into lower income developments and vice versa. The statute envisions a preventive approach, not simply a corrective approach. The purpose of HUD's rule is to help PHAs achieve a successful preventive approach to poverty concentration. Moreover, under this final rule only those general occupancy developments with average incomes significantly above or below the PHA average must be addressed.

Comment: HUD's final rule should clarify that it does not apply to State Housing Finance Agencies (HFAs) and other similar state housing agencies. The rule is ambiguous as to whether it applies to state HFAs. The rule should be rewritten to provide a clear exemption for statewide agencies, such as state HFAs.

HUD Response. The deconcentration provisions do not apply to statewide agencies except to the extent that they

are operating public housing; they apply to all public housing except for those developments exempted by the deconcentration provisions. In all the rulemaking stages of the PHA Plan rule, this is the first time this question has been raised. HUD believes that this is clear, and no additional statement is needed in the rule.

Comment: Is deconcentration applicable to a public housing development undergoing modernization? HUD needs to clarify at the final rule stage whether the requirement to deconcentrate is applicable to a development undergoing modernization which requires the residents to be relocated to other developments.

HUD Response. A PHA's deconcentration policy is not applicable to involuntary transfers among developments as this final rule makes clear.

Comment: HUD should clarify that a PHA's deconcentration policy applies to all mixed-finance developments/buildings that receive HUD operating subsidy. HUD should provide at the final rule stage that the deconcentration requirement does not apply to existing mixed-finance where investors, developers and PHAs have already entered into HUD-approved contracts which require the income mix in the developments, and should not apply to future developments. The following highlights the differences among commenters on the applicability of the deconcentration requirement to mixed-finance developments:

The final rule should make clear that it applies to any mixed finance development or building or unit that receives HUD operating subsidy. It should not matter that the development is owned or managed by an entity other than the PHA. These developments should not be exempt from the requirement to deconcentrate poverty.

The final rule must exempt, at a minimum, existing mixed-finance developments. PHAs and developers contractually obligate themselves to maintain specified income tiers and follow a prescribed admissions and occupancy policy in operating these properties. HOPE VI/mixed finance transactions (both closed and future transactions) should be specifically excluded from the deconcentration rule. HUD is already successful in achieving income mixing in HOPE VI and mixed finance units, and application of the deconcentration requirement will reduce not increase the success rates of these types of units in achieving income mixing.

HUD Response. The final rule exempts public housing units operated in accordance with a HUD-approved mixed finance plan using HOPE VI or public housing funds awarded before the effective date of this final rule, provided that the PHA certifies (and includes reasons for the certification) as part of its PHA Plan (which may be accomplished either in the annual Plan submission or as a significant amendment to its PHA Plan) that exemption from the regulation is necessary to honor an existing contractual agreement or be consistent with a mixed finance plan, including provisions regarding the incomes of public housing residents to be admitted to that development, which has been developed in consultation with residents with rights to live at the affected development and other interested persons. HUD recognizes that for many of these developments, as commenters have indicated, PHAs are contractually obligated to maintain specified income tiers, or their HOPE VI funding proposal assumed such tiers.

HUD, however, is not granting a blanket exemption for all mixed-finance or HOPE VI developments. As noted in the October 21, 1999 final rule, in response to a similar comment received under that rulemaking, the Public Housing Reform Act does not limit applicability of the deconcentration requirement to traditional public housing. (See 64 FR 56854, middle column.)

Comment: Data by development and building should be collected on an annual basis to determine effectiveness of income growth policies. HUD's rule should require yearly collection of data by development and by building even for developments or buildings that may be exempt from the deconcentration requirement.

HUD Response. The PHA's deconcentration policy must be included each year in the PHA's Annual Plan submission. The required steps for deconcentrating poverty, as provided in the rule, include a determination of the average income of all families residing in covered developments and an assessment of which developments fall outside the Established Income Range. At the final rule stage, HUD has limited the PHA's average income determination to developments, and not buildings. After consideration of comments, HUD acknowledges the concerns that an analysis of income by building may result in increased administrative burden for PHAs without a corresponding increased benefit in promoting deconcentration of poverty. HUD declines the commenter's

suggestion to require an income determination for developments that are not subject to deconcentration.

Comment: The incomes of public housing residents constantly fluctuate which makes annual determinations of average income unreliable. PHAs may experience significant differences in income levels from year to year because residents initiate and terminate employment fairly frequently. PHAs should have the option of recalculating the average development incomes more often than once a year if they so choose. Because income fluctuates constantly, does compliance with the deconcentration requirement mean that families would have to move if the "higher income building" in which they reside decreases (i.e., becomes a low income building) or vice-versa?

HUD Response. HUD believes that the additional flexibility provided by this final rule addresses this concern.

Comment: A family's return to a development should not be limited to a right of return to the same site. Some HOPE VI proposals include scattered sites which may include the original site that is being revitalized along with other sites or may include entirely new sites. The deconcentration policy should not interfere with any PHA commitment to families who have the right of return to this type of HOPE VI development or other development.

HUD Response. Neither the statutory requirement to deconcentrate poverty nor the requirements of this rule interfere with any commitments made by a PHA to a family with respect to a family's right to return to a site, including new sites, following revitalization.

Comment: The rule needs to address more fully unit refusal by a family and whether removing a family from a waiting list for refusal to accept a unit constitutes an adverse action against the family. Removing a family from the waiting list for reasons due entirely or in part to the family's refusal to accept a deconcentration offer of a unit constitutes an adverse action against the family. The rule needs to clearly provide that a family cannot be removed for refusing a deconcentration offer of a unit.

HUD Response. Removing a family from the waiting list for the family's refusal to accept a unit offered as part of the PHA's strategy to deconcentrate poverty is an adverse action prohibited by the statute. A family cannot be removed from the waiting list for this reason. However, a PHA may uniformly limit the number of offers to each applicant.

Comment: The proposed rule violates the statutory requirement that HUD finalize the agency plan rule only after considering comments presented through an enhanced rulemaking process. Congress mandated that the final rule implement the PHA Agency Plans be subject to an enhanced rulemaking process that would allow for more public input into the process. HUD was required to convene two public forums at which those making recommendations could respond to concerns regarding the proposed agency plan rule prior to implementation. While HUD conducted such forums, the deconcentration provisions in the April 17, 2000 proposed rule were not included in the prior rule and were not the subject of discussion at these forums.

HUD Response. HUD complied with the statutory mandate to undertake enhanced rulemaking before implementation of the PHA Plan final rule, which was issued on October 21, 1999. This enhanced rulemaking covered all aspects of the PHA Plan. Moreover, the statute does not require HUD to undertake enhanced rulemaking for every amendment or change HUD subsequently makes to the PHA Plan rule. The April 17, 2000 proposed rule was limited to clarifying a PHA's requirements to deconcentrate by income and affirmatively furthering fair housing, and adding language that allowed for HUD to further simplify the PHA Plan submission for PHAs permitted to submit a streamlined plan. (HUD already has implemented the streamlining amendment through a final rule published on August 14, 2000 (65 FR 49484).) Although HUD republished the entire PHA Plan rule on April 17, 2000, with the exception of these two areas, no substantive changes were made to the rule. The rule was republished for the convenience of the reader, and to make plain language changes.

Comment: The rule is not in compliance with the Regulatory Flexibility Act, Unfunded Mandates Reform Act and the Executive Order on Federalism. HUD's proposed rule would have a significant economic impact on a substantial number of small entities and would impose an unfunded federal mandate and substantial direct compliance costs on local jurisdictions. Compliance with the deconcentration requirement will require software modifications and additional data entry on a building-by-building analysis, and the creation and implementation of new procedure manuals and these actions will have a significant economic impact on housing authorities.

HUD Response. HUD disagrees with the commenters that the proposed rule would have imposed a significant economic impact on a substantial number of small entities. HUD, however, appreciates these comments, and specifically solicited comments about the impact on small entities under its Regulatory Flexibility Act statement on whether PHAs believed the proposed rule would have a significant economic impact on small entities. HUD believes that the changes made in the rule at the final rule stage minimize concerns raised by the commenters. The rule is not in violation of the Executive Order on Federalism or Unfunded Mandates. Public housing is federally funded and the deconcentration requirement established by Congress is to ensure that every effort is made to address concentration of poverty in federally funded housing.

V. Findings and Certifications

Paperwork Reduction Act Statement

The information collection requirements contained in the PHA Plan were previously approved by the Office of Management and Budget in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520), at the time of publication of the PHA Plan final rule on October 21, 1999, and assigned OMB control number 2577–0226. This final rule published today only makes changes to the deconcentration component of the PHA Annual Plan's statement of the PHA's deconcentration and other policies that govern eligibility, selection and admissions. A modification to HUD's existing and approved information collection requirements for this rule has been submitted to OMB for review and approval under the Paperwork Reduction Act. The modification, when approved, will be announced through separate notice. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection displays a valid control number.

Regulatory Flexibility Act

The Secretary, in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), has reviewed and approved this rule, and in so doing certifies that this rule does not have a significant economic impact on a substantial number of small entities. This rule amends HUD's Public Housing Agency Plan regulations to fully reflect the importance of deconcentration by income in public housing and the importance of affirmatively furthering

fair housing. This rule does not create an undue burden on small PHAs. This rule exempts several types of developments, including developments with fewer than 100 units, from the requirement to deconcentrate poverty in public housing.

Executive Order 13132, Federalism

Executive Order 13132 (entitled "Federalism") prohibits, to the extent practicable and permitted by law, an agency from promulgating a regulation that has federalism implications and either imposes substantial direct compliance costs on State and local governments and is not required by statute, or preempts State law, unless the relevant requirements of section 6 of the Executive Order are met. This rule does not have federalism implications and does not impose substantial direct compliance costs on State and local governments or preempt State law within the meaning of the Executive Order.

Environmental Impact

The Finding of No Significant Impact with respect to the environment was prepared during the interim rulemaking stage of the Public Housing Agency Plan regulations in accordance with HUD regulations in 24 CFR part 50 that implement section 102(2)(C) of the National Environmental Policy Act of 1969 (42 U.S.C. 4223). That Finding remains applicable to this rule, and is available for public inspection between 7:30 a.m. and 5:30 p.m. weekdays in the Office of the Rules Docket Clerk, Office of General Counsel, Room 10276, Department of Housing and Urban Development, 451 7th Street, SW, Washington, DC 20410.

Regulatory Review

The Office of Management and Budget (OMB) reviewed this rule under Executive Order 12866, *Regulatory Planning and Review*. OMB determined that this rule is a "significant regulatory action," as defined in section 3(f) of the Order (although not economically significant, as provided in section 3(f)(1) of the Order). Any changes made to the final rule after its submission to OMB are identified in the docket file, which is available for public inspection in the office of the Department's Office of General Counsel, Regulations Division, Room 10276, 451 Seventh Street, SW, Washington, DC 20410-0500.

Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4; approved March 22, 1995) (UMRA) establishes requirements for Federal

agencies to assess the effects of their regulatory actions on State, local, and tribal governments, and on the private sector. This rule does not impose any Federal mandates on any State, local, or tribal governments, or on the private sector, within the meaning of the UMRA.

Catalog of Federal Domestic Assistance

The Catalog of Federal Domestic Assistance numbers applicable to the programs affected by this rule are 14.850 and 14.855.

List of Subjects in 24 CFR Part 903

Administrative practice and procedure, Public housing, Reporting and recordkeeping requirements

For the reasons stated in the preamble, HUD revises part 903 of title 24 of the Code of Federal Regulations to read as follows:

PART 903—PUBLIC HOUSING AGENCY PLANS

Sec.

Subpart A—Deconcentration of Poverty and Fair Housing in Program Admissions

903.1 What is the purpose of this subpart?

903.2 With respect to admissions, what must a PHA do to deconcentrate poverty in its developments and comply with fair housing requirements?

Subpart B—PHA Plans

903.3 What is the purpose of this subpart?

903.4 What are the public housing agency plans?

903.5 When must a PHA submit the plans to HUD?

903.6 What information must a PHA provide in the 5-Year Plan?

903.7 What information must a PHA provide in the Annual Plan?

903.9 May HUD request additional information in the Annual Plan of a troubled PHA?

903.11 Are certain PHAs eligible to submit a streamlined Annual Plan?

903.13 What is a Resident Advisory Board and what is its role in development of the Annual Plan?

903.15 What is the relationship of the public housing agency plans to the Consolidated Plan?

903.17 What is the process for obtaining public comment on the plans?

903.19 When is the 5-Year Plan or Annual Plan ready for submission to HUD?

903.21 May the PHA amend or modify a plan?

903.23 What is the process by which HUD reviews, approves, or disapproves an Annual Plan?

903.25 How does HUD ensure PHA compliance with its plans?

Authority. 42 U.S.C. 1437c; 42 U.S.C. 3535(d).

Subpart A—Deconcentration of Poverty and Fair Housing in Program Admissions

§ 903.1 What is the purpose of this subpart?

The purpose of this subpart is to specify the process which a Public Housing Agency, as part of its annual planning process and development of an admissions policy, must follow in order to develop and apply a policy that provides for deconcentration of poverty and income mixing in certain public housing developments and to affirmatively further fair housing in admissions.

References to the "1937 Act" in this part refer to the U.S. Housing Act of 1937 (42 U.S.C. 1437 *et seq.*)

§ 903.2 With respect to admissions, what must a PHA do to deconcentrate poverty in its developments and comply with fair housing requirements?

(a) *General.* The PHA's admission policy includes the PHA's policy designed to promote deconcentration of poverty and income mixing in accordance with section 16(a)(3)(B) of the 1937 Act (42 U.S.C. 1437n), which is submitted to HUD as part of the PHA Annual Plan process. Deconcentration of poverty and income mixing is promoted by a policy that provides for bringing higher income tenants into lower income developments and lower income tenants into higher income developments.

(1) The provisions of this section apply to applicants to and residents seeking voluntary transfers within covered public housing developments ("covered developments" as specified in paragraph (b) of this section).

(2) The statutory requirement to design a policy to provide for deconcentration and income mixing is not to be construed to impose or require any specific income or racial quotas for any development or developments.

(b) *Applicability of deconcentration of poverty and income mixing requirements.*

(1) *Developments subject to deconcentration of poverty and income mixing requirements.* The deconcentration requirements of this subpart apply to general occupancy, family public housing developments, excluding those developments listed in paragraph (b)(2) of this section. Developments to which this subpart is applicable are referred to as "covered developments".

(2) *Developments not subject to deconcentration of poverty and income mixing requirements.* This subpart does not apply to the following public housing developments:

(i) Public housing developments operated by a PHA with fewer than 100 public housing units;

(ii) Public housing developments operated by a PHA which house only elderly persons or persons with disabilities, or both;

(iii) Public housing developments operated by a PHA which consist of only one general occupancy, family public housing development;

(iv) Public housing developments approved for demolition or for conversion to tenant-based assistance; and

(v) Public housing developments which include public housing units operated in accordance with a HUD-approved mixed-finance plan using HOPE VI or public housing funds awarded before the effective date of this rule, provided that the PHA certifies (and includes reasons for the certification) as part of its PHA Plan (which may be accomplished either in the annual Plan submission or as a significant amendment to its PHA Plan) that exemption from the regulation is necessary to honor an existing contractual agreement or be consistent with a mixed finance plan, including provisions regarding the incomes of public housing residents to be admitted to that development, which has been developed in consultation with residents with rights to live at the affected development and other interested persons.

(c) *Deconcentration of poverty and income mixing.*

(1) *Steps for implementation.* To implement the statutory requirement to deconcentrate poverty and provide for income mixing in covered public housing developments, a PHA must comply with the following steps:

(i) *Step 1.* A PHA shall determine the average income of all families residing in all the PHA's covered developments. A PHA may use median income, instead of average income, provided that the PHA includes a written explanation in its PHA Annual Plan justifying use of median income in the PHA's Annual Plan.

(ii) *Step 2.* A PHA shall determine the average income of all families residing in each covered development. In determining average income for each development, a PHA has the option of adjusting its income analysis for unit size in accordance with procedures prescribed by HUD.

(iii) *Step 3.* A PHA shall determine whether each of its covered developments falls above, within or below the Established Income Range. The Established Income Range is 85 percent to 115 percent (inclusive of 85

percent and 115 percent) of the PHA-wide average income for covered developments as defined in Step 1.

(iv) *Step 4.* A PHA with covered developments having average incomes outside the Established Income Range may explain or justify the income profile for these developments as being consistent with and furthering two sets of goals: the goals of deconcentration of poverty and income mixing as specified by the statute (bringing higher income tenants into lower income developments and vice versa); and the local goals and strategies contained in the PHA Annual Plan. Elements of explanations or justifications that may satisfy these requirements may include, but shall not be limited to the following:

(A) The covered development or developments are subject to consent decrees or other resident selection and admission plans mandated by court action;

(B) The covered development or developments are part of PHA's programs, strategies or activities specifically authorized by statute, such as mixed-income or mixed-finance developments, homeownership programs, self-sufficiency strategies, or other strategies designed to deconcentrate poverty, promote income mixing in public housing, increase the incomes of public housing residents, or the income mix is otherwise subject to individual review and approval by HUD;

(C) The covered development's or developments' size, location, and/or configuration promote income deconcentration, such as scattered site or small developments;

(D) The income characteristics of the covered development or developments are sufficiently explained by other circumstances.

(v) *Step 5.* Where the income profile for a covered development is not explained or justified in the PHA Annual Plan submission, the PHA shall include in its admission policy its specific policy to provide for deconcentration of poverty and income mixing in applicable covered developments. Depending on local circumstances, a PHA's deconcentration policy (which may be undertaken in conjunction with other efforts such as efforts to increase self-sufficiency or current residents) may include but is not limited to providing for one or more of the following actions:

(A) Providing incentives designed to encourage families with incomes below the Established Income Range to accept units in developments with incomes above the Established Income Range, or vice versa, including rent incentives,

affirmative marketing plans, or added amenities;

(B) Targeting investment and capital improvements toward developments with an average income below the Established Income Range to encourage applicant families whose income is above the Established Income Range to accept units in those developments;

(C) Establishing a preference for admission of working families in developments below the Established Income Range;

(D) Skipping a family on the waiting list to reach another family in an effort to further the goals of the PHA's deconcentration policy;

(E) Providing such other strategies as permitted by statute and determined by the PHA in consultation with the residents and the community, through the PHA Annual Plan process, to be responsive to the local context and the PHA's strategic objectives.

(2) *Determination of compliance with deconcentration requirement.* HUD shall consider a PHA to be in compliance with this subpart if:

(i) The PHA's income analysis shows that the PHA has no general occupancy family developments to which the deconcentration requirements apply; that is, the average incomes of all covered developments are within the Established Income Range;

(ii) The PHA has covered developments with average incomes above or below the Established Income Range and the PHA provides a sufficient explanation in its Annual Plan that supports that the income mix of such development or developments is consistent with and furthers the goal of deconcentration of poverty and income mixing and also the locally determined goals of the PHA's Annual and Five Year Plans, and the PHA therefore need not take further action to deconcentrate poverty and mix incomes; or

(iii) The PHA's deconcentration policy provides specific strategies the PHA will take that can be expected to promote deconcentration of poverty and income mixing in developments with average incomes outside of the Established Income Range.

(3) *Right of return.* If a PHA has provided that a family that resided in a covered public housing development has a right to admission to a public housing unit in that development after revitalization, the requirements of paragraph (c) of this section do not preclude fulfilling that commitment or a PHA's commitment to return a family to another development after revitalization.

(4) *Family's discretion to refuse a unit.* A family has the sole discretion

whether to accept an offer of a unit made under a PHA's deconcentration policy. The PHA may not take any adverse action toward any eligible family for choosing not to accept an offer of a unit under the PHA's deconcentration policy. In accordance with the PHA's established policies, the PHA may uniformly limit the number of offers received by applicants.

(5) *Relationship to income targeting requirement.* Nothing in this section relieves a PHA of the obligation to meet the requirement to admit annually at least 40 percent families whose incomes are below 30 percent of area median income as provided by section 16(a)(2) of the 1937 Act, 42 U.S.C. 1437n(a)(2).

(d) *Fair housing requirements.* All admission and occupancy policies for public housing and Section 8 tenant-based housing programs must comply with Fair Housing Act requirements and with regulations to affirmatively further fair housing. The PHA may not impose any specific income or racial quotas for any development or developments.

(1) *Nondiscrimination.* A PHA must carry out its PHA Plan in conformity with the nondiscrimination requirements in Federal civil rights laws, including title VI of the Civil Rights Act of 1964 and the Fair Housing Act. A PHA cannot assign persons to a particular section of a community or to a development or building based on race, color, religion, sex, disability, familial status or national origin for purposes of segregating populations (§ 1.4(b)(1)(ii) of this title).

(2) *Affirmatively Furthering Fair Housing.* PHA policies that govern eligibility, selection and admissions under its PHA Plan should be designed to reduce racial and national origin concentrations. Any affirmative steps or incentives a PHA plans to take must be stated in the admission policy.

(i) HUD regulations provide that PHAs should take affirmative steps to overcome the effects of conditions which resulted in limiting participation of persons because of their race, national origin or other prohibited basis (§ 1.4(b)(1)(iii) and (6)(ii) of this title).

(ii) Such affirmative steps may include but are not limited to, appropriate affirmative marketing efforts; additional applicant consultation and information; and provision of additional supportive services and amenities to a development.

(3) *Validity of certification.* (i) HUD will take action to challenge the PHA's certification under § 903.7(o) where it appears that a PHA Plan or its implementation:

(A) Does not reduce racial and national origin concentration in developments or buildings and is perpetuating segregated housing; or

(B) Is creating new segregation in housing.

(ii) If HUD challenges the validity of a PHA's certification, the PHA must establish that it is providing a full range of housing opportunities to applicants and tenants or that it is implementing actions described in paragraph (d)(2)(ii) of this section.

(e) *Relationship between poverty deconcentration and fair housing.* The requirements for poverty deconcentration in paragraph (c) of this section and for fair housing in paragraph (d) of this section arise under separate statutory authorities and are independent.

Subpart B—PHA Plans

§ 903.3 What is the purpose of this subpart?

(a) This subpart specifies the requirements for PHA plans, required by section 5A of the United States Housing Act of 1937 (42 U.S.C. 1437c–1).

(b) The purpose of the plans is to provide a framework for:

- (1) Local accountability; and
- (2) An easily identifiable source by which public housing residents, participants in the tenant-based assistance program, and other members of the public may locate basic PHA policies, rules and requirements concerning the PHA's operations, programs and services.

§ 903.4 What are the public housing agency plans?

(a) *Types of plans.* There are two public housing agency plans. They are:

(1) The 5-Year Plan (the 5-Year Plan) that a public housing agency (PHA) must submit to HUD once every five PHA fiscal years. The 5-Year Plan covers the five PHA fiscal years immediately following the date on which the 5-Year Plan is due to HUD; and

(2) The Annual Plan (Annual Plan) that the PHA must submit to HUD for each fiscal year immediately following the date on which the Annual Plan is due to HUD and for which the PHA receives:

(i) Section 8 tenant-based assistance (under section 8(o) of the U.S. Housing Act of 1937, 42 U.S.C. 1437f(o)) (tenant-based assistance); or

(ii) Amounts from the public housing operating fund or capital fund (under section 9 of the U.S. Housing Act of 1937 (42 U.S.C. 1437g) (public housing)).

(b) *Format.* HUD may prescribe the format of submission (including electronic format submission) of the plans. HUD also may prescribe the format of attachments to the plans and documents related to the plan that the PHA does not submit but may be required to make available locally. PHAs will receive appropriate notice of any prescribed format.

(c) *Applicability.* The requirements of this subpart only apply to a PHA that receives the type of assistance described in paragraph (a) of this section.

(d) *Authority for waivers.* In addition to the waiver authority provided in § 5.110 of this title, the Secretary may, subject to statutory limitations, waive any provision of this title on a program-wide basis, and delegate this authority in accordance with section 106 of the Department of Housing and Urban Development Reform Act of 1989 (42 U.S.C. 3535(q)) where the Secretary determines that such waiver is necessary for the effective implementation of this part.

§ 903.5 When must a PHA submit the plans to HUD?

(a) *5-Year Plan.* (1) The first PHA fiscal year that is covered by the requirements of this part as amended on December 22, 2000, is the PHA fiscal year that begins July 2001. This 5-Year Plan submitted by a PHA must be submitted for the 5-year period beginning July 1, 2001.

(2) For all PHAs, the first 5-Year Plans are due 75 days before the commencement of their fiscal year.

(3) For all PHAs, after submission of their first 5-Year Plan, all subsequent 5-Year Plans must be submitted once every 5 PHA fiscal years, no later than 75 days before the commencement of the PHA's fiscal year.

(4) PHAs may choose to update their 5-Year Plans every year as good management practice and must update their 5-Year Plans that were submitted for PHA fiscal years beginning before July 1, 2001, to comply with the requirements of this part as amended on December 22, 2000, at the time they submit their next Annual Plan for fiscal years beginning on or after July 1, 2001. PHAs must explain any substantial deviation from their 5-Year Plans in their Annual Plans. (Substantial deviation is determined by the PHA in accordance with criteria provided by the PHA in its Annual Plan in accordance with § 903.7(r).)

(b) *The Annual Plan.* (1) The first PHA fiscal year that is covered by the requirements of this part as amended on December 22, 2000, is the PHA fiscal year that begins July 1, 2001.

(2) For all PHAs, the first Annual Plans are due 75 days before the commencement of their fiscal year.

(3) For all PHAs, after submission of the first Annual Plan, all subsequent Annual Plans will be due no later than 75 days before the commencement of their fiscal year.

§ 903.6 What information must a PHA provide in the 5-Year Plan?

(a) A PHA must include in its 5-Year Plan a statement of:

(1) The PHA's mission for serving the needs of low-income, very low-income and extremely low-income families in the PHA's jurisdiction; and

(2) The PHA's goals and objectives that enable the PHA to serve the needs of the families identified in the PHA's Annual Plan. For HUD, the PHA and the public to better measure the success of the PHA in meeting its goals and objectives, the PHA must adopt quantifiable goals and objectives for serving those needs wherever possible.

(b) After submitting its first 5-Year Plan, a PHA in its succeeding 5-Year Plans, must address:

(1) The PHA's mission, goals and objectives for the next 5 years; and

(2) The progress the PHA has made in meeting the goals and objectives described in the PHA's previous 5-Year Plan.

§ 903.7 What information must a PHA provide in the Annual Plan?

With the exception of the first Annual Plan submitted by a PHA, the Annual Plan must include the information provided in this section. HUD will advise PHAs by separate notice, sufficiently in advance of the first Annual Plan due date, of the information, described in this section that must be part of the first Annual Plan submission, and any additional instructions or directions that may be necessary to prepare and submit the first Annual Plan. The information described in this section applies to both public housing and tenant-based assistance, except where specifically stated otherwise. The information that the PHA must submit for HUD approval under the Annual Plan includes the discretionary policies of the various plan components or elements (for example, rent policies) and not the statutory or regulatory requirements that govern these plan components and that provide no discretion on the part of the PHA in implementation of the requirements. The PHA's Annual Plan must be consistent with the goals and objectives of the PHA's 5-Year Plan.

(a) *A statement of housing needs.* (1) This statement must address the

housing needs of the low-income and very low-income families who reside in the jurisdiction served by the PHA, and other families who are on the public housing and Section 8 tenant-based assistance waiting lists, including:

(i) Families with incomes below 30 percent of area median (extremely low-income families);

(ii) Elderly families and families with disabilities;

(iii) Households of various races and ethnic groups residing in the jurisdiction or on the waiting list.

(2) A PHA must make reasonable efforts to identify the housing needs of each of the groups listed in paragraph (a)(1) of this section based on information provided by the applicable Consolidated Plan, information provided by HUD, and other generally available data.

(i) The identification of housing needs must address issues of affordability, supply, quality, accessibility, size of units and location.

(ii) The statement of housing needs also must describe the ways in which the PHA intends, to the maximum extent practicable, to address those needs, and the PHA's reasons for choosing its strategy.

(b) *A statement of the PHA's deconcentration and other policies that govern eligibility, selection, and admissions.* This statement must describe the PHA's policies that govern resident or tenant eligibility, selection and admission. This statement also must describe any PHA admission preferences, and any occupancy policies that pertain to public housing units and housing units assisted under section 8(o) of the 1937 Act, as well as any unit assignment policies for public housing. This statement must include the following information:

(1) *Deconcentration Policy.* The PHA's deconcentration policy applicable to public housing, as described in § 903.2(a).

(2) *Waiting List Procedures.* The PHA's procedures for maintaining waiting lists for admission to the PHA's public housing developments. The statement must address any site-based waiting lists, as authorized by section 6(s) of the 1937 Act (42 U.S.C. 1437d(s)), for public housing. Section 6(s) of the 1937 Act permits PHAs to establish a system of site-based waiting lists for public housing that is consistent with all applicable civil rights and fair housing laws and regulations. Notwithstanding any other regulations, a PHA may adopt site-based waiting lists where:

(i) The PHA regularly submits required occupancy data to HUD's

Multifamily Tenant Characteristics Systems (MTCS) in an accurate, complete and timely manner;

(ii) The system of site-based waiting lists provides for full disclosure to each applicant of any option available to the applicant in the selection of the development in which to reside, including basic information about available sites (location, occupancy, number and size of accessible units, amenities such as day care, security, transportation and training programs) and an estimate of the period of time the applicant would likely have to wait to be admitted to units of different sizes and types (e.g., regular or accessible) at each site;

(iii) Adoption of site-based waiting lists would not violate any court order or settlement agreement, or be inconsistent with a pending complaint brought by HUD;

(iv) The PHA includes reasonable measures to assure that adoption of site-based waiting lists is consistent with affirmatively furthering fair housing, such as reasonable marketing activities to attract applicants regardless of race or ethnicity;

(v) The PHA provides for review of its site-based waiting list policy to determine if the policy is consistent with civil rights laws and certifications through the following steps:

(A) As part of the submission of the Annual Plan, the PHA shall assess changes in racial, ethnic or disability-related tenant composition at each PHA site that may have occurred during the implementation of the site-based waiting list, based upon MTCS occupancy data that has been confirmed to be complete and accurate by an independent audit (which may be the annual independent audit) or is otherwise satisfactory to HUD;

(B) At least every three years the PHA uses independent testers or other means satisfactory to HUD, to assure that the site-based waiting list is not being implemented in a discriminatory manner, and that no patterns or practices of discrimination exist, and providing the results to HUD;

(C) Taking any steps necessary to remedy the problems surfaced during the review; and

(D) Taking the steps necessary to affirmatively further fair housing.

(3) *Other admissions policies.* The PHA's admission policies that include any other PHA policies that govern eligibility, selection and admissions for the public housing (see part 960 of this title) and tenant-based assistance programs (see part 982, subpart E of this title). (The information requested on site-based waiting lists and

deconcentration is applicable only to public housing.)

(c) *A statement of financial resources.* This statement must address the financial resources that are available to the PHA for the support of Federal public housing and tenant-based assistance programs administered by the PHA during the plan year. The statement must include a listing, by general categories, of the PHA's anticipated resources, such as PHA operating, capital and other anticipated Federal resources available to the PHA, as well as tenant rents and other income available to support public housing or tenant-based assistance. The statement also should include the non-Federal sources of funds supporting each Federal program, and state the planned uses for the resources.

(d) *A statement of the PHA's rent determination policies.* This statement must describe the PHA's basic discretionary policies that govern rents charged for public housing units, applicable flat rents, and the rental contributions of families receiving tenant-based assistance. For tenant-based assistance, this statement also shall cover any discretionary minimum tenant rents and payment standard policies.

(e) *A statement of the PHA's operation and management.* (1) This statement must list the PHA's rules, standards, and policies that govern maintenance and management of housing owned, assisted, or operated by the PHA.

(2) The policies listed in this statement must include a description of any measures necessary for the prevention or eradication of pest infestation. Pest infestation includes cockroach infestation.

(3) This statement must include a description of PHA management organization, and a listing of the programs administered by the PHA.

(4) The information requested on a PHA's rules, standards and policies regarding management and maintenance of housing applies only to public housing. The information requested on PHA program management and listing of administered programs applies to public housing and tenant-based assistance.

(f) *A statement of the PHA grievance procedures.* This statement describes the grievance and informal hearing and review procedures that the PHA makes available to its residents and applicants. These procedures include public housing grievance procedures and tenant-based assistance informal review procedures for applicants and hearing procedures for participants.

(g) *A statement of capital improvements needed.* With respect to public housing only, this statement describes the capital improvements necessary to ensure long-term physical and social viability of the PHA's public housing developments, including the capital improvements to be undertaken in the year in question and their estimated costs, and any other information required for participation in the Capital Fund. PHAs also are required to include 5-Year Plans covering large capital items.

(h) *A statement of any demolition and/or disposition.* (1) *Plan for Demolition/Disposition.* With respect to public housing only, a description of any public housing development, or portion of a public housing development, owned by the PHA for which the PHA has applied or will apply for demolition and/or disposition approval under section 18 of the 1937 Act (42 U.S.C. 1437p), and the timetable for demolition and/or disposition. The application and approval process for demolition and/or disposition is a separate process. Approval of the PHA Plan does not constitute approval of these activities.

(2) *Interim Plan for Demolition/Disposition.* (i) Before submission of the first Annual Plan, a PHA may submit an interim PHA Annual Plan solely for demolition/disposition. The interim plan must provide:

(A) The required description of the action to be taken;

(B) A certification of consistency with the Consolidated Plan;

(C) A description of how the plan is consistent with the Consolidated Plan;

(D) A relocation plan that includes the availability of units in the area and adequate funding; and

(E) Confirmation that a public hearing was held on the proposed action and that the resident advisory board was consulted.

(ii) Interim plans for demolition/disposition are subject to PHA Plan procedural requirements in this part (see §§ 903.13, 903.15, 903.17, 903.19, 903.21, 903.23, 903.25), with the following exception. If a resident advisory board has not yet been formed, the PHA may seek a waiver of the requirement to consult with the resident advisory board on the grounds that organizations that adequately represent residents for this purpose were consulted.

(iii) The actual application for demolition or disposition may be submitted at the same time as submission of the interim plan or at a later date.

(i) *A statement of the public housing developments designated as housing for elderly families or families with disabilities or elderly families and families with disabilities.*

(1) With respect to public housing only, this statement identifies any public housing developments owned, assisted, or operated by the PHA, or any portion of these developments, that:

(i) The PHA has designated for occupancy by:

(A) Only elderly families;

(B) Only families with disabilities; or

(C) Elderly families and families with disabilities; and

(ii) The PHA will apply for designation for occupancy by:

(A) Only elderly families;

(B) Only families with disabilities; or

(C) Elderly families and families with disabilities as provided by section 7 of the 1937 Act (42 U.S.C. 1437e).

(2) The designated housing application and approval process is a separate process. Approval of the PHA Plan does not constitute approval of these activities.

(j) *A statement of the conversion of public housing to tenant-based assistance.* (1) This statement describes:

(i) Any building or buildings that the PHA is required to convert to tenant-based assistance under section 33 of the 1937 Act (42 U.S.C. 1437z-5);

(ii) The status of any building or buildings that the PHA may be required to convert to tenant-based assistance under section 202 of the Fiscal Year 1996 HUD Appropriations Act (42 U.S.C. 14371 note); or

(iii) The PHA's plans to voluntarily convert under section 22 of the 1937 Act (42 U.S.C. 1437t).

(2) The statement also must include an analysis of the developments or buildings required to be converted under section 33.

(3) For both voluntary and required conversions, the statement must include the amount of assistance received commencing in Federal Fiscal Year 1999 to be used for rental assistance or other housing assistance in connection with such conversion.

(4) The application and approval processes for required or voluntary conversions are separate approval processes. Approval of the PHA Plan does not constitute approval of these activities.

(5) The information required under this paragraph (j) of this section is applicable to public housing and only that tenant-based assistance which is to be included in the conversion plan.

(k) *A statement of homeownership programs administered by the PHA.*

(1) This statement describes:

(i) Any homeownership programs administered by the PHA under section 8(y) of the 1937 Act (42 U.S.C. 1437f(y));

(ii) Any homeownership programs administered by the PHA under an approved section 5(h) homeownership program (42 U.S.C. 1437c(h));

(iii) An approved HOPE I program (42 U.S.C. 1437aaa); or

(iv) Any homeownership programs for which the PHA has applied to administer or will apply to administer under section 5(h), the HOPE I program, or section 32 of the 1937 Act (42 U.S.C. 1437z-4).

(2) The application and approval process for homeownership under the programs described in paragraph (k) of this section, with the exception of the section 8(y) homeownership program, are separate processes. Approval of the PHA Plan does not constitute approval of these activities.

(l) *A statement of the PHA's community service and self-sufficiency programs.* (1) This statement describes:

(i) Any PHA programs relating to services and amenities coordinated, promoted or provided by the PHA for assisted families, including programs provided or offered as a result of the PHA's partnership with other entities;

(ii) Any PHA programs coordinated, promoted or provided by the PHA for the enhancement of the economic and social self-sufficiency of assisted families, including programs provided or offered as a result of the PHA's partnerships with other entities, and activities under section 3 of the Housing and Community Development Act of 1968 and under requirements for the Family Self-Sufficiency Program and others. The description of programs offered shall include the program's size (including required and actual size of the Family Self-Sufficiency program) and means of allocating assistance to households.

(iii) How the PHA will comply with the requirements of section 12(c) and (d) of the 1937 Act (42 U.S.C. 1437j(c) and (d)). These statutory provisions relate to community service by public housing residents and treatment of income changes in public housing and tenant-based assistance recipients resulting from welfare program requirements. PHAs must address any cooperation agreements, as described in section 12(d)(7) of the 1937 Act (42 U.S.C. 1437j(d)(7)), that the PHA has entered into or plans to enter into.

(2) The information required by paragraph (l) of this section is applicable to both public housing and tenant-based assistance, except that the information regarding the PHA's compliance with the community service

requirement applies only to public housing.

(m) *A statement of the PHA's safety and crime prevention measures.*

(1) With respect to public housing only, this statement describes the PHA's plan for safety and crime prevention to ensure the safety of the public housing residents that it serves. The plan for safety and crime prevention must be established in consultation with the police officer or officers in command of the appropriate precinct or police departments. The plan also must provide, on a development-by-development or jurisdiction wide-basis, the measures necessary to ensure the safety of public housing residents.

(2) The statement regarding the PHA's safety and crime prevention plan must include the following information:

(i) A description of the need for measures to ensure the safety of public housing residents;

(ii) A description of any crime prevention activities conducted or to be conducted by the PHA; and

(iii) A description of the coordination between the PHA and the appropriate police precincts for carrying out crime prevention measures and activities.

(3) If the PHA expects to receive drug elimination program grant funds, the PHA must submit, in addition to the information required by paragraph (m)(1) of this section, the plan required by HUD's Public Housing Drug Elimination Program regulations (see part 761 of this title).

(4) If HUD determines at any time that the security needs of a public housing development are not being adequately addressed by the PHA's plan, or that the local police precinct is not assisting the PHA with compliance with its crime prevention measures as described in the Annual Plan, HUD may mediate between the PHA and the local precinct to resolve any issues of conflict.

(n) *A statement of the PHA's policies and rules regarding ownership of pets in public housing.* This statement describes the PHA's policies and requirements pertaining to the ownership of pets in public housing. The policies must be in accordance with section 31 of the 1937 Act (42 U.S.C. 1437a-3).

(o) *Civil rights certification.* (1) The PHA must certify that it will carry out its plan in conformity with title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d-2000d-4), the Fair Housing Act (42 U.S.C. 3601-19), section 504 of the Rehabilitation Act of 1973 (29 U.S.C. 794), and title II of the Americans with Disabilities Act of 1990 (42 U.S.C. 12101 et seq.). The PHA also must certify that it will affirmatively further fair housing.

(2) The certification is applicable to both the 5-Year Plan and the Annual Plan.

(3) A PHA shall be considered in compliance with the certification requirement to affirmatively further fair housing if the PHA fulfills the requirements of § 903.2(b) and:

(i) Examines its programs or proposed programs;

(ii) Identifies any impediments to fair housing choice within those programs;

(iii) Addresses those impediments in a reasonable fashion in view of the resources available;

(iv) Works with local jurisdictions to implement any of the jurisdiction's initiatives to affirmatively further fair housing that require the PHA's involvement; and

(v) Maintains records reflecting these analyses and actions.

(p) *Recent results of PHA's fiscal year audit.* This statement provides the results of the most recent fiscal year audit of the PHA conducted under section 5(h)(2) of the 1937 Act (42 U.S.C. 1437c(h)).

(q) *A statement of asset management.* To the extent not covered by other components of the PHA Annual Plan, this statement describes how the PHA will carry out its asset management functions with respect to the PHA's public housing inventory, including how the PHA will plan for long-term operating, capital investment, rehabilitation, modernization, disposition, and other needs for such inventory.

(r) *Additional information to be provided.* (1) For all Annual Plans following submission of the first Annual Plan, a PHA must include a brief statement of the PHA's progress in meeting the mission and goals described in the 5-Year Plan;

(2) A PHA must identify the basic criteria the PHA will use for determining:

(i) A substantial deviation from its 5-Year Plan; and

(ii) A significant amendment or modification to its 5-Year Plan and Annual Plan.

(3) A PHA must include such other information as HUD may request of PHAs, either on an individual or across-the-board basis. HUD will advise the PHA or PHAs of this additional information through advance notice.

§ 903.9 May HUD request additional information in the Annual Plan of a troubled PHA?

HUD may request that a PHA that is at risk of being designated as troubled or is designated as troubled in accordance with section 6(j)(2) of the

1937 Act (42 U.S.C. 1437d(j)(2)), the Public Housing Management Assessment Program (part 901 of this title) or the Public Housing Assessment System (part 902 of this chapter) include its operating budget. The PHA also must include or reference any applicable memorandum of agreement with HUD or any plan to improve performance, and such other material as HUD may prescribe.

§ 903.11 Are certain PHAs eligible to submit a streamlined Annual Plan?

(a) Yes, the following PHAs may submit a streamlined Annual Plan, as described in paragraph (b) of this section:

(1) PHAs that are determined to be high performing PHAs as of the last annual or interim assessment of the PHA before the submission of the 5-Year or Annual Plan;

(2) PHAs with less than 250 public housing units (small PHAs) and that have not been designated as troubled in accordance with section 6(j)(2) of the 1937 Act; and

(3) PHAs that only administer tenant-based assistance and do not own or operate public housing.

(b) All streamlined plans must provide information on how the public may reasonably obtain additional information on the PHA policies contained in the standard Annual Plan, but excluded from their streamlined submissions.

(c) A streamlined plan must include the information provided in this paragraph (c). The Secretary may reduce the information requirements of streamlined Plans further, with adequate notice.

(1) For high performing PHAs, the streamlined Annual Plan must include the information required by § 903.7(a), (b), (c), (d), (g), (h), (k), (m), (n), (o), (p) and (r). The information required by § 903.7(m) must be included only to the extent this information is required for PHA's participation in the public housing drug elimination program and the PHA anticipates participating in this program in the upcoming year. The information required by § 903.7(k) must be included only to the extent that the PHA participates in homeownership programs under section 8(y).

(2) For small PHAs that are not designated as troubled or that are not at risk of being designated as troubled under section 6(j)(2) of the 1937 Act the streamlined Annual Plan must include the information required by § 903.7(a), (b), (c), (d), (g), (h), (k), (m), (n), (o), (p) and (r). The information required by § 903.7(k) must be included only to the extent that the PHA participates in

homeownership programs under section 8(y). The information required by § 903.7(m) must be included only to the extent this information is required for the PHA's participation in the public housing drug elimination program and the PHA anticipates participating in this program in the upcoming year.

(3) For PHAs that administer only tenant-based assistance, the streamlined Annual Plan must include the information required by § 903.7(a), (b), (c), (d), (e), (f), (k), (l), (o), (p) and (r).

§ 903.13 What is a Resident Advisory Board and what is its role in development of the Annual Plan?

(a) A Resident Advisory Board refers to a board or boards, as provided in paragraph (b) of this section, whose membership consists of individuals who adequately reflect and represent the residents assisted by the PHA.

(1) The role of the Resident Advisory Board (or Resident Advisory Boards) is to assist and make recommendations regarding the development of the PHA plan, and any significant amendment or modification to the PHA plan.

(2) The PHA shall allocate reasonable resources to assure the effective functioning of Resident Advisory Boards. Reasonable resources for the Resident Advisory Boards must provide reasonable means for them to become informed on programs covered by the PHA Plan, to communicate in writing and by telephone with assisted families and hold meetings with those families, and to access information regarding covered programs on the internet, taking into account the size and resources of the PHA.

(b) Each PHA must establish one or more Resident Advisory Boards, as provided in paragraph (b) of this section.

(1) If a jurisdiction-wide resident council exists that complies with the tenant participation regulations in part 964 of this title, the PHA shall appoint the jurisdiction-wide resident council or the council's representatives as the Resident Advisory Board. If the PHA makes such appointment, the members of the jurisdiction-wide resident council or the council's representatives shall be added or another Resident Advisory Board formed to provide for reasonable representation of families receiving tenant-based assistance where such representation is required under paragraph (b)(2) of this section.

(2) If a jurisdiction-wide resident council does not exist but resident councils exist that comply with the tenant participation regulations, the PHA shall appoint such resident councils or their representatives to serve

on one or more Resident Advisory Boards. If the PHA makes such appointment, the PHA may require that the resident councils choose a limited number of representatives.

(3) Where the PHA has a tenant-based assistance program of significant size (where tenant-based assistance is 20% or more of assisted households), the PHA shall assure that the Resident Advisory Board (or Boards) has reasonable representation of families receiving tenant-based assistance and that a reasonable process is undertaken to choose this representation.

(4) Where or to the extent that resident councils that comply with the tenant participation regulations do not exist, the PHA shall appoint Resident Advisory Boards or Board members as needed to adequately reflect and represent the interests of residents of such developments; provided that the PHA shall provide reasonable notice to such residents and urge that they form resident councils with the tenant participation regulations.

(c) The PHA must consider the recommendations of the Resident Advisory Board or Boards in preparing the final Annual Plan, and any significant amendment or modification to the Annual Plan, as provided in § 903.21 of this title.

(1) In submitting the final plan to HUD for approval, or any significant amendment or modification to the plan to HUD for approval, the PHA must include a copy of the recommendations made by the Resident Advisory Board or Boards and a description of the manner in which the PHA addressed these recommendations.

(2) Notwithstanding the 75-day limitation on HUD review, in response to a written request from a Resident Advisory Board claiming that the PHA failed to provide adequate notice and opportunity for comment, HUD may make a finding of good cause during the required time period and require the PHA to remedy the failure before final approval of the plan.

§ 903.15 What is the relationship of the public housing agency plans to the Consolidated Plan?

(a) The PHA must ensure that the Annual Plan is consistent with any applicable Consolidated Plan for the jurisdiction in which the PHA is located. The Consolidated Plan includes a certification that requires the preparation of an Analysis of Impediments to Fair Housing Choice.

(1) The PHA must submit a certification by the appropriate State or local officials that the Annual Plan is consistent with the Consolidated Plan

and include a description of the manner in which the applicable plan contents are consistent with the Consolidated Plans.

(2) For State agencies that are PHAs, the applicable Consolidated Plan is the State Consolidated Plan.

(b) A PHA may request to change its fiscal year to better coordinate its planning with the planning done under the Consolidated Plan process, by the State or local officials, as applicable.

§ 903.17 What is the process for obtaining public comment on the plans?

(a) The PHA's board of directors or similar governing body must conduct a public hearing to discuss the PHA plan (either the 5-Year Plan and/or Annual Plan, as applicable) and invite public comment on the plan(s). The hearing must be conducted at a location that is convenient to the residents served by the PHA.

(b) Not later than 45 days before the public hearing is to take place, the PHA must:

(1) Make the proposed PHA plan(s), the required attachments and documents related to the plans, and all information relevant to the public hearing to be conducted, available for inspection by the public at the principal office of the PHA during normal business hours; and

(2) Publish a notice informing the public that the information is available for review and inspection, and that a public hearing will take place on the plan, and the date, time and location of the hearing.

(c) PHAs shall conduct reasonable outreach activities to encourage broad public participation in the PHA plans.

§ 903.19 When is the 5-Year Plan or Annual Plan ready for submission to HUD?

A PHA may adopt its 5-Year Plan or its Annual Plan and submit the plan to HUD for approval only after:

(a) The PHA has conducted the public hearing;

(b) The PHA has considered all public comments received on the plan;

(c) The PHA has made any changes to the plan, based on comments, after consultation with the Resident Advisory Board or other resident organization.

§ 903.21 May the PHA amend or modify a plan?

(a) A PHA, after submitting its 5-Year Plan or Annual Plan to HUD, may amend or modify any PHA policy, rule, regulation or other aspect of the plan. If the amendment or modification is a

significant amendment or modification, as defined in § 903.7(r)(2), the PHA:

(1) May not adopt the amendment or modification until the PHA has duly called a meeting of its board of directors (or similar governing body) and the meeting, at which the amendment or modification is adopted, is open to the public; and

(2) May not implement the amendment or modification, until notification of the amendment or modification is provided to HUD and approved by HUD in accordance with HUD's plan review procedures, as provided in § 903.23.

(b) Each significant amendment or modification to a plan submitted to HUD is subject to the requirements of §§ 903.13, 903.15, and 903.17.

§ 903.23 What is the process by which HUD reviews, approves, or disapproves an Annual Plan?

(a) *Review of the plan.* When the PHA submits its Annual Plan to HUD, including any significant amendment or modification to the plan, HUD reviews the plan to determine whether:

(1) The plan provides all the information that is required to be included in the plan;

(2) The plan is consistent with the information and data available to HUD;

(3) The plan is consistent with any applicable Consolidated Plan for the jurisdiction in which the PHA is located; and

(4) The plan is not prohibited or inconsistent with the 1937 Act or any other applicable Federal law.

(b) *Disapproval of the plan.* (1) HUD may disapprove a PHA plan, in its entirety or with respect to any part, or disapprove any significant amendment or modification to the plan, only if HUD determines that the plan, or one of its components or elements, or any significant amendment or modification to the plan:

(i) Does not provide all the information that is required to be included in the plan;

(ii) Is not consistent with the information and data available to HUD;

(iii) Is not consistent with any applicable Consolidated Plan for the jurisdiction in which the PHA is located; or

(iv) Is not consistent with applicable Federal laws and regulations.

(2) Not later than 75 days after the date on which the PHA submits its plan or significant amendment or modification to the plan, HUD will issue

written notice to the PHA if the plan or a significant amendment or modification has been disapproved. The notice that HUD issues to the PHA must state with specificity the reasons for the disapproval. HUD may not state as a reason for disapproval the lack of time to review the plan.

(3) If HUD fails to issue the notice of disapproval on or before the 75th day after the date on which the PHA submits its plan or significant amendment or modification to the plan, HUD shall be considered to have determined that all elements or components of the plan required to be submitted and that were submitted, and to be reviewed by HUD were in compliance with applicable requirements and the plan has been approved.

(4) The provisions of paragraph (b)(3) of this section do not apply to troubled PHAs. The plan of a troubled PHA must be approved or disapproved by HUD through written notice.

(c) *Designation of due date as submission date for first plan submissions.* For purposes of the 75-day period described in paragraph (b) of this section, the first 5-year and Annual Plans submitted by a PHA will be considered to have been submitted no earlier than the due date as provided in § 903.5.

(d) *Public availability of the approved plan.* Once a PHA's plan has been approved, a PHA must make the approved plan and the required attachments and documents related to the plan, available for review and inspection, at the principal office of the PHA during normal business hours.

§ 903.25 How does HUD ensure PHA compliance with its plan?

A PHA must comply with the rules, standards and policies established in the plans. To ensure that a PHA is in compliance with all policies, rules, and standards adopted in the plan approved by HUD, HUD shall, as it deems appropriate, respond to any complaint concerning PHA noncompliance with its plan. If HUD should determine that a PHA is not in compliance with its plan, HUD will take whatever action it deems necessary and appropriate.

Dated: December 14, 2000.

Harold Lucas,

Assistant Secretary for Public and Indian Housing.

[FR Doc. 00-32550 Filed 12-21-00; 8:45 am]

BILLING CODE 4210-33-P



Federal Register

**Friday,
December 22, 2000**

Part VIII

Federal Trade Commission

16 CFR Part 432

**Trade Regulation Rule Relating to Power
Output Claims for Amplifiers Utilized in
Home Entertainment Products; Final Rule**

FEDERAL TRADE COMMISSION

16 CFR Part 432

Trade Regulation Rule Relating To Power Output Claims For Amplifiers Utilized in Home Entertainment Products

AGENCY: Federal Trade Commission.

ACTION: Final rule.

SUMMARY: The Federal Trade Commission ("Commission" or "FTC"), pursuant to section 18 of the Federal Trade Commission Act, issues final amendments to its Trade Regulation Rule on Power Output Claims for Amplifiers Utilized in Home Entertainment Products ("Amplifier Rule" or "Rule"). The Commission amends the Rule to: exempt sellers who make power output claims in media advertising from the requirement to disclose total rated harmonic distortion and the associated power bandwidth and impedance ratings; clarify the manner in which the Rule's testing procedures apply to self-powered subwoofer-satellite combination speaker systems; and reduce the preconditioning power output requirement from one-third of rated power to one-eighth of rated power. This document constitutes the Commission's Statement of Basis and Purpose for the amendments.

EFFECTIVE DATES: This Rule is effective on February 20, 2001.

ADDRESSES: Requests for copies of the amended Rule and the Statement of Basis and Purpose should be sent to the Consumer Response Center, Federal Trade Commission, Room 130, 600 Pennsylvania Ave., N.W., Washington, DC 20580.

FOR FURTHER INFORMATION CONTACT: Dennis Murphy, Economist, Division of Consumer Protection, Bureau of Economics, (202) 326-3524, or Neil Blickman, Attorney, Division of Enforcement, Bureau of Consumer Protection, (202) 326-3038, Federal Trade Commission, Washington, DC 20580.

SUPPLEMENTARY INFORMATION:**Statement of Basis and Purpose***Part A—Introduction*

This document is published pursuant to section 18 of the FTC Act, 15 U.S.C. 57a *et seq.*, the provisions of Part 1, Subpart B of the Commission's Rules of Practice, 16 CFR 1.14, and 5 U.S.C. 551 *et seq.* This authority permits the Commission to promulgate, modify, and repeal trade regulation rules that define with specificity acts or practices that are unfair or deceptive in or affecting

commerce within the meaning of section 5(a)(1) of the FTC Act, 15 U.S.C. 45(a)(1). The Commission undertook this rulemaking proceeding as part of the Commission's ongoing program of evaluating trade regulation rules and industry guides to determine their effectiveness, impact, cost and need.

The Amplifier Rule was promulgated on May 3, 1974 (39 FR 15387), to assist consumers in purchasing power amplification equipment for home entertainment purposes by standardizing the measurement and disclosure of various performance characteristics of the equipment. On April 7, 1997, the Commission published a **Federal Register** Notice ("FRN") seeking comment on the Rule as part of an ongoing project to review all Commission rules and guides to determine their current effectiveness and impact (62 FR 16500). This FRN sought comment on the costs and benefits of the Rule, what changes in the Rule would increase its benefits to purchasers and how those changes would affect compliance costs, and whether technological or marketplace changes have affected the Rule. The FRN also sought comment on issues related to the Rule's product coverage, test procedures, and disclosure requirements.

The comments in response to the FRN generally expressed continuing support for the Rule, stating that it has given consumers a standardized method of comparing the power output of audio amplifiers, and has created a level playing field among competitors. The comments also suggested that there have been technological and marketplace changes that may warrant modifications to the Rule's testing and disclosure requirements, and a clarification of the Rule's applicability to self-powered loudspeakers for use with personal computers and home stereo systems. Certain comments also recommended that the Commission expand the Rule's coverage to include automotive sound amplification products. On the basis of this review, the Commission determined to retain the Rule, but to seek additional comment on possible amendments to the Rule.

The Commission published an Advanced Notice of Proposed Rulemaking ("ANPR") on July 9, 1998 (63 FR 37238), seeking public comment on whether it should initiate a rulemaking proceeding by publishing a Notice of Proposed Rulemaking ("NPR") under section 18 of the FTC Act, 15 U.S.C. 57a. The ANPR solicited specific comment on whether the Commission should (1) eliminate certain disclosure requirements in media advertising; (2)

clarify testing procedures for self-powered speakers; and (3) amend certain required test procedures that may impose unnecessary costs on manufacturers. The ANPR also announced that the Commission had determined not to initiate a proceeding to amend the Rule to cover power ratings for automotive sound amplification equipment. Finally, the Commission published elsewhere in the July 9, 1998 **Federal Register** a Notice of Final Action announcing a non-substantive technical amendment to the Rule clarifying that the Rule covered self-powered loudspeakers for use in the home (63 FR 37234).

The ANPR elicited five comments.¹ Based on the comments responding to the ANPR, and on other evidence discussed below, the Commission published an NPR on July 19, 1999 (64 FR 38610).² In the NPR, the Commission proposed amending the Rule to (1) exempt sellers who make power output claims in media advertising from the requirement to disclose total rated harmonic distortion and the associated power bandwidth and impedance rating; (2) clarify the manner in which the rule's testing procedures apply to self-powered subwoofer-satellite combination speaker systems; and (3) reduce the preconditioning power output requirement from one-third of rated power to one-eighth of rated power.³ The NPR elicited five comments.⁴

In the NPR, the Commission also announced that pursuant to 16 CFR

¹ The commenters were: Consumer Electronics Manufacturers Association (CEMA)(1); Wass Audio-Digital (Wass)(2); Sonance (Sonance)(3); PHI Acoustics (PHI)(4); and Velodyne Acoustics, Inc. (Velodyne)(5).

² In accordance with section 18 of the FTC Act, 15 U.S.C. 57a, the Commission submitted this NPR to the Chairman of the Committee on Commerce, Science, and Transportation, United States Senate, and the Chairman of the Committee on Commerce, United States House of Representatives, 30 days prior to its publication in the **Federal Register**.

³ The Commission solicited public comments on its NPR until September 17, 1999. In response to a request from the Consumer Electronics Manufacturers Association, however, the Commission granted an extension of the comment period until October 15, 1999 (64 FR 51087 (Sept. 21, 1999)). CEMA recently changed its name to the Consumer Electronics Association.

⁴ The commenters were: EKSC (EKSC)(1); Audio Research (Audio Research)(2); QSC Audio (QSC)(3); Thomson Consumer Electronics, Inc. (Thomson)(4); and Consumer Electronics Manufacturers Association (CEMA)(5). The comments on the Commission's ANPR and NPR are cited as "(Name of Commenter), (designated comment number), p. ___." All Rule ANPR and NPR comments are on the public record and are available for public inspection in the Public Reference Room, Room 130, Federal Trade Commission, 600 Pennsylvania Ave., NW, Washington, DC, from 8:30 a.m. to 5:00 p.m., Monday through Friday, except federal holidays.

1.20, it would follow expedited procedures in this proceeding, and (1) publish an NPR; (2) solicit written comments on the Commission's proposals to amend the Rule; (3) hold an informal hearing, if requested by interested parties; (4) obtain a final recommendation from staff; and (5) announce final Commission action in a notice published in the **Federal Register**.⁵ There were no requests for hearings in the five comments received in response to the NPR. The Commission, therefore, did not hold public hearings in this matter.

Part B—Analysis of Amendments

1. Amendment to Required Disclosures Section of the Amplifier Rule

a. Background. Section 432.2 of the Rule requires disclosure of maximum rated total harmonic distortion ("THD"), power bandwidth, and impedance whenever a power claim is made in any advertising, including advertising by retail stores, direct mail merchants, and manufacturers. In the ANPR, the Commission concluded tentatively that improvements in amplifier technology since the Rule's promulgation in 1974 appeared to have reduced the benefits to consumers of disclosure of THD in media advertising. In the ANPR, the Commission also concluded tentatively that an insufficient number of consumers would understand the meaning and significance of the remaining triggered disclosures concerning power bandwidth and impedance to justify their publication in media advertising. Accordingly, the ANPR sought comment on whether the Commission should initiate a rulemaking proceeding to amend the Rule to exempt media advertising, including advertising on the Internet, from disclosure of THD and the associated power bandwidth and impedance ratings when a power output claim is made. In the ANPR, the Commission tentatively concluded further that the proposed exemption should be conditioned on the requirement that the primary power output specification disclosed in any advertising distributed through the media be the manufacturer's rated minimum sine wave continuous average power output, per channel, at an impedance of 8 ohms, or, if the

amplifier is not designed for an 8-ohm impedance, at the impedance for which the amplifier is primarily designed.

Finally, the ANPR explained the Commission's tentative conclusion that publication of all other power output claims currently subject to the Rule, including those appearing in manufacturer specification sheets that are either in print or reproduced on the Internet, should continue to trigger the requirement that the seller provide the full complement of disclosures concerning power bandwidth, maximum harmonic distortion, and impedance, so that interested consumers could obtain this information prior to purchase.

The Commission received four comments on the tentatively proposed exemption of THD, bandwidth, and impedance disclosures in media advertising. CEMA, the principal trade association for the electronics industry, supported the proposed exemption, including the requirement that the primary power output specification disclosed in media advertising be continuous per-channel output at an 8-ohm impedance (unless the amplifier is designed primarily for a different impedance level).⁶ Velodyne, a manufacturer of powered loudspeakers, also supported the exemption of THD and bandwidth disclosures in media advertising, stating that they contain little useful information for today's consumer.⁷ This commenter suggested, however, that the standardized impedance value for power output claims be 4 ohms rather than the proposed 8 ohms.⁸ No explanation was provided for this suggestion. Wass opposed elimination of the required THD, bandwidth, and impedance disclosures in advertising, stating that sellers could take unfair advantage of the consumer through in-store sales techniques that obscure the true performance capabilities of an amplifier.⁹ Sonance stated simply that the relationship between power and distortion is vital to specifying power output, and recommended against the tentatively proposed exemption.¹⁰

Based on its review of the comments on its ANPR, the Commission stated in the NPR that it had reason to believe that the disclosure of THD, power bandwidth, and impedance in media advertising that contains a triggering power output claim no longer provided sufficient consumer benefit to justify the

associated increase in advertising costs. The Commission concluded in both the ANPR and the NPR that very few amplifiers in today's market generate high levels of THD (e.g., more than one percent) using the FTC testing protocol. Further, the Commission concluded that those few amplifiers that do generate appreciable levels of THD tend to be very expensive vacuum tube designs that are sold to a specialized group of consumers that may not consider THD specifications an important consideration in their purchase decisions. Thus, it did not appear that sales personnel at retail stores would have an appreciable incentive to mislead consumers concerning the distortion characteristics of an amplifier. Finally, the Commission concluded that consumers who are interested in the Rule's THD, power bandwidth, and impedance specifications would be able to find such information relatively easily in product brochures at retail stores or on the Internet.

Commenters on the ANPR did not agree on which impedance value should serve as the standard for power output claims in media advertising under the tentatively proposed disclosure exemption. CEMA endorsed the value of 8 ohms suggested in the ANPR. Velodyne, however, commented that the standardized impedance value should be 4 ohms. The Commission concluded in the NPR that, under the proposed exemption, for amplifiers designed to drive a specific loudspeaker in an integrated powered configuration, the seller could base power output claims on an impedance of 4 ohms, if the amplifier is powering a loudspeaker that is rated at a nominal impedance of 4 ohms. Although the Commission stated in the NPR that it had reason to believe that the majority of non-powered loudspeakers are rated at a nominal impedance of 8 ohms, and that this value should therefore be adopted as the basis for power output claims in media advertising for separate stand-alone amplifiers, the NPR solicited further comment on whether the Commission's tentative conclusion on this issue was correct.

Accordingly, in the NPR the Commission proposed amending section 432.2 of the Rule to exempt advertising disseminated through the media, including advertising on the Internet, from disclosure of total rated harmonic distortion and the associated power bandwidth and impedance ratings when a power output claim is made. The Commission further proposed that the exemption for advertising disseminated through the media be conditioned on

⁵ 64 FR 38610, 38614. The Commission stated that using expedited procedures would support the agency's goals of clarifying existing regulations, when necessary, and eliminating obsolete or unnecessary regulation without an undue expenditure of resources, while ensuring that the public has an opportunity to submit data, views and arguments on whether the Commission should amend the Rule.

⁶ CEMA, (1), pp.2-3.

⁷ Velodyne, (5), p.1.

⁸ Id.

⁹ Wass, (2), p.3.

¹⁰ Sonance, (3), p.1.

the requirement that the primary power output specification disclosed in any media advertising be the manufacturer's rated minimum sine wave continuous average power output, per channel, at an impedance of 8 ohms, or, if the amplifier is not designed for an 8-ohm impedance, at the impedance for which the amplifier is primarily designed. Publication of all other power output claims currently subject to the Rule, including those appearing in manufacturer specification sheets that are either in print or reproduced on the Internet, would continue to trigger the requirement that the seller provide the full complement of disclosures concerning maximum harmonic distortion, power bandwidth, and impedance, so that interested consumers could obtain this information prior to purchase.

b. *Discussion of NPR Comments.* The Commission received four comments on the proposed exemption of THD, bandwidth, and impedance disclosures in media advertising. Thomson Consumer Electronics, which markets audio and video equipment under the RCA and ProScan brand names, supported the proposed exemption, stating that “* * * the consumer typically understands little from these disclosures.”¹¹ Thomson recommended, however, that the Commission monitor developments once the exemption is in place to ensure that industry members do not take advantage of the disclosure requirements to inflate power output claims.¹²

Audio Research Corporation, a manufacturer of electronic audio equipment specializing in vacuum tube designs, opposed the proposed exemption, stating that “[c]onsumers are a lot more sophisticated than consumers were when the original rules were issued” and, therefore, understand the THD disclosures.¹³ Audio Research agreed, however, that the Commission should select an impedance of 8 ohms as the basis for primary power output specifications in the event the Commission adopts the proposed exemption of THD disclosures in media advertising.¹⁴

QSC Audio Products, a manufacturer of professional audio power amplifiers, did not believe that the currently required distortion and power bandwidth disclosures were sufficiently burdensome to justify the proposed exemption in media advertising. Like

Audio Research, however, QSC supported an impedance value of 8 ohms as the basis for primary power output specifications in media advertising should an exemption be adopted, stating that 8 ohms “* * * is a reasonable value for typical impedance.”¹⁵

CEMA reversed its position taken in earlier comments in this rulemaking proceeding and opposed the proposed exemption. According to CEMA, members recently have “* * * expressed concerns about inconsistent power output claims in retail advertising for amplifiers and receivers, especially multichannel products.”¹⁶ These members report that certain relatively low cost multichannel receivers, for which distortion information in advertising is not disclosed, have distortion levels well in excess of one percent at rated power. Although CEMA continues to regard total harmonic distortion levels below one percent are inaudible to consumers, CEMA stated that levels above that amount can become significant. As a result, CEMA stated that “* * * consumers are unable to make accurate price-versus-performance comparisons for such multichannel audio products.”¹⁷ CEMA did not provide the Commission with any specific examples of such problematic advertisements for multichannel amplifiers. Nor did CEMA state that they were aware of any similar advertisements for conventional monophonic or two-channel stereo amplifiers.

CEMA proposed that the Commission help consumers make “apples-to-apples” comparisons of amplifiers by setting certain minimum requirements for the various elements of the current THD disclosures.¹⁸ CEMA maintained that such standardization would prevent power output claims from becoming “* * * qualitative measurements used by manufacturers (or retailers) to differentiate products with respect to consumer’s perceptions of quality.”¹⁹ Specifically, CEMA recommended that total harmonic distortion be disclosed as “less than or equal to one percent.” Under CEMA’s recommendation, “(M)anufacturers and retailers would continue to be free to make secondary, qualitative claims of lower distortion in order to differentiate their products further (e.g., “0.5% THD,” “.01% THD,” etc.).”²⁰ CEMA did not indicate what

form of disclosure would be required in the event an amplifier’s THD at rated power was greater than one percent.

To further standardize distortion disclosures, CEMA proposed that the “power bandwidth” associated with the rated THD disclosure be the single frequency 1000 Hz, rather than the customary 20Hz–20kHz. CEMA commented that “* * * claims concerning bandwidth, especially claims about wide bandwidth, could be regarded as qualitative claims to the consumer.”²¹ CEMA recommended that the Commission adopt 1000 Hz as the basis for primary power output claims, and allow advertisers to make secondary qualitative claims, such as “Ultra-wide Bandwidth” or “20–20 kHz” in advertising or at the point of sale for purposes of product differentiation.²²

Finally, in addressing the issue of the appropriate impedance value for primary power output claims, CEMA stated that “* * * loudspeakers today typically exhibit impedances of 4 to 8 ohms.”²³ CEMA recommended that primary power output claims be based on an impedance value of 6 ohms. CEMA did not specify whether most loudspeakers are rated at an impedance of 8 ohms, 4 ohms, or some impedance value within that range.

c. *Rule Amendment and Reasons Therefor.* Based on its review of the comments and other evidence contained in this rulemaking proceeding, the Commission has reason to believe that the disclosure of THD, power bandwidth, and impedance in media advertising that contains a triggering power output claim no longer provides sufficient consumer benefit to justify the associated increase in advertising costs. One commenter on the NPR supported the proposed exemption. Two other commenters opposed the proposed exemption, but did not provide any evidence that consumers typically understand the significance of the THD, power bandwidth, and impedance disclosures.

Finally, although CEMA had supported the proposed exemption in its comment on the ANPR, it opposed the proposed exemption in its comment on the NPR. The basis for this change in position was based on its allegation that power output claims in certain advertising for multi-channel theater amplifiers were based on very high levels of total harmonic distortion. CEMA did not provide any evidence or suggest that advertisements for conventional monophonic or

¹¹ Thomson, (4), p.1.

¹² Id., pp. 1–2.

¹³ Audio Research, (2), p.1.

¹⁴ Id.

¹⁵ QSC, (3), p.1.

¹⁶ CEMA, (5), p.2.

¹⁷ Id.

¹⁸ Id., p.3.

¹⁹ Id.

²⁰ Id.

²¹ Id., pp.2–3.

²² Id., p. 3.

²³ Id.

stereophonic amplifiers contain power output claims based on similarly high levels of THD.

The Commission presented evidence in the ANPR indicating that very few amplifiers in today's market generate appreciable levels of THD (e.g., more than one percent) at rated power using the FTC testing protocol for monophonic or stereophonic amplifiers. The Commission is publishing elsewhere in this **Federal Register** a Supplemental Notice of Proposed Rulemaking that addresses testing and disclosure issues specific to multi-channel amplifiers such as those used in home theater applications. The Commission believes that the concerns raised by CEMA will be addressed more appropriately in that rulemaking proceeding. The Commission does not believe that CEMA's comment provides a basis for rejecting the proposed exemption of THD, power bandwidth, and impedance disclosures in media advertising for conventional monophonic and stereophonic amplifiers. Similarly, the Commission does not believe CEMA has provided evidence that would provide a basis for altering the current requirements governing the format of THD disclosures or the choice of power bandwidth for power output claims for conventional monophonic and stereophonic amplifiers.

Two of the commenters on the NPR supported the proposal to base power output claims on a nominal impedance of 8 ohms, or on the nominal impedance for which the amplifier is primarily designed. CEMA proposed a value of 6 ohms, but did not provide any evidence that this value was more representative of loudspeakers currently in use than was the proposed value of 8 ohms.

Accordingly, the Commission is amending section 432.2 of the Rule to exempt advertising disseminated through the media, including advertising on the Internet, from disclosure of total rated harmonic distortion and the associated power bandwidth and impedance ratings when a power output claim is made. The exemption for advertising disseminated through the media is conditioned on the requirement that the primary power output specification disclosed in any media advertising be the manufacturer's rated minimum sine wave continuous average power output, per channel, at an impedance of 8 ohms, or, if the amplifier is not designed for an 8-ohm impedance, at the impedance for the amplifier is primarily designed. Publication of all other power output claims currently subject to the Rule, including those appearing in any

product brochure or manufacturer specification sheets that are either in print or reproduced on the Internet, will continue to trigger the requirement that the seller provide the full complement of disclosures concerning maximum total harmonic distortion, power bandwidth, and impedance, so that interested consumers can obtain this information prior to purchase.

2. Amendment Relating to Self-Powered Loudspeakers

a. *Background.* When the FRN was published, the Rule did not specifically mention self-powered speakers as an example of sound amplification equipment manufactured or sold for home entertainment purposes. In the FRN, the Commission solicited comment on its tentative conclusion that the Rule covers: (A) Self-powered speakers for use with (1) home computers, (2) home sound systems, (3) home multimedia systems; and (B) other sound power amplification equipment for home computers. On July 9, 1998, the Commission published in the **Federal Register** a non-substantive technical amendment to the Rule to clarify that the Rule applies to the types of self-powered loudspeakers enumerated above (63 FR 37234).

In the ANPR published elsewhere in the July 9, 1998 **Federal Register** (63 FR 37238), the Commission explained that comments received in response to the FRN indicated that a clarification was needed concerning the testing procedure that should be followed in applying the Rule's continuous power rating protocol to self-powered subwoofer-satellite combination speaker systems that employ two or more power amplifiers sharing a common power supply. These comments recommended two alternative approaches for such combination self-powered speakers. The first proposed procedure was for power measurements to be made with all associated channels of both the subwoofer and satellite amplifiers driven simultaneously to full power using a test tone at the system's crossover frequency. The second proposal was to allow manufacturers of such equipment to test the subwoofer and satellite amplifiers separately over their respective frequency bandwidth.

In the ANPR, the Commission sought comment on its tentative conclusion that the second procedure was more appropriate, given the types of power demands combination self-powered speakers would most likely encounter in actual home use. The Commission received three comments on its proposal to amend section 432.2 of the Rule to include a note stating that, for self-

powered combination speaker systems that employ two or more amplifiers dedicated to different portions of the audio frequency spectrum, only those channels dedicated to the same audio frequency spectrum need be fully driven to rated per channel power under section 432.2(a)(2).

CEMA supported the Commission's clarification, stating that this approach would allow self-powered subwoofers to be rated over their operating frequency range and at their appropriate impedance value.²⁴ Sonance also endorsed the tentative proposal to restrict the power tests of such equipment to each amplifier's intended operating range.²⁵ Velodyne disagreed with the Commission's proposal and stated that power rating tests for self-powered combination subwoofer-satellite loudspeakers should be conducted with all channels operating simultaneously. It proposed that the amplifiers driving the subwoofer and satellites should be given a test signal within each amplifier's typical range, and suggested a combination 60Hz–1,000Hz tone.²⁶ Velodyne stated that the power supply was the most costly and critical component determining an amplifier's continuous power output capability, and that the primary quantitative measurement of interest to consumers is the amount of watts the power supply can deliver.²⁷

Based on the comments submitted in response to the FRN and the ANPR, the Commission tentatively concluded in the NPR that the most appropriate method of testing self-powered combination subwoofer-satellite loudspeaker systems under the Rule was to require simultaneous operation only of those channels dedicated to the same portion of the audio frequency spectrum. The Commission stated in both the ANPR and the NPR that it did not have sufficient evidence to conclude that in-home use, under even strenuous conditions, typically would place maximum continuous power demands simultaneously on both the subwoofer and satellite amplifiers at the crossover frequency. Rather, the Commission concluded in the NPR that such demands would be more likely to occur in portions of the audio spectrum that would be assigned primarily either to the subwoofer amplifier or the satellite amplifier. In contrast, conventional stand-alone stereo amplifiers, which incorporate left and right-channel amplifiers that must reproduce signals

²⁴ CEMA, (1), p. 3.

²⁵ Sonance, (3), p. 1.

²⁶ Velodyne, (5), p. 3.

²⁷ Id.

covering the full musical frequency bandwidth, would more commonly be required to meet simultaneous continuous power demands that are present in both channels (such as might occur when a pipe organ plays a sustained pedal tone in the deep bass).

In addition, the Commission stated in the NPR that a simultaneous power test of both the subwoofer and the satellite amplifiers would, from a practical standpoint, require a single test signal at the crossover frequency, or a single combination set of tones, such as the 60Hz–1,000Hz composite signal suggested by Velodyne. The Commission concluded that the resulting power and THD specifications might not be valid over the full frequency range over which each amplifier was designed to operate.

Accordingly, in the NPR the Commission proposed amending section 432.2(a)(2) of the Rule to include a clarifying note stating that, when measuring maximum per channel output of self-powered combination speaker systems that employ two or more amplifiers dedicated to different portions of the audio frequency spectrum, only those channels dedicated to the same audio frequency spectrum need be fully driven to rated per channel power.

b. *Discussion of NPR Comments.* The Commission received five comments concerning the proposed clarification of testing procedures for self-powered combination speaker systems. Thomson Consumer Electronics and Audio Research endorsed the proposal without qualification.²⁸ QSC Audio stated that it had no strong opinion on the proposed clarification, and was “* * * willing to support the proposed regime of loading only one frequency range at a time.”²⁹ QSC noted, however, that a “rational” standard for powered speakers would rate maximum acoustic output, distortion, and frequency bandwidth as a system, “* * * without regard for internal details such as amplifier power and driver impedance.”³⁰ QSC cautioned, however, that such acoustic measurements initially “* * * will not be familiar to consumers and such specifications tend to be overly detailed.”³¹

Two other commenters explicitly favored a testing protocol based on the acoustic output of the self-powered speaker system over a protocol limited to the performance of the amplifier(s) alone. These commenters proposed

testing procedures that would apply to all self-powered speaker systems, whether individual powered subwoofers, powered satellite speakers, or self-powered combination subwoofer-satellite speakers that share a common power supply. Specifically, EKSC commented that the separate testing of amplifiers contained in self-powered speakers “* * * does the consumer little good.”³² EKSC proposed a two-part test procedure that would measure (1) the total harmonic distortion produced by a self-powered loudspeaker when producing a sound pressure level of 96 decibels, and (2) the maximum sound pressure level the loudspeaker could produce without exceeding 10 percent harmonic distortion. According to EKSC, results from the first test would allow consumers to compare the harmonic distortion characteristics of self-powered loudspeaker systems when producing a standard level of sound pressure. The second test would provide consumers with comparative information on the maximum sound pressure self-powered speaker systems could produce prior to the onset of severe distortion.³³

CEMA also favored a test protocol based on acoustic output measurements for self-powered loudspeaker systems. CEMA commented that an amplifier power rating in isolation “* * * inherently ignores the performance capability of the acoustical portion of the system, and hence is incomplete and inaccurate as a performance comparison tool.”³⁴ CEMA stated that an appropriate acoustical output standard would measure such performance characteristics as the sensitivity of the loudspeaker system (expressed as sound pressure output level per input volt), and the maximum sound pressure output that the system can achieve within specified frequency bandwidth and distortion limits.³⁵

c. *Rule Amendment and Reasons Therefor.* Based on the comments submitted in response to the NPR, the Commission concludes that the most appropriate method of testing self-powered combination subwoofer-satellite loudspeaker systems under the Rule is to restrict measurements to the electrical performance of the component amplifier(s) alone, and to require simultaneous operation only of those channels dedicated to the same portion of the audio frequency spectrum. Three commenters endorsed this procedure or found it acceptable. None of the

commenters recommended any alternative method of measuring the power output characteristics of amplifiers contained in such self-powered speaker systems.

Two commenters recommended that the Commission reject any test protocol limited to measuring the power output of the amplifier alone, and proposed instead that the Commission develop and adopt a testing and disclosure methodology based on the acoustic output of the entire self-powered speaker system. The Commission does not necessarily disagree that, at least in principle, such a protocol would provide more complete and meaningful comparative performance information for consumers than would a protocol limited to the power and distortion performance of the amplifier(s) alone. The Commission does not, however, have the necessary expertise and resources to undertake such a complex and uncertain rulemaking proceeding. The Commission believes that the development of an acoustic output measurement and disclosure protocol for self-powered loudspeakers would be, more appropriately, the responsibility of industry members and their trade associations.

Further, many marketers of self-powered loudspeakers may well continue to advertise separate power output measurements for the component amplifiers in these systems before, and even after, any such acoustic output protocol is formulated. Thus, there would still be a need to clarify the testing procedure for self-powered combination satellite and subwoofer loudspeakers under the Rule so that consumers will not be confused by conflicting power output claims. The Commission believes, therefore, that the Rule's continuous power output protocol and any future industry acoustic output protocol could coexist in a complementary fashion.

Accordingly, the Commission is amending section 432.2(a)(2) to include a clarifying note stating that, when measuring maximum per channel output of self-powered combination speaker systems that employ two or more amplifiers dedicated to different portions of the audio frequency spectrum, only those channels dedicated to the same audio frequency spectrum need be fully driven to rated per channel power.

3. Amendments to the Amplifier Rule Preconditioning Requirement

a. *Background.* Section 432.3(c) of the Rule specifies that an amplifier must be preconditioned by simultaneously operating all channels at one-third of

²⁸ Thomson, (4), p. 2; Audio Research, (2), p. 2.

²⁹ QSC, (3), p. 1.

³⁰ Id., pp. 1–2.

³¹ Id., p. 2.

³² EKSC, (1), p. 1.

³³ Id., pp. 1–2.

³⁴ CEMA, (5), p. 4.

³⁵ Id., pp. 4–5.

rated power output for one hour using a sinusoidal wave at a frequency of 1,000 Hz. The ANPR sought comment on whether the Commission should amend the Rule to reduce the preconditioning power output requirement from one-third of rated power to a lower figure, such as one-eighth of rated power.

CEMA supported reducing the preconditioning power output requirement to below the current one-third power, stating that the current requirement is "beyond what can be expected through normal use in the home" and is "harsh and unrealistic."³⁶ CEMA claimed that in order to meet the physical conditions presented by the Rule's existing preconditioning requirement, manufacturers must design and incorporate in amplifiers larger and costlier heat sinks.³⁷ CEMA listed several alternative solutions, including operation at idle during preconditioning, operation at a small fixed power representative of average power during typical in-home operation, or preconditioning at one-eighth power. CEMA further stated that the one-eighth power option "has the virtue of being consistent with current industry and international testing specifications."³⁸

Velodyne stated that a preconditioning period is not really necessary, but that the Commission should follow Underwriters Laboratories' ("UL") one-eighth power requirement if the preconditioning requirement is retained.³⁹ Velodyne did not provide any explanation for its conclusion that no preconditioning period of any kind was necessary under the Rule.

Wass concluded, from a series of calculations, that reducing the preconditioning requirement from one-third to one-eighth power would reduce the thermal stress (expressed in "watts of heat" delivered to an amplifier's heatsink) by approximately 24 percent.⁴⁰ Wass, however, opposed amending the Rule to provide such a reduction in specified preconditioning power output because the consumer would get "a poorer unit."⁴¹ Wass did not provide any evidence, however, that would allow the Commission to compare the magnitude of the alleged reduction in amplifier quality with the magnitude of the associated reduction in manufacturing costs resulting from

the one-eighth power preconditioning standard.

Finally, Sonance stated that the one-third power preconditioning requirement should be retained and enforced evenly.⁴² Sonance saw no technical problem with the requirement, stating that many generations of consumer electronic products have been built to this standard.⁴³

Based on the comments, the Commission tentatively concluded that the current one-third power preconditioning requirement imposed unnecessary costs on amplifier manufacturers and was not needed to measure amplifiers accurately under conditions that represent actual in-home use. Accordingly, in the NPR the Commission proposed amending section 432.3(c) of the Rule by reducing the specified per-channel power output during preconditioning from one-third of rated power output for one hour to one-eighth of rated power output for one hour.

b. Discussion of NPR Comments. The Commission received four comments on the proposed amendment. Audio Research opposed the proposed amendment, stating that "the purpose of the original rule-making was to insure an acceptable level of quality (the 1/3 power, 1 hour pre-conditioning test) as well as a reasonable level of static performance."⁴⁴ The remaining three commenters all supported the proposed reduction in the preconditioning power output requirement.

QSC stated that "we strongly support reducing the pre-conditioning power level to 1/8 of rated power." QSC noted that this power output level matches that " * * * used by safety agencies to assess AC current draw and component temperature rise, and also corresponds to the highest likely average program level, where some attempt is made to limit gross clipping."⁴⁵ Thomson Consumer Electronics stated that the proposed one-eighth power level for preconditioning would provide " * * * a more realistic condition to that experienced in typical operation of the amplifier and represents a reasonable manner in which to precondition for testing."⁴⁶

CEMA reiterated its earlier support for this amendment, citing attendant reductions in manufacturing and testing costs.⁴⁷ CEMA also stated that the proposed reduction in the

preconditioning power output requirement would facilitate preconditioning at an impedance of four ohms, and thus allow more manufacturers of high power amplifiers to provide realistic power output specifications for this impedance load.⁴⁸ Finally, CEMA commented that the proposed amendment would render the preconditioning requirement more consistent with testing protocols for UL and the European Union, which " * * * typically specify amplifier preconditioning at one-eighth of rated power for a period of less than one hour."⁴⁹ In this regard, CEMA proposed that the Commission reduce the required preconditioning period from one hour to thirty minutes.⁵⁰

c. Rule Amendment and Reasons Therefor. Based on the comments submitted in response to the NPR, the Commission concludes that the current one-third power preconditioning requirement imposes unnecessary costs on amplifier manufacturers and should be reduced to one-eighth of rated power. All but one of the commenters on the NPR supported this reduction. The dissenting commenter was concerned that lowering the preconditioning power requirement would jeopardize the Rule's intended purpose of helping assure an acceptable level of quality in the amplifier market.

The Commission believes that the proposed amendment is consistent with the original intent of the Rule. The preconditioning requirement was not imposed as a quality-assurance mechanism that would place maximum stress on an amplifier's heat dissipation capabilities. This requirement merely was intended to bring an amplifier to normal operating temperature and to stabilize its components so that the subsequent power output tests would provide performance specifications representative of the performance consumers could expect in normal operation in the home. Indeed, at the time the Rule was promulgated in 1974, the Commission was not aware that preconditioning at one-third of rated power would place such severe thermal stress on solid state amplifiers, particularly high power units operating into a resistive load of four ohms.

Only one of the NPR comments, and none of the comments received in connection with earlier phases of this proceeding, recommended a preconditioning period shorter than one hour. The one commenter that recommended a shorter preconditioning

³⁶ CEMA, (1), p. 2.

³⁷ Id.

³⁸ Id.

³⁹ Velodyne, (5), p. 1.

⁴⁰ Wass, (2), p. 2.

⁴¹ Id.

⁴² Sonance, (3), p. 1.

⁴³ Id.

⁴⁴ Audio Research, (2), p. 1.

⁴⁵ QSC, (3), p. 2.

⁴⁶ Thomson, (4), p. 1.

⁴⁷ CEMA, (5), p. 5.

⁴⁸ Id.

⁴⁹ Id.

⁵⁰ Id.

period of thirty minutes did not provide any technological justifications for the proposed reduction in preconditioning time. Thus, the Commission does not believe that the Rulemaking record provides an adequate basis for amending the one-hour preconditioning period prescribed by the Rule.

Accordingly, the Commission is amending section 432.3(c) of the Rule by reducing the specified per-channel power output during preconditioning from one-third of rated power output for one hour to one-eighth of rated power output for one hour.

d. Additional Preconditioning Amendment. As discussed in Part B(2) above, in the NPR the Commission proposed amending the Rule to clarify the manner in which power tests should be conducted for self-powered subwoofer-satellite combination loudspeaker systems. In reviewing the technical issues related to this proposed amendment, the Commission tentatively concluded in the NPR that clarification also was required concerning the manner in which powered subwoofers should be preconditioned under the Rule.

Section 432.3(c) of the Rule specifies a preconditioning sinusoidal test tone of 1,000Hz. The Commission stated in the NPR that most self-powered subwoofer systems incorporate crossover circuitry that filters out frequencies above the bass range. Depending upon the crossover frequency and the steepness of the crossover slope, such crossover circuitry may severely attenuate a test tone of 1,000Hz and prevent the subwoofer amplifier from being driven to one-third rated power (as required by the Rule at the time the NPR was published), or even to one-eighth of rated power (as required by the amended Rule). Thus, it appeared to the Commission that testers of self-powered subwoofers would need to select a preconditioning frequency considerably lower than 1,000Hz.

The Commission, therefore, tentatively concluded in the NPR that the Rule should be amended to clarify the preconditioning procedure for self-powered subwoofers. The Commission also concluded, however, that any such amendment should not specify the precise frequency of the test tone that is to be used in preconditioning powered subwoofers. The Commission stated that powered subwoofers may differ widely in the portion of the bass spectrum over which they are designed to operate, and, consequently, there may not be a single preconditioning frequency that is appropriate for all powered subwoofers. The Commission tentatively concluded in the NPR, therefore, that testers of

powered subwoofers should have the flexibility to choose for the sinusoidal preconditioning signal any frequency within the intended operating bandwidth of the subwoofer amplifier that will allow the amplifier to be driven for one hour to the required proportion of rated power output.

Accordingly, in the NPR the Commission proposed amending section 432.3(c) of the Rule by adding an explanatory note stating that for amplifiers utilized as a component in a self-powered subwoofer system, the sinusoidal wave used as a preconditioning signal may be any frequency within the amplifier's intended operating bandwidth that will allow the amplifier to be driven to one-eighth of rated power for one hour.

e. Discussion of NPR Comments. The Commission received only one comment that directly addressed the choice of preconditioning frequency for self-powered subwoofer systems. Audio Research supported the proposed amendment, stating that such subwoofers should be preconditioned “* * * at any frequency within the claimed bandwidth.”⁵¹ Another commenter on the NPR, QSC Audio, stated that powered speakers should be preconditioned using “band-limited pink noise.”⁵² QSC, however, did not distinguish between subwoofers and other types of powered loudspeaker systems, and did not specify which frequency ranges should be selected as appropriate band-limited pink noise test signals. Finally, CEMA and EKSC restricted their comments on self-powered speakers to the need for acoustic output tests of the entire speaker system, and did not address the choice of preconditioning test signal frequency for the amplifiers contained in self-powered subwoofers.

f. Rule Amendment and Reasons Therefor. Based on its review of the NPR comments, the Commission has concluded that testers of self-powered subwoofers should have the flexibility to choose for the sinusoidal preconditioning signal any frequency within the intended operating bandwidth of the subwoofer amplifier that will allow the amplifier to be driven for one hour to one-eighth of rated power output. No comments stated that this approach was technologically flawed or otherwise undesirable. One commenter specifically endorsed the proposed preconditioning amendment. Accordingly, the Commission is amending section 432.3(c) of the Rule

by adding an explanatory note stating that for amplifiers utilized as a component in a self-powered subwoofer system, the sinusoidal wave used as a preconditioning signal may be any frequency within the amplifier's intended operating bandwidth that will allow the amplifier to be driven to one-eighth of rated power for one hour.

Part C—Regulatory Analysis And Regulatory Flexibility Act Requirements

Under section 22 of the FTC Act, 15 U.S.C. 57b, the Commission must issue a preliminary regulatory analysis for a proceeding to amend a rule only when it (1) estimates that the amendment will have an annual effect on the national economy of \$100,000,000 or more; (2) estimates that the amendment will cause a substantial change in the cost or price of certain categories of goods or services; or (3) otherwise determines that the amendment will have a significant effect upon covered entities or upon consumers. A final regulatory analysis is not required because the Commission finds that the amendments to the Rule will not have such effects on the national economy, on the cost of sound amplification equipment, or on covered businesses or consumers.

The Regulatory Flexibility Act (“RFA”), 5 U.S.C. 601–12, requires that the agency conduct an analysis of the anticipated economic impact of the proposed amendments on small businesses. The purpose of a regulatory flexibility analysis is to ensure that the agency considers impact on small entities and examines regulatory alternatives that could achieve the regulatory purpose while minimizing burdens on small entities. Section 605 of the RFA, 5 U.S.C. 605, provides that such an analysis is not required if the agency head certifies that the regulatory action will not have a significant economic impact on a substantial number of small entities.

Since the Amplifier Rule covers manufacturers and importers of power amplification equipment for use in the home, the Commission preliminarily concluded in the NPR that any amendments to the Rule may affect a substantial number of small businesses. Nevertheless, the Commission concluded that the proposed amendments would not have a significant economic impact upon such entities. Specifically, the Commission stated that the proposed change in the preconditioning protocol and the proposed exemption of disclosure of THD, bandwidth, and impedance specifications in media advertising would allow a moderate reduction in

⁵¹ Audio Research, (2), p. 2.

⁵² QSC, (3), p. 2.

amplifier manufacturing and advertising costs that would benefit both small and large businesses. The Commission also concluded that the proposed clarification of testing procedures for combination subwoofer-satellite self-powered loudspeaker systems was the least burdensome application of the Rule among the alternative proposals suggested by commenters, and would not have a significant or disproportionate impact on the testing costs of small manufacturers of such power amplification equipment.

Based on available information, therefore, in the NPR the Commission certified under the RFA that the proposed amendments to the Amplifier Rule, if promulgated, would not have a significant economic impact on a substantial number of small businesses. To ensure that no significant economic impact was being overlooked, however, the Commission requested comments on this issue. The Commission received no comments on this aspect of its NPR. Consequently, the Commission concludes that a regulatory flexibility analysis is not required, and certifies, under section 605 of the RFA, 5 U.S.C. 605, that the Rule it has adopted will not have a significant economic impact on a substantial number of small entities.

Part D—Paperwork Reduction Act

The Amplifier Rule contains various information collection requirements for which the Commission has obtained clearance until August 31, 2002, under the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*, Office of Management and Budget (“OMB”) Control Number 3084–0105. In the NPR, the Commission preliminarily concluded that the proposed amendments to the Rule to clarify the manner in which the Rule’s testing procedures apply to self-powered subwoofer-satellite combination speaker systems, and reduce the preconditioning power output requirement from one-third of rated power to one-eighth of rated power, if enacted, would not increase or alter the paperwork burden associated with the Rule’s requirements. The Commission stated in the NPR that these amendments would not increase the paperwork burden for businesses because for purposes of performing the tests necessary for affected entities to make the disclosures required under the Rule amplifiers must continue to be preconditioned for one hour. In the NPR, the Commission also preliminarily concluded that the proposed amendment of the Rule to exempt from media advertising disclosure of an amplifier’s total rated harmonic

distortion and the associated power bandwidth and impedance ratings when a power output claim for an amplifier is made would reduce the Rule’s paperwork burden. Although the exemption for media advertising would be conditioned on the requirement that the amplifier’s primary power output specification continue to be disclosed in any media advertising, the Commission stated that the net effect of the proposed amendment would be to reduce the Rule’s paperwork burden for businesses. To ensure that no significant paperwork burden was being overlooked, however, the Commission requested comments on this issue. The Commission received no comments on this aspect of its NPR.

Thus, the Commission concludes on the basis of the information now before it that the amendments to the Amplifier Rule will decrease the paperwork burden associated with compliance with the Rule. As discussed, the Rule requires disclosures if an advertisement makes a power output claim. The Commission has estimated that approximately 1,200 advertisements annually would be required to carry the FTC disclosures. The cost of these disclosures is limited to the time needed to draft and review the language pertaining to power output specifications. The Commission has estimated the time involved for this task to be a maximum of one hour per advertisement, for a total burden of 1,200 hours.⁵³ Because the Commission is amending the Rule to exempt from media advertising disclosure of an amplifier’s total rated harmonic distortion and the associated power bandwidth and impedance ratings, the Commission estimates the time involved for the aforementioned tasks to be a maximum of 45 minutes per advertisement, for a total burden of 900 hours. Thus, the net effect of the amendment is to reduce the Rule’s paperwork burden for businesses by 900 hours. In addition, since there were no additional “collection of information” requirements included in the proposed amendments to the Rule, the Commission was not required to submit them to OMB during this proceeding for clearance under the Paperwork Reduction Act.

List of Subjects in 16 CFR Part 432

Amplifiers, Home entertainment products, Trade practices.

For the reasons set out in the preamble, 16 CFR Part 432 is amended as follows:

PART 432—POWER OUTPUT CLAIMS FOR AMPLIFIERS UTILIZED IN HOME ENTERTAINMENT PRODUCTS

1. The authority citation for part 432 continues to read as follows:

Authority: 38 Stat. 717, as amended; (15 U.S.C. 41–58).

2. Section 432.2 is revised to read as follows:

§ 432.2 Required disclosures.

(a) Whenever any direct or indirect representation is made of the power output, power band or power frequency response, or distortion characteristics of sound power amplification equipment, the following disclosure shall be made clearly, conspicuously, and more prominently than any other representations or disclosures permitted under this part: The manufacturer’s rated minimum sine wave continuous average power output, in watts, per channel (if the equipment is designed to amplify two or more channels simultaneously) at an impedance of 8 ohms, or, if the amplifier is not designed for an 8-ohm impedance, at the impedance for which the amplifier is primarily designed, measured with all associated channels fully driven to rated per channel power. *Provided*, however, when measuring maximum per channel output of self-powered combination speaker systems that employ two or more amplifiers dedicated to different portions of the audio frequency spectrum, such as those incorporated into combination subwoofer-satellite speaker systems, only those channels dedicated to the same audio frequency spectrum should be considered associated channels that need be fully driven simultaneously to rated per channel power.

(b) In addition, whenever any direct or indirect representation is made of the power output, power band or power frequency response, or distortion characteristics of sound power amplification equipment in any product brochure or manufacturer specification sheet, the following disclosures also shall be made clearly, conspicuously, and more prominently than any other representations or disclosures permitted under this part:

(1) The manufacturer’s rated power band or power frequency response, in Hertz (Hz), for the rated power output required to be disclosed in paragraph (a) of this section; and

(2) The manufacturer’s rated percentage of maximum total harmonic distortion at any power level from 250 mW to the rated power output, and its corresponding rated power band or power frequency response.

⁵³ 64 FR 36877, 36879 (July 8, 1999).

3. Section 432.3(c) is revised to read as follows:

§ 432.3 Standard test conditions.

* * * * *

(c) The amplifier shall be preconditioned by simultaneously operating all channels at one-eighth of rated power output for one hour using

a sinusoidal wave at a frequency of 1,000 Hz; *provided, however*, that for amplifiers utilized as a component in a self-powered subwoofer system, the sinusoidal wave used as a preconditioning signal may be any frequency within the amplifier's intended operating bandwidth that will

allow the amplifier to be driven to one-eighth of rated power for one hour;

* * * * *

By direction of the Commission.

Donald S. Clark,
Secretary.

[FR Doc. 00-32392 Filed 12-21-00; 8:45 am]

BILLING CODE 6750-01-P



Federal Register

**Friday,
December 22, 2000**

Part IX

Environmental Protection Agency

**40 CFR Parts 136 and 437
Effluent Limitations Guidelines,
Pretreatment Standards, and New Source
Performance Standards for the
Centralized Waste Treatment Point Source
Category; Final Rule**

ENVIRONMENTAL PROTECTION AGENCY**40 CFR Parts 136 and 437**

[FRL-6863-8]

RIN 2040-AB78

Effluent Limitations Guidelines, Pretreatment Standards, and New Source Performance Standards for the Centralized Waste Treatment Point Source Category**AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Final rule.

SUMMARY: This final rule represents the culmination of the Agency's effort to develop Clean Water Act (CWA) effluent limitations guidelines and standards for wastewater discharges from the centralized waste treatment industry. This final regulation generally applies to wastewater discharges associated with the operation of new and existing centralized waste treatment facilities which accept hazardous or non-hazardous industrial wastes,

wastewater, and/or used material from off-site for treatment of the wastes and/or recovery of materials from the wastes.

EPA expects compliance with this regulation to reduce the discharge of conventional pollutants by at least 9.7 million pounds per year and toxic and non-conventional pollutants by at least 9.3 million pounds per year. EPA estimates the annual cost of the rule will be \$35.1 million (pre-tax \$1997). EPA estimates that the annual benefits of the rule will range from \$2.56 million to \$8.09 million (\$1997).

This final rule also amends EPA's Guidelines Establishing Test Procedures for the Analysis of Pollutants (40 CFR Part 136) to add 10 semivolatile organic pollutants to Method 625 and 6 semivolatile organic pollutants to Method 1625.

DATES: This regulation shall become effective January 22, 2001. In accordance with 40 CFR 23.2, this action is considered promulgated for purposes of judicial review as of 1 pm Eastern Daylight Time on January 5, 2001.

ADDRESSES: The public record for this rulemaking has been established under docket number W-98-21 and is located in the Water Docket, East Tower Basement, 401 M St. SW, Washington, DC 20460. The record is available for inspection from 9 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. For access to the docket materials, call (202) 260-3027 to schedule an appointment. You may have to pay a reasonable fee for copying.

FOR FURTHER INFORMATION CONTACT: For technical information concerning today's final rule, contact Ms. Jan Matuszko at (202) 260-9126 or Mr. Timothy Connor at (202) 260-3164. For economic information contact Dr. William Wheeler at (202) 260-7905.

SUPPLEMENTARY INFORMATION:**Regulated Entities**

Entities potentially regulated by this action include facilities of the following types that discharge pollutants to waters of the U.S.:

Category	Examples of regulated entities
Industry	- Discharges from stand-alone waste treatment and recovery facilities receiving materials from off-site. These facilities may treat hazardous or non-hazardous waste, hazardous or non-hazardous wastewater, and/or used material from off-site, for disposal, recycling, or recovery. - Certain discharges from waste treatment systems at facilities primarily engaged in other industrial operations. Thus, industrial facilities which process their own, on-site generated, process wastewater with hazardous or non-hazardous wastes, wastewaters, and/or used material received from off-site, in certain circumstances, may be subject to this rule with respect to a portion of their discharge.

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be regulated by this action. This table lists the types of entities that EPA is aware could potentially be regulated by this action. Other types of entities not listed in the table could also be regulated. To determine whether your facility is regulated by this action, you should carefully examine the applicability criteria listed in Section 437.1 and the definitions in Section 437.2 of the rule and detailed further in Section V of this preamble. If you still have questions regarding the applicability of this action to a particular entity (after consulting Section V), consult one of the persons listed for technical information in the preceding **FOR FURTHER INFORMATION CONTACT** section.

Compliance Dates

Existing direct dischargers must comply with limitations based on the best practicable technology currently available, the best conventional pollutant control technology, and the

best available technology economically achievable as soon as their National Pollutant Discharge Elimination System (NDPES) permits includes such limitations. Existing indirect dischargers subject to today's regulations must comply with the pretreatment standards for existing sources no later than December 22, 2003. New direct and indirect discharging sources must comply with applicable guidelines and standards on the date the new sources begin discharging.

Supporting Documentation

The final regulations are supported by several major documents:

1. "Development Document for Final Effluent Limitations Guidelines and Standards for the Centralized Waste Treatment Industry" (EPA-821-R-00-020) referred to in the preamble as the final technical development document (TDD). This TDD presents the technical information that formed the basis for EPA's decisions concerning the final rule. In it, EPA describes, among other things, the data collection activities, the

wastewater treatment technology options considered, the pollutants found in CWT wastewaters, and the estimation of costs to the industry to comply with final limitations and standards.

2. "Economic Analysis of Final Effluent Limitations Guidelines and Standards for the Centralized Waste Treatment Industry" (EPA-821-R-00-024) referred to in this preamble as the Final EA. The EA estimates the economic and financial costs of compliance with the final regulation on individual process lines, facilities and companies.

3. "Detailed Costing Document for the Final Effluent Limitations Guidelines and Standards for the Centralized Waste Treatment Industry" (EPA-821-R-00-021) referred to in this preamble as the Final Costing Document. This document presents the methodology used to estimate compliance costs for this final rule.

4. "Cost Effectiveness Analysis of Final Effluent Limitations Guidelines and Standards for the Centralized Waste

Treatment Industry" (EPA-821-R-00-023) referred to in this preamble as the Cost Effectiveness Report.

5. "Environmental Assessment for the Final Effluent Limitations Guidelines and Standards for the Centralized Waste Treatment Industry" (EPA-821-R-00-022) referred to as the Final Environmental Assessment in this preamble.

How To Obtain Supporting Documents

All of the supporting documents are available from the Office of Water Resource Center, MC-4100, U.S. EPA, 401 M Street, SW, Washington, DC 20460; telephone (202) 260-7786 for publication requests.

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 Appendix 1: Definitions, Acronyms, and Abbreviations

I. Legal Authority

The U.S. Environmental Protection Agency is promulgating these regulations under the authority of Sections 301, 304, 306, 307, 308, 402, and 501 of the Clean Water Act, 33 U.S.C. 1311, 1314, 1316, 1317, 1318, 1342, and 1361.

II. Background

A. Clean Water Act

Congress adopted the Clean Water Act (CWA) to “restore and maintain the chemical, physical, and biological integrity of the Nation’s waters” (Section 101(a), 33 U.S.C. 1251(a)). To achieve this goal, the CWA prohibits the discharge of pollutants into navigable waters except in compliance with the statute. The Clean Water Act confronts the problem of water pollution on a number of different fronts. Its primary reliance, however, is on establishing restrictions on the types and amounts of pollutants discharged from various industrial, commercial, and public sources of wastewater.

Congress recognized that regulating only those sources that discharge effluent directly into the nation’s waters would not be sufficient to achieve the CWA’s goals. Consequently, the CWA requires EPA to promulgate nationally applicable pretreatment standards that restrict pollutant discharges for those who discharge wastewater indirectly through sewers flowing to publicly-owned treatment works (POTWs) (Section 307(b) and (c), 33 U.S.C. 1317(b) and (c)). National pretreatment standards are established for those pollutants in wastewater from indirect dischargers which may pass through or interfere with POTW operations. Generally, pretreatment standards are designed to ensure that wastewater from direct and indirect industrial dischargers are subject to similar levels of treatment. In addition, POTWs are required to implement local pretreatment limits applicable to their industrial indirect dischargers to satisfy any local requirements (40 CFR 403.5).

Direct dischargers must comply with effluent limitations in National Pollutant Discharge Elimination System (NPDES) permits; indirect dischargers must comply with pretreatment standards. These limitations and standards are established by regulation for categories of industrial dischargers and are based on the degree of control that can be achieved using various levels of pollution control technology.

1. Best Practicable Control Technology Currently Available (BPT)—Section 304(b)(1) of the CWA

In the regulations, EPA defines BPT effluent limits for conventional, priority,¹ and non-conventional pollutants. In specifying BPT, EPA looks at a number of factors. EPA first considers the cost of achieving effluent reductions in relation to the effluent reduction benefits. The Agency also considers the age of the equipment and facilities, the processes employed and any required process changes, engineering aspects of the control technologies, non-water quality environmental impacts (including energy requirements), and such other factors as the Agency deems appropriate (CWA 304(b)(1)(B)). Traditionally, EPA establishes BPT effluent limitations based on the average of the best performances of facilities within the industry of various ages, sizes, processes or other common characteristic. Where existing performance is uniformly inadequate, EPA may require higher levels of control than currently in place in an industrial category if the Agency determines that the technology can be practically applied.

2. Best Conventional Pollutant Control Technology (BCT)—Section 304(b)(4) of the CWA

The 1977 amendments to the CWA required EPA to identify effluent reduction levels for conventional pollutants associated with BCT for discharges from existing industrial point sources. In addition to other factors specified in Section 304(b)(4)(B), the CWA requires that EPA establish BCT limitations after consideration of a two part “cost-reasonableness” test. EPA

¹ In the initial stages of EPA CWA regulation, EPA efforts emphasized the achievement of BPT limitations for control of the “classical” pollutants (e.g., TSS, pH, BOD5). However, nothing on the face of the statute explicitly restricted BPT limitations to such pollutants. Following passage of the Clean Water Act of 1977 with its requirement for point sources to achieve best available technology limitations to control discharges of toxic pollutants, EPA shifted its focus to address the listed priority pollutants under the guidelines program. BPT guidelines continue to include limitations to address all pollutants.

explained its methodology for the development of BCT limitations in July 1986 (51 FR 24974).

Section 304(a)(4) designates the following as conventional pollutants: biochemical oxygen demand (BOD5), total suspended solids (TSS), fecal coliform, pH, and any additional pollutants defined by the Administrator as conventional. The Administrator designated oil and grease as an additional conventional pollutant on July 30, 1979 (44 FR 44501).

3. Best Available Technology Economically Achievable (BAT)—Section 304(b)(2) of the CWA

In general, BAT effluent limitations guidelines represent the best economically achievable performance of plants in the industrial subcategory or category. The factors considered in assessing BAT include the cost of achieving BAT effluent reductions, the age of equipment and facilities involved, the process employed, potential process changes, and non-water quality environmental impacts, including energy requirements. The Agency retains considerable discretion in assigning the weight to be accorded these factors. BAT limitations may be based on effluent reductions attainable through changes in a facility’s processes and operations. As with BPT, where existing performance is uniformly inadequate, BAT may require a higher level of performance than is currently being achieved based on technology transferred from a different subcategory or category. BAT may be based upon process changes or internal controls, even when these technologies are not common industry practice.

4. New Source Performance Standards (NSPS)—Section 306 of the CWA

NSPS reflect effluent reductions that are achievable based on the best available demonstrated control technology. New facilities have the opportunity to install the best and most efficient production processes and wastewater treatment technologies. As a result, NSPS should represent the most stringent controls attainable through the application of the best available control technology for all pollutants (i.e., conventional, non-conventional, and priority pollutants). In establishing NSPS, EPA is directed to take into consideration the cost of achieving the effluent reduction and any non-water quality environmental impacts and energy requirements.

5. Pretreatment Standards for Existing Sources (PSES)—Section 307(b) of the CWA

PSES are designed to prevent the discharge of pollutants that pass through, interfere-with, or are otherwise incompatible with the operation of publicly-owned treatment works (POTW). The CWA authorizes EPA to establish pretreatment standards for pollutants that pass through POTWs or interfere with treatment processes or sludge disposal methods at POTWs. Pretreatment standards for existing sources are technology-based and analogous to BAT effluent limitations guidelines.

The General Pretreatment Regulations, which set forth the framework for the implementation of national effluent guidelines and standards, are found at 40 CFR Part 403. Those regulations contain a definition of pass-through that addresses localized rather than national instances of pass-through and establish pretreatment standards that apply to all non-domestic discharges.

6. Pretreatment Standards for New Sources (PSNS)—Section 307(b) of the CWA

Like PSES, PSNS are designed to prevent the discharges of pollutants that pass through, interfere-with, or are otherwise incompatible with the operation of POTWs. PSNS are to be issued at the same time as NSPS. New indirect dischargers have the opportunity to incorporate into their plants the best available demonstrated technologies. The Agency considers the same factors in promulgating PSNS as it considers in promulgating NSPS.

B. Section 304(m) Requirements

Section 304(m) of the CWA, added by the Water Quality Act of 1987, requires EPA to establish schedules for (1) reviewing and revising existing effluent limitations guidelines and standards ("effluent guidelines") and (2) promulgating new effluent guidelines. On January 2, 1990, EPA published an Effluent Guidelines Plan (55 FR 80) that established schedules for developing new and revised effluent guidelines for several industry categories. One of the industries for which the Agency established a schedule was the Hazardous Waste Treatment Industry.

The Natural Resources Defense Council (NRDC) and Public Citizen, Inc. filed suit against the Agency, alleging violation of Section 304(m) and other statutory authorities requiring promulgation of effluent guidelines (*NRDC et al. v. Reilly*, Civ. No. 89-2980

(D.D.C.)). Under the terms of the consent decree in that case, as amended, EPA agreed, among other things, to propose effluent guidelines for the "Centralized Waste Treatment Industry" category by April 31, 1994 and take final action by August 2000.

C. The Land Disposal Restrictions Program

1. Introduction to RCRA Land Disposal Restrictions (LDR)

The Hazardous and Solid Waste Amendments (HSWA) to the Resource Conservation and Recovery Act (RCRA), enacted on November 8, 1984, largely prohibit the land disposal of untreated hazardous wastes. Once a hazardous waste is prohibited from land disposal, the statute provides only two options for legal land disposal: Meet the treatment standard for the waste prior to land disposal, or dispose of the waste in a land disposal unit that has been found to satisfy the statutory no-migration-test. A no-migration-unit is one from which there will be no migration of hazardous constituents for as long as the waste remains hazardous (RCRA Sections 3004(d),(e),(g)(5)).

Under section 3004, the treatment standards that EPA develops may be expressed as either constituent concentration levels or as specific methods of treatment. The criteria for these standards is that they must substantially diminish the toxicity of the waste or substantially reduce the likelihood of migration of hazardous constituents from the waste so that short-term and long-term threats to human health and the environment are minimized (RCRA Section 3004(m)(1)). For purposes of the restrictions, the RCRA program defines land disposal to include any placement of hazardous waste in a landfill, surface impoundment, waste pile, injection well, land treatment facility, salt dome formation, salt bed formation, or underground mine or cave. Land disposal restrictions are published in 40 CFR Part 268.

EPA has used hazardous waste treatability data as the basis for land disposal restrictions standards. First, EPA has identified Best Demonstrated Available Treatment Technology (BDAT) for each listed hazardous waste. BDAT is that treatment technology that EPA finds to be the most effective for a waste, which is also readily available to generators and treaters. In some cases, EPA has designated, for a particular wastestream, a treatment technology which has been shown to successfully treat a similar, but more difficult to treat, wastestream. This ensured that the

land disposal restrictions standards for a listed wastestream were achievable since they always reflected the actual treatability of the waste itself or of a more refractory waste.

As part of the Land Disposal Restrictions (LDR), Universal Treatment Standards (UTS) were promulgated as part of the RCRA phase two final rule (July 27, 1994). The UTS are a series of concentrations for wastewaters and non-wastewaters that provide a single treatment standard for each constituent. Previously, the LDR regulated constituents according to the identity of the original waste; thus, several numerical treatment standards might exist for each constituent. The UTS simplified the standards by having only one treatment standard for each constituent in any waste residue.

The LDR treatment standards established under RCRA may differ from the Clean Water Act effluent guidelines published here today both in their format and in the numerical values set for each constituent. The differences result from the use of different legal criteria for developing the limits and resulting differences in the technical and economic criteria and data sets used for establishing the respective limits.

The difference in format between the LDR and effluent guidelines is that LDR establishes a single daily limit for each pollutant parameter whereas the effluent guidelines generally establish monthly and daily limits. Additionally, the effluent guidelines provide for several types of discharge, including new vs. existing sources, and indirect vs. direct discharge.

The differences in numerical limits established under the Clean Water Act may differ, not only from LDR and UTS, but also from point-source category to point-source category (for example, Electroplating, 40 CFR Part 413; and Metal Finishing, 40 CFR Part 433). The effluent guidelines and standards are industry-specific, subcategory-specific, and technology-based. The numerical limits are typically based on different data sets that reflect the performance of specific wastewater management and treatment practices. Differences in the limits reflect consideration of the CWA statutory factors that the Administrator is required to evaluate in developing technically and economically achievable limitations and standards. A consequence of these differing approaches is that similar wastestreams can be regulated at different levels.

2. Overlap Between LDR Standards and the Centralized Waste Treatment Industry Effluent Guidelines

EPA's survey for this guideline identified no facilities discharging wastewater effluent to land disposal units. There is, consequently, no overlap between this regulation for the CWT Industry and the Universal Treatment Standards. Any CWT facility, however, discharging effluent to a land disposal unit that meets these limitations and standards would meet the Universal Treatment Standards.

III. Centralized Waste Treatment Industry Effluent Guideline Rulemaking History

A. January 27, 1995 Proposal

On January 27, 1995, EPA proposed regulations (60 FR 5464) to reduce discharges to navigable waters of toxic, conventional, and non-conventional pollutants in wastewater from facilities defined in the proposal as "centralized waste treatment facilities." As proposed, these effluent limitations guidelines and standards would have applied to "any facility that treats any hazardous or non-hazardous industrial waste received from off-site by tanker truck, trailer/roll-off bins, drums, barge or other forms of shipment." The proposal did not extend to facilities that received waste from off-site solely via pipeline. Facilities

proposed for regulation included both stand-alone waste treatment and recovery facilities that treat waste received from off-site, as well as those facilities that treat on-site generated process wastewater with wastes received from off-site.

The Agency proposed limitations and standards for an estimated 85 facilities in three subcategories. EPA proposed limitations and standards for three subcategories for the centralized waste treatment (CWT) industry: metal-bearing waste treatment and recovery, oily waste treatment and recovery, and organic waste treatment and recovery. EPA based the BPT effluent limitations proposed in 1995 on the technologies listed in Table III.A-1 below. EPA based BCT, BAT, NSPS, PSES, and PSNS on the same technologies as BPT.

TABLE III.A-1.—TECHNOLOGY BASIS FOR 1995 PROPOSAL

Proposed subpart	Name of subcategory	Technology basis
A	Metal-Bearing Waste Treatment and Recovery	Selective Metals Precipitation, Pressure Filtration, Secondary Precipitation, Solid-Liquid Separation, and Tertiary Precipitation. For Metal-Bearing Waste Which Includes Concentrated Cyanide Streams: Pretreatment by Alkaline Chlorination at Elevated Operating Conditions.
B	Oily Waste Treatment and Recovery	Emulsion Breaking/Gravity Separation and Ultrafiltration; or Emulsion Breaking/Gravity Separation, Ultrafiltration, Carbon Adsorption, and Reverse Osmosis.
C	Organic Waste Treatment and Recovery	Equalization, Air Stripping, Biological Treatment, and Multimedia Filtration.

B. September 16, 1996 Notice of Data Availability

Based on comments received on the 1995 proposal and new information, EPA reexamined its conclusions about the Oily Waste Treatment and Recovery subcategory, or "oils subcategory." (The 1995 proposal had defined facilities in this subcategory as "facilities that treat, and/or recover oil from oily waste received from off-site.") Subsequently, in September 1996 EPA announced the availability of the new data on this subcategory (61 FR 48800). EPA explained that it had underestimated the size of the oils subcategory, and that the data used to develop the original proposal may have mischaracterized this portion of the CWT industry. EPA had based its original estimates on the size of this segment of the industry on information obtained from the 1991 Waste Treatment Industry Questionnaire. The basis year for the questionnaire was 1989. However, many of the new oils facilities discussed in this notice began operation after 1989. EPA concluded that many of these

facilities may have started up or modified their existing operations in response to requirements in EPA regulations, specifically, the provisions of 40 CFR 279, promulgated on September 10, 1992 (Standards for the Management of Used Oil). These regulations govern the handling of used oils under the Solid Waste Disposal Act and the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA). EPA's 1996 notice discussed the additional facilities, provided a revised description of the subcategory, and described how the 1995 proposal limitations and standards, if promulgated, would have affected such facilities. The notice, among other items, also solicited comments on the use of dissolved air flotation as a treatment technology for this subcategory.

C. January 13, 1999 Supplemental Proposal

On January 13, 1999 (64 FR 2280), EPA published a supplemental proposal that represented the Agency's second

look at Clean Water Act national effluent guidelines and standards for wastewater discharges from centralized waste treatment facilities. The supplemental proposal presented revised limitations and standards based on the new information obtained from comments to the 1996 Notice of Data Availability and additional field sampling data. It also included changes to the scope of the rule.

In the supplemental proposal, the Agency proposed limitations and standards that EPA estimated would apply to 206 facilities in three subcategories. These subcategories were the same as those proposed in 1995: metal-bearing waste treatment and recovery, used/waste oil treatment and recovery, and organic waste treatment. EPA based the BPT effluent limitations proposed in 1999 on different technologies than those selected at the time of the 1995 proposal. The technology bases for the supplemental proposal are listed in Table III.C-1 below.

TABLE III.C-1.—TECHNOLOGY BASIS FOR 1999 PROPOSAL

Proposed subpart	Name of subcategory	Technology basis
A	Metal-Bearing Waste Treatment and Recovery	Batch Precipitation, Liquid-Solid Separation, Secondary Precipitation, Clarification, and Sand Filtration. For Metal-Bearing Waste Which Includes Concentrated Cyanide Streams: Alkaline Chlorination in a two step process.
B	Used/Waste Oil Treatment and Recovery	Emulsion Breaking/Gravity Separation, Secondary Gravity Separation and Dissolved Air Flotation.
C	Organic Waste Treatment	Equalization and Biological Treatment.

For the metals subcategory, EPA proposed limitations and standards for BCT, BAT, and PSES based on the same technologies as BPT, but based NSPS and PSNS on a different technology: selective metals precipitation, liquid-solid separation, secondary precipitation, liquid-solid separation, tertiary precipitation, and clarification.

For the oils subcategory, EPA proposed to base BCT, BAT, NSPS, and PSNS on the same technologies as BPT, but based PSES on a different technology: emulsion breaking/gravity separation and dissolved air flotation.

For the organics subcategory, EPA proposed to base BCT, BAT, NSPS, PSES, and PSNS on the same technologies as BPT.

IV. Re-Consideration of Significant Proposal Issues and Summary of Significant Changes Since Proposal

A. Oils Subcategory—Consideration of Regulatory Options on the Basis of the RCRA Classification of the Waste Receipts

As explained in the 1999 proposal, among other alternatives, EPA was considering whether it should develop limitations and standards for two categories (rather than a single category) of oils treatment facilities. The Small Business Advocacy Review (SBAR) Panel for this rule, convened by EPA in November 1997, discussed this option. For a detailed summary of the panel's findings and discussion, see the 1999 proposal and "Final Report of the SBREFA Small Business Advocacy Review Panel on EPA's Planned Proposed Rule for Effluent Limitations Guidelines and Standards for the Centralized Waste Treatment Industry" (DCN 21.5.1). Under this approach EPA would establish different limitations and standards for oils subcategory facilities depending on whether they treat RCRA subtitle C hazardous wastes (either exclusively or in combination with non-hazardous wastes) or treat only non-hazardous wastes.

At the time of the SBAR Panel, EPA had collected certain information on facilities that treat a mixture of

hazardous and non-hazardous wastes as well as facilities that treat non-hazardous wastes only. The bulk of the data was from RCRA facilities treating RCRA subtitle C hazardous waste together with non-hazardous waste. The data on wastestreams did not show a significant difference in the types of pollutants for the streams being treated at RCRA and at non-RCRA permitted facilities or the treatability of those pollutants. Although the data did suggest that pollutant concentrations tended to be somewhat higher in raw waste going to RCRA permitted facilities, which in turn suggested that treatment would be more cost-effective at such facilities, the information EPA had collected from non-RCRA permitted facilities was insufficient to support the conclusion that EPA should differentiate between oils facilities on the basis of RCRA classification of the wastes treated at the facility. Consequently, EPA did not propose different regulatory requirements for facilities based on distinctions between hazardous and non-hazardous wastes.

EPA, following the SBAR panel, collected wastewater samples at twelve other facilities that treat only non-hazardous materials. EPA collected the samples in order to broaden the database with additional information on the pollutant profiles of the wastes that are treated at these facilities. While EPA included the analytical results of the sampling efforts in the Appendix of the technical development document for the proposal, EPA had not, at the time of the proposal, reviewed the data in detail or compared the data to the earlier data it had collected. As the proposal also explained, EPA planned to review the data in detail and present a preliminary assessment of its findings at a public hearing during the comment period for the proposal.

At a public hearing on February 18, 1999, EPA described the relevant sampling data, the constraints of evaluating this data, and a comparison of data from hazardous and non-hazardous wastestreams. This data showed that, while the mean and

median values of influent concentration of hazardous wastestream data are greater than for non-hazardous wastestreams for most pollutants examined, the ranges of concentration for the hazardous and non-hazardous wastestreams overlap for most pollutants. In its presentation, EPA indicated that it planned to re-examine the oils subcategory in terms of pollutant loadings, removals, limitations and standards, costs, impacts, and benefits. EPA requested comment on this issue, and extended the comment period for this issue to 30 days after the public hearing. EPA's presentation is included in the public record for this rulemaking as DCN 28.1.1. [Other supporting information is in Section 28.]

Five commenters provided specific input on basing regulatory options for the oils subcategory on the RCRA classification of the waste receipts. Two commenters supported differentiation on this basis. They asserted that there are significant differences between facilities that accept non-hazardous wastes and those that accept a combination of hazardous and non-hazardous waste in terms of pollutant loadings and the number and type of pollutants, the types of treatment methods employed, and price structures. Three commenters opposed differentiation based on RCRA classification. These commenters do not believe that RCRA classification is a critical distinction, but rather believe that RCRA classification often has no impact on the treatability of the waste or final effluent quality. They commented that non-hazardous waste receipts have approximately the same constituents as hazardous waste receipts. From an environmental perspective, they believe that it is irrelevant whether the source of the pollutants of concern is a hazardous or non-hazardous facility.

EPA has reexamined this data using the same standards it applied earlier in this rulemaking for determining pollutants of concern for this industry (see Chapter 6 of the Final Technical

Development Document). Based on this review, EPA determined that the pollutants of concern for non-hazardous facilities are largely the same as those previously identified for the oils subcategory (EPA had based its earlier conclusion on data from facilities processing a mix of hazardous and non-hazardous waste receipts).

EPA also looked to see if the treatment technologies at strictly non-hazardous facilities differ from those at facilities that accept both hazardous and non-hazardous wastes. EPA's database shows that the range of treatment technologies employed at both types of facilities is similar.

Essentially, the only operational difference EPA has observed between hazardous and non-hazardous oils treatment facilities is that hazardous oils waste facilities treat wastes with higher influent concentrations. EPA's data show that the average pollutant concentrations in non-hazardous wastes are lower than in hazardous wastes. Consequently, pollutant loadings, removals and treatment cost estimates will differ to some extent depending on the RCRA classification of the wastes that are treated. As explained above, however, both types of facilities treat for the same pollutants and the concentration ranges of these pollutants overlap at hazardous and non-hazardous operations. In these circumstances, the characteristics of wastes treated at hazardous operations do not require a different treatment technology from that used at non-hazardous operations. The choice of treatment technology for a particular facility is a function primarily of the effluent concentration required, not of any inherent differences in the wastes being treated. As a result, EPA concluded that there is no basis in the chemistry of the wastewaters being treated which supported development of different limitations and standards for hazardous and non-hazardous oils facilities. Furthermore, after evaluating treatment technology costs, EPA found that the costs for RCRA permitted facilities were equivalent to those for non-RCRA facilities, although, as noted above, loadings reductions at the non-RCRA permitted facilities will generally be lower. Given these factors, EPA decided that it should not develop different limitations and standards for RCRA hazardous and non-hazardous oils facilities. DCN 33.1.1 discusses the determination in more detail. EPA notes, however, that its estimates of loadings, removals, and revenue generated from treating the different types of wastes take account of differences in the type of wastes treated.

B. Consideration of Regulatory Options on the Basis of Revenue

As detailed in the 1999 proposal, among other alternatives, EPA looked at whether it should develop alternative regulatory requirements for the oils subcategory facilities based on revenue because of potential adverse economic consequences to small businesses. The SBAR Panel, convened by EPA, discussed this option. Among the regulatory alternatives discussed by the panel and detailed in the 1999 proposal was limiting the scope of the rule to minimize impacts. Under this approach, EPA would not establish national pretreatment standards for indirect dischargers owned by small companies with less than \$6 million in annual revenue. EPA did not propose to limit the scope of the rule based on this approach but did request comment on the issue.

Concerning the recommendation that EPA establish alternative limitations and standards on the basis of revenue, commenters largely supported EPA's conclusion that this approach should not be adopted. Commenters stated that small businesses should be subject to the same standards and requirements as other industrial users in this category because:

- The limitations and standards are economically achievable for small CWT facilities;
- The perception that small CWT facilities do not have the potential to cause significant impacts to the environment is not true;
- The quantity of pollutants present and the toxicity of the pollutants are the only relevant factors for determining impacts to receiving streams and POTWs from CWT discharges;
- The business size is irrelevant to the impact of a facility's discharges;
- A small facility can have as great an impact on the environment as a large facility;
- There would be no incentive to ensure wastes are adequately treated at all CWT facilities;
- Small facilities could operate at a fraction of the cost (since they would not have to meet the limitations and standards) and capture more market share leading to more wastes going to the POTW untreated; and
- Large facilities could easily manipulate their corporate structure to take advantage of small business exemptions.

None of the commenters supported a small business exclusion, but a few noted that EPA should look at reducing monitoring requirements for small businesses in order to reduce their costs

of compliance without compromising effective treatment. None of the commenters provided EPA with any other suggestions on ways to mitigate small business concerns that EPA had not already considered. After careful consideration of the comments and its database, EPA has decided that it should not limit the scope of today's rule based on revenue. EPA did reassess the costs for all of the alternatives discussed in the proposal for the final rule. Chapter 8 of the Final EA includes a full presentation of the costs of the alternatives.

C. Consideration of Regulatory Options on the Basis of Flow

As detailed in the 1999 proposal, among other alternatives, EPA looked at whether it should develop alternative regulatory requirements for the oils subcategory facilities based on wastewater flow level because of potential adverse economic consequences to small businesses. The SBAR Panel, convened by EPA, discussed this option. Among the regulatory alternatives discussed by the panel and detailed in the 1999 proposal was limiting the scope of the rule to minimize impacts. Under this approach, EPA would not establish national pretreatment standards for indirect oils dischargers with flows under 3.5 million gallons per year, or alternately for non-hazardous oils facilities with flows under either 3.5 or 7.5 MGY. The SBAR Panel noted, in particular, that excluding indirect dischargers with flows of less than 3.5 MGY would significantly reduce the economic impact of the rule on small businesses while reducing pollutant removals by an estimated 6%. (See Section X.M of this preamble for a more detailed discussion of regulatory flexibility options and their projected impacts.) EPA did not propose to limit the scope of the rule based on these approaches but did request comment on the issue.

Concerning the recommendation that EPA establish alternative limitations and standards on the basis of flow, commenters largely supported EPA's conclusion that this approach should not be adopted. Commenters stated that low flow facilities should be subject to the same standards and requirements as other industrial users in this category because:

- The perception that small CWT facilities do not have the potential to cause significant impacts to the environment is not true;
- The amount of pollutants in wastewater for a CWT facility is not a function solely of the volume of wastes that the facility receives;

- The quantity of pollutants present and the toxicity of the pollutants are the only relevant factors for determining impacts to receiving streams and POTWs from CWT discharges;

- A small facility can have as great an impact on the environment as a large facility;

- There would be no incentive to ensure wastes are adequately treated at all CWT facilities; and

- Small facilities could operate at a fraction of the cost (since they would not have to meet the limitations and standards) and capture more market share leading to more wastes going to the POTW untreated.

None of the commenters supported an exclusion based on flow, but a few noted that EPA should look at reducing monitoring requirements for small businesses in order to reduce their costs of compliance without compromising effective treatment. None of the commenters provided EPA with any other suggestions on ways to mitigate small business concerns that EPA had not already considered. After careful consideration of the comments and its database, EPA has decided that it should not limit the scope of today's rule based on flow. EPA did reassess the costs for all of the alternatives discussed in the proposal for the final rule. Chapter 8 of the Final EA includes a full presentation of the costs of the alternatives.

D. Consideration of Indicator Parameters for the Oils Subcategory

As detailed in the proposal, EPA looked at various ways to reduce the costs of this rule (particularly the costs to small businesses) while ensuring proper treatment of off-site wastes. One of the options considered by EPA and discussed in the proposal was providing an alternative compliance-monitoring regime for indirect discharging facilities. Under this alternative monitoring approach, facilities could choose to (1) monitor for all regulated pollutants, or (2) monitor for the conventional parameters, metal parameters, and monitor for the regulated organic pollutants in this subcategory using an indicator parameter such as hexane extractable material (HEM) or silica gel treated-hexane extractable material (SGT-HEM). The proposal further noted that EPA was conducting a study to determine which organic pollutants are measured by SGT-HEM and HEM and solicited comment on the use of indicator parameters.

Many commenters responded to EPA's request with essentially an equivalent number opposing and favoring the use of indicator parameters.

The commenters that supported its use cited the decreased analytical costs and the wide range of organic compounds that can be measured with these analyses. Commenters that did not support the use of SGT-HEM or HEM as indicator pollutants raised a number of concerns including the following:

- These measurements are non-specific and highly subject to interferences;

- No direct and quantified correlation has ever been developed between HEM (or SGT-HEM) and specific organic pollutants;

- There is no evidence that regulating HEM or SGT-HEM would result in adequate regulation of toxics;

- The determination has not been made that the organic pollutants of interest are measured by either HEM or SGT-HEM; and

- SGT-HEM does not measure all of the regulated pollutants, particularly polycyclic aromatic hydrocarbons (PAHs).

None of the commenters suggested possible alternative indicator parameters.

During its development of proposed effluent limitations guidelines and pretreatment standards for the industrial laundries point source category, EPA evaluated the suitability of SGT-HEM and HEM as indicator parameters for that rulemaking. EPA presented the results of its study in a Notice of Data Availability on December 23, 1998 (63 FR 71054). In the study, EPA attempted to identify compounds present in HEM/SGT-HEM extracts from industrial laundry wastewaters using gas chromatography/mass spectroscopy (GC/MS) in order to determine which pollutants of concern might be components of, and therefore measured by, HEM or SGT-HEM. However, EPA was only able to identify approximately two percent of the constituents present in the wastestream. Most of these constituents identified were alkanes. In general, the data from this study also do not support the use of SGT-HEM as an appropriate indicator parameter for the organic pollutants present in CWT wastewaters since few of these pollutants were identified in the HEM/SGT-HEM extract.

As part of its consideration of the use of an indicator parameter for this rule, EPA again reviewed the data from the industrial laundries study as well as the data collected here. EPA statistically analyzed the relationship between seven organic pollutants and SGT-HEM or HEM. EPA's data show general trends of increasing concentrations of HEM and SGT-HEM with increasing concentrations of organic pollutants. However, the data demonstrate

substantial variability and, despite this general trend, EPA noted that the non-detected values for organics were associated with just about every level of HEM and SGT-HEM and conversely, that high levels of some organic pollutants were associated with low levels of HEM/SGT-HEM. As a result, EPA cannot demonstrate that establishing a numerical limit for SGT-HEM or HEM would provide consistent control of the organic pollutants by the model treatment technologies.

Therefore, while EPA is cognizant of the cost savings that can be achieved in some instances by using indicator parameters, EPA has rejected this alternative monitoring approach for CWT wastewaters.

E. Consideration of Reduced Monitoring for Small Businesses

Another alternative discussed in the proposal which could reduce costs to small businesses was to develop different limitations and pretreatment standards for small businesses based on an assumption of less frequent monitoring for facilities owned and operated by small businesses. The proposal explained that there were three major issues presented by this approach. First, EPA NPDES and pretreatment regulations (applicable to State-authorized program as well) do not require facilities to indicate whether they are small or large businesses in obtaining NPDES or POTW local pretreatment program discharge permits. EPA was concerned about the manner in which the small business determination could be made. Second, EPA does not generally establish nationally applicable monitoring frequency requirements. EPA expressed concern that permitting authorities would be reluctant to reduce monitoring frequencies on EPA's recommendation alone. Third, while the technology basis and the long-term averages for the limitations would be the same, the monthly average limitations based upon reduced monitoring assumptions would be higher. EPA expressed concern that higher monthly average limitations for facilities with less frequent required monitoring might allow these facilities to target a less stringent level of treatment than that reflected by the long-term average. EPA solicited comment on all these issues as well as ways to ensure that any monitoring relief the Agency might provide would not jeopardize treatment performance or the environment.

EPA only received direct comments on this issue from state and local control authorities. These commenters did not support reduced monitoring frequencies

for small businesses. They believe that the control authority should continue to establish monitoring frequencies on a case by case basis taking into account the probable impact of the discharge to the surface water or POTW, compliance history of the facility, and other relevant factors. Further they expressed concern over the burden of verifying and maintaining the confidentiality of the economic information provided by facilities claiming the small business status.

Therefore, after careful consideration of comments and its database, EPA has rejected adopting alternative limitations and standards based on reduced monitoring requirements for small businesses.

F. Multiple Wastestream Subcategory Consideration

In the 1999 proposal, EPA proposed to establish limitations and standards for three subcategories of CWT facilities: facilities treating either metal, oily, or organic wastes and wastewater. Section VII of the proposal detailed this subcategorization scheme. See 64 FR 2300 (1999). While EPA did not propose limitations and standards for a multiple wastestream subcategory, the proposal did discuss EPA's consideration of a multiple wastestream subcategory. The proposal explained that multiple wastestream subcategory limitations, if adopted, would apply to facilities that treat wastes in more than one subcategory. EPA would establish limitations and standards for the multiple wastestream subcategory by combining pollutant limitations from the three subcategories, where relevant, and selecting the most stringent value where they overlap.

EPA's consideration of this option responded to comments to the 1995 proposal and the 1996 Notice of Data Availability. The primary reason some members of the waste treatment industry favored development of a multiple wastestream subcategory was to simplify implementation for facilities treating wastes covered by multiple subcategories. As detailed in the proposal, EPA's primary reason for not proposing (and adopting) this option was its concern that facilities that accept wastes in multiple subcategories need to provide effective treatment of all waste receipts. This concern was based on EPA's data that showed such facilities did not currently have adequate treatment-in-place. While these facilities meet their permit limitations, EPA concluded that compliance was likely achieved through co-dilution of dissimilar wastes rather than treatment. As a result, EPA determined that

adoption of "multiple wastestream subcategory" limitations as described above could arguably encourage ineffective treatment.

EPA solicited comments on ways to develop a "multiple wastestream subcategory" which ensures treatment rather than dilution. The vast majority of comments on the 1999 proposal supported the establishment of a multiple wastestream subcategory for this rule, and re-iterated their concerns about implementing the three-subcategory scheme at multiple-subcategory facilities. One commenter suggested a way to implement a fourth subcategory while ensuring treatment. This commenter suggested that EPA follow the approach taken for the Pesticide Formulating, Packaging and Repackaging (PFPR) Point Source category (40 CFR Part 455). Under this approach, multiple wastestream subcategory facilities would have the option of (1) monitoring for compliance with the appropriate subcategory limitations after each treatment step or (2) monitoring for compliance with the multiple wastestream subcategory limitations at a combined discharge point and certifying that equivalent treatment to that which would be required for each subcategory waste separately is installed and properly designed, maintained, and operated. This option would eliminate the use of the combined wastestream formula or building block approach in calculating limits or standards for multiple wastestream subcategory CWT facilities (The combined wastestream formula and the building block approach are discussed in more detail in Chapter 14 of the Final Technical Development Document). Commenters suggested that an equivalent treatment system could be defined as a wastewater treatment system that is demonstrated to achieve comparable removals to the treatment system on which EPA based the limitations and standards. Ways of demonstrating equivalence might include data from recognized sources of information on pollution control, treatability tests, or self-monitoring data showing comparable removals to the applicable pollution control technology.

EPA has now concluded that the approaches adopted in the PFPR rule address the concerns identified earlier. EPA agrees with commenters that developing appropriate limitations on a site-specific basis for multiple wastestream facilities presents many challenges and that the use of a multiple wastestream subcategory would simplify implementation of the rule. Moreover, the limits applied to multiple wastestream treaters would be a

compilation of the most stringent limits from each applicable subcategory and would generally be similar to or stricter than the limits calculated via the application of the combined wastestream formula or building block approach. Most significantly, the equivalent treatment certification requirement would address EPA's concerns that the wastes receive adequate treatment.

Therefore, for today's final rule, EPA has established a fourth subcategory: the multiple wastestream subcategory. Section XIII.A.5.b details the manner in which EPA envisions the multiple wastestream subcategory will be implemented. Further, EPA is preparing a guidance manual to aid permit writers/control authorities and CWT facilities in implementing the certification process.

G. Analytical Methods

Section 304(h) of the Clean Water Act directs EPA to promulgate guidelines establishing test procedures for the analysis of pollutants. These test procedures (methods) are used to determine the presence and concentration of pollutants in wastewater, and are used for compliance monitoring and for filing applications for the NPDES program under 40 CFR 122.21, 122.41, 122.44 and 123.25, and for the implementation of the pretreatment standards under 40 CFR 403.10 and 403.12. EPA publishes test procedures for the wastewater program at 40 CFR 136.3. Currently approved methods for metals and cyanide are included in the table of approved inorganic test procedures at 40 CFR 136.3, Table I-B. Table I-C at 40 CFR 136.3 lists approved methods for measurement of non-pesticide organic pollutants, and Table I-D lists approved methods for the toxic pesticide pollutants and for other pesticide pollutants. Dischargers must use the test methods promulgated at 40 CFR Part 136.3 or incorporated by reference in the tables to monitor pollutant discharges from the centralized waste treatment (CWT) industry, unless specified otherwise in part 437 or by the permitting authority.

Today's final rule amends 40 CFR Part 136, Appendix A, to specify the applicability of certain methods for specific wastestreams. The amendments accomplish several objectives, which are outlined in the following paragraphs. Briefly, the amendments clarify EPA's intent regarding the applicability of Methods 625 and 1625 for some of the pollutant parameters in today's rule for Centralized Waste Treatment facilities and also for some of

the pollutant parameters in 40 CFR 445 (Landfills Point Source Category).

The 1999 CWT proposal (at 64 FR 2297) stated that 11 CWT semivolatile organic pollutants and two CWT volatile organic pollutants (2-butanone and 2-propanone) were not listed in Table I-C at 40 CFR 136.3. Even though these 13 analytes were not shown in Table I-C, there were already approved test methods for six of these 13, as follows: EPA Method 1624 lists 2-butanone and 2-propanone, provides performance data for these two analytes, and is an approved method for these two analytes. EPA Method 1625 lists four of the 11 CWT semivolatile organic pollutants with relevant performance data and is an approved method for these four analytes (alpha-terpineol, carbazole, n-decane, and n-octadecane).

In the 1999 CWT proposal, EPA proposed to expand the analyte list for the already-approved methods and also to allow modified versions of Methods 625 and 1625. The Docket for the proposed rulemaking included the proposed modifications to Methods 625 and 1625 regarding expansion of the analyte list. The expanded list covered 17 pollutants in total, including all of the proposed CWT semivolatile organic pollutants. For 7 of those analytes, performance data were not available for either method and these data were not included in the Docket at proposal. EPA also noted its plans for further validation of the method modifications.

Since proposal, EPA has gathered performance data on the additional seven CWT analytes and additional analytes of interest for other industry categories. In January 2000, EPA amended Methods 625 and 1625 by adding the performance data for the additional analytes. The amendments consist of text, performance data, and quality control (QC) acceptance criteria for the additional analytes. This information will allow a laboratory to practice the methods with the additional analytes as an integral part. The QC acceptance criteria for the additional analytes were validated in single-laboratory studies. The January 2000 amendments were part of the rulemaking notice for the effluent limitations guidelines and standards for the Landfills Point Source Category (65 FR 3008, January 19, 2000). EPA's intent was to promulgate amendments to Methods 625 and 1625 that would allow the use of those methods for specific pollutants regulated in 40 CFR Part 445 (i.e., Landfills) for purposes of that rule only. Some of the pollutants had also been included in the CWT proposal. Subsequent to the Landfills promulgation, EPA received inquiries

about the scope and applicability of the amendments to the test methods. In response to those inquiries, EPA published a notice of data availability (NODA) and request for comment on the data collected for the additional analytes (see 65 FR 41391, July 5, 2000).

The NODA clarified EPA's intent regarding the method amendments by explaining that the amendments published on January 19, 2000 " * * * are applicable only to the five regulated pollutants in the Landfills rule when found in the wastestreams regulated under that rule." (65 FR 41392) The NODA also announced EPA's plans to further amend the methods in the final CWT rulemaking (i.e., today's rulemaking) to specify that the revisions to Methods 625 and 1625 apply to the pollutants promulgated in today's rule and only for the wastestreams regulated in today's rule. In today's amendments to 40 CFR Part 136, Appendix A, EPA thus clarifies its intent regarding the scope of method amendments. Specifically, the amendments include additional text to the Introduction section of the attachment at the end of Methods 625 and 1625 and footnotes to Tables in the attachment. The amendments delineate the scope of Methods 625 and 1625 regarding compliance with monitoring requirements for the wastestreams covered by 40 CFR Parts 437 and 445. In addition, EPA deleted from the attachment to the methods those analytes not covered by the Landfills and CWT final rules.

H. Statistical Methodology Changes

Chapter 10 of the Final Technical Development Document provides a detailed description of the data and methodology used to develop long-term averages, variability factors and limitations and standards for today's final rule. Today's final rule encompasses the following changes in the statistical methodology since the 1999 proposal.

1. Metals Option 4 Long-Term Average and Limitations Calculations

EPA used two different data sets collected at a single facility in developing long-term averages and limitations for Option 4 in the Metals Subcategory. At the time of the proposal, EPA analyzed these data sets separately. That is, even though these data were collected from the same facility, EPA averaged each data set separately and then used the medians of the two sets of averages, just as if the data were from two different facilities. In other effluent guidelines, EPA has often taken this approach when the data

were collected by two different data sources. Following comment on this issue, EPA reviewed the data and determined that the data were collected in overlapping time periods. As such, for the final rule, EPA has combined this data together into a single data set and calculated averages accordingly. This has the effect of giving more weight than in the original analysis to the data set with more observations and the result, in most instances, is that the final metals subcategory limitations are less stringent than those proposed in January 1999.

2. Variability Factors

The proposal discussed two different approaches to calculating variability factors—one based on pollutant variability factors and one based on group variability factors. The pollutant variability factor is the average of the variability factors from facilities with the model technologies for the option, and the group variability factor is the median of the pollutant variability factors from pollutants with similar chemical structures. At the time of the proposal, EPA generally used the product of the group variability factor and the pollutant long-term average in calculating each pollutant limitation and solicited comment on this approach. After receiving comments that supported using the pollutant variability factors, EPA assessed the range of values for the pollutant variability factors within each group. Contrary to EPA's expectations for chemically similar pollutants to be treated similarly by each treatment technology, EPA noted a wide range of values for the pollutant variability factors within each group. EPA determined that it is more likely that such ranges resulted from unique features in the data rather than differences in treatment between chemically similar pollutants. But, because of the range in values, EPA concluded that pollutant limitations would be best calculated using the pollutant variability factors. Because it determined that pollutant variability factors were the most appropriate choice for calculating limitations, EPA relaxed its dataset requirements slightly to allow calculation of a few additional pollutant variability factors beyond those in the proposal. For the few pollutants where pollutant variability factors still could not be calculated because the datasets contained too few detected values (which are used to establish variance estimates for the variability factors), EPA concluded that its use of group variability factors provides reasonable estimates of pollutant specific

variability factors. After a final review and evaluation of the data and resulting limitations, EPA determined that the final limitations appropriately incorporate the variability of the pollutant concentrations discharged by the CWT industry.

I. Significant Changes in Treatment Technology Cost Estimates

Chapter 11 of the Final Technical Development Document provides a detailed description of the data and methodology used to develop compliance cost estimates for the final CWT regulation. This section provides a summary of major changes in the costing methodology since the 1999 proposal.

1. RCRA Permit Modification Costs Removed

In estimating compliance costs for the proposed regulation, EPA included RCRA permit modification capital costs as one component of the total capital costs. This was an error. The wastewater treatment unit exemption at 40 CFR 264.1(g)(6), 40 CFR 265.1(c)(10), and 40 CFR 270.1(c)(2)(v) exempts, from RCRA permit modification requirements, wastewater treatment units at facilities that are subject to NPDES or pretreatment requirements under the Clean Water Act. Thus, CWT facilities would not need to modify their RCRA permits as a result of this rule and would not incur these RCRA permit modification costs. The final rule does not include these RCRA permit modification costs.

2. Altered DAF Costs for Oils Subcategory Includes Increased Holding Tank Capacity

At the time of the proposal, for facilities with flow rates less than 20 gallons per minute (gpm), EPA included cost estimates for a holding tank. EPA included the holding tank because it assumed that facilities with flow rates less than 20 gpm would not operate their DAF systems every day.

Regardless of the flow rate, EPA's design assumption for the holding tank was one day of storage. EPA received comment that many oils subcategory facilities may require more than 24 hours of storage and thus, EPA did not allow adequate holding capacity for all facilities. In response to this comment, EPA has altered the DAF capital costs to include holding tanks capable of retaining enough flow volume to operate the minimum size DAF system for one 24-hour period, in addition to the holding tank capacity costed at proposal.

3. Nutrient Addition, Heating, and Sludge Disposal Costs Included in the Organic Subcategory Compliance Cost Estimates

At the time of the proposal, EPA estimated operational costs for the technology option selected as the basis for the organics subcategory limitations on the actual practices used at the facility sampled during EPA's sampling episode. This did not include chemical addition or heating of wastes. In response to public comment concerning the need, on occasion, for chemical addition (nutrient addition, pH control, etc.) and heating of the waste during cold temperature months, EPA modified its capital and O&M cost estimates for sequencing batch reactor (SBR) treatment to include costs for nutrient addition and adjustments for cold operating conditions. These adjustments are detailed in Section 3.1 of the "Final Costing Document."

Additionally, at the time of the proposal, EPA included capital costs and O&M costs for sludge processing equipment associated with the organics subcategory, but failed to include costs for sludge disposal. EPA has corrected this oversight, and added a separate cost estimate for SBR system sludge disposal.

J. Significant Changes in Oils Subcategory Loadings Estimates

At the time of the 1999 proposal, EPA did not distinguish between facilities with RCRA permits and facilities without RCRA permits when it estimated current pollutant loadings for the oils subcategory. Rather, EPA had seven sets of data representing effluent from emulsion breaking/gravity separation that were collected at various types of oils subcategory facilities. For each pollutant of concern, and for each data set, EPA calculated the mean concentration of the data collected over the sampling episode. Then, for the remaining facilities in the oils subcategory (*i.e.*, those facilities for which EPA did not have facility-specific information), EPA randomly assigned one of the seven data sets. For facilities that had additional treatment-in-place, EPA then reduced these current loadings estimates as detailed in Chapter 12 of the Final Technical Development Document.

For the final CWT rule, EPA has altered this approach. In estimating loadings and removals for the oils subcategory, EPA used data specific to either RCRA or non-RCRA permitted facilities. EPA no longer estimates current performance by randomly assigning a data set as described above.

Rather, for each pollutant of concern, EPA has calculated a single concentration value for RCRA permitted facilities and a single concentration value for non-RCRA permitted facilities; both values represent effluent from emulsion breaking/gravity separation. (This is assumed to be the minimum treatment in-place at all oils facilities; only removals beyond this and any other in-place treatment are projected to result from this rule.) The specific methodology used to calculate these values and EPA's final methodology used to estimate pollutant loadings and removals for the entire CWT industry are detailed in Chapter 12 of the Final Technical Development Document.

K. Changes in POTW Percent Removal Estimates

EPA establishes pretreatment standards for those BAT pollutants that pass through POTWs. Therefore, for indirect dischargers, before establishing pretreatment standards, EPA examines whether the pollutants discharged by the industry "pass through" POTWs to waters of the U.S. or interfere with POTW operations or sludge disposal practices. Generally, to determine if pollutants pass through POTWs, EPA compares the percentage of the pollutant removed by well-operated POTWs achieving secondary treatment with the percentage of the pollutant removed by facilities meeting BAT effluent limitations.

The primary source of the POTW percent removal data is the "Fate of Priority Pollutants in Publicly Owned Treatment Works" (EPA 440/1-82/303, September 1982), commonly referred to as the "50-POTW Study." The 50-POTW Study presents data on the performance of 50 well-operated POTWs that employ secondary biological treatment in removing pollutants.

At the time of the 50-POTW sampling program, which spanned approximately 2½ years (July 1978 to November 1980), EPA collected samples at selected POTWs across the U.S. The samples were subsequently analyzed by either EPA or EPA-contract laboratories using test procedures (analytical methods) specified by the Agency or in use at the laboratories. Laboratories typically reported the analytical method used along with the test results. However, for those cases in which the laboratory specified no analytical method, EPA was able to identify the method based on the nature of the results and knowledge of the methods available at the time.

Each laboratory reported results for the pollutants for which it tested. If the

laboratory found a pollutant to be present, the laboratory reported a result. If the laboratory found the pollutant not to be present, the laboratory reported either that the pollutant was "not detected" or a value with a "less than" sign (<) indicating that the pollutant was below that value. The value reported along with the "less than" sign was the lowest level to which the laboratory believed it could reliably measure. EPA subsequently established these lowest levels as the "minimum levels" of quantitation (MLs). In some instances, different laboratories reported different MLs for the same pollutant using the same analytical method.

Because of the variety of reporting protocols among the 50-POTW Study laboratories (pages 27 to 30, 50-POTW Study), EPA reviewed the percent removal calculations used in the pass-through analysis for previous industry studies, including those performed when developing the CWT proposal and effluent guidelines for Organic Chemicals, Plastics, and Synthetic Fibers Manufacturing, Landfills, and Commercial Hazardous Waste Combustors. EPA found that, for 12 parameters, different analytical MLs were reported for different rulemaking studies (10 of the 25 metals, cyanide, and one of the 41 organics).

To provide consistency for data analysis and establishment of removal efficiencies, EPA reviewed the 50-POTW Study, standardized the reported MLs for use in the CWT final rules and other rulemaking efforts. (This review of the 50-POTW Study analytical laboratory reporting practices and standardization of ML values is described further in DCN 33.3.1).

In using the 50-POTW Study data to estimate percent removals, EPA has established data editing criteria for determining pollutant percent removals. Some of the editing criteria are based on differences between POTW and industry BAT treatment system influent concentrations. For many toxic pollutants, POTW influent concentrations were much lower than those of BAT treatment systems. For many pollutants, particularly organic pollutants, the effluent concentrations from both POTW and BAT treatment systems, were below the level that could be found or measured. As noted in the 50-POTW Study, analytical laboratories reported pollutant concentrations below the analytical ML, qualitatively, as "not detected" or "trace," and reported a measured value above this level. Subsequent rulemaking studies such as the 1987 OCPSF study used the analytical method ML established in 40 CFR Part 136 for laboratory data

reported below the analytical ML. Use of the nominal ML may overestimate the effluent concentration and underestimate the percent removal. Because the data collected for evaluating POTW percent removals included both effluent and influent levels that were close to the analytical MLs, EPA devised hierarchical data editing criteria to exclude data with low influent concentration levels, thereby minimizing the possibility that low POTW removals might simply reflect low influent concentrations instead of being a true measure of treatment effectiveness.

EPA has generally used hierarchical data editing criteria for the pollutants in the 50-POTW Study. For the final CWT rule, the editing criteria include

(1) Substitute the standardized pollutant-specific analytical ML for values reported as "not detected," "trace," "less than [followed by a number]," or a number less than the standardized analytical ML,

(2) Retain pollutant influent and corresponding effluent values if the average pollutant influent level is greater than or equal to 10 times the pollutant ML (10xML), and

(3) If none of the average pollutant influent concentrations are at least 10 times the ML, then retain average influent values greater than or equal to two times the ML (2xML) along with the corresponding average effluent values. (EPA used 2xML for the final rule, instead of the 20 µg/l criterion used at proposal, because it more accurately reflects the pollutant-specific data than using a fixed numerical cut-off. For 67 percent of the of pollutants, 2xML is 20 µg/l.)

EPA then calculates each POTW percent removal for each pollutant based on its average influent and its average effluent values. The national POTW percent removal used for each pollutant in the pass-through test is the median value of all the POTW pollutant specific percent removals.

The 50-POTW study provided performance data for 48 pollutants of concern for both the 1999 proposal and today's final rule (15 metals, 31 organics, cyanide, and ammonia). These corrections resulted in lower national POTW performance (median percent removal) for 5 metals and ammonia; in higher performance for 5 metals; and no change for the remaining 5 metals, 31 organics, and cyanide.

V. Scope/Applicability of the Regulation

Many of the commenters had questions about what waste treatment facilities were subject to the guideline

and in what circumstances. The sections which follow address these issues.

A. Overview

A broad spectrum of facilities engage in waste treatment and waste recovery operations. For some, waste treatment and recovery is their only business. Many of these facilities treat wastes generated in a variety of industries. In addition, there are also a significant number of facilities that are dedicated exclusively to the recovery of a single metal. For other facilities, waste treatment is merely an ancillary component of the industrial operation at the facility. There are still others engaged in industrial activities that the acceptance and treatment of waste (not generated in their own production operations) represents a substantial and integral aspect of the business.

EPA has always intended that these guidelines would regulate the first category of waste treaters. It has struggled, however, with how to draw the line, for purposes of applying this rule between the other types of operations. For example, as noted above, there are certain industries that recover a single metal. EPA has already developed guidelines specifically addressing their particular industrial processes and pollutants. In those circumstances it would make little sense to subject them to regulations developed for waste treatment operations treating a mixture of different wastes.² The data collected for this effort, however, clearly show that there are other industrial operations whose waste treatment operations treat a variety of wastes from on-site and off-site sources. The wastes treated at these industries do not look substantially different from those being treated at facilities engaged exclusively in waste treatment. The discussion below explains how EPA has decided to strike the balance.

The universe of facilities which are potentially subject to this guideline generally includes the following. First, except where noted otherwise, EPA is establishing limitations and standards for stand-alone waste treatment and recovery facilities receiving materials from off-site—classic "centralized waste treaters." These facilities may treat either for disposal or for recovery or recycle hazardous or non-hazardous waste, hazardous or non-hazardous

² EPA has already established national effluent guidelines and standards for certain metals recovery operations. See, for example, subpart C of 40 CFR part 421—Nonferrous Metals Manufacturing Point Source Category that establishes limitations and standards applicable to discharges resulting from the recovery, processing and remelting of aluminum scraps to produce metallic aluminum alloys.

wastewater, or used material received from off-site. Second, while EPA is generally not subjecting discharges from waste treatment systems at facilities primarily engaged in other industrial operations to the scope of this rule, the rule will regulate at least a portion of their wastewater in certain circumstances. Thus, industrial facilities which process their own, on-site generated, process wastewater along with hazardous or non-hazardous wastes, wastewaters, and/or used material received from off-site may be subject to this rule with respect to a portion of their discharge unless certain conditions are met.

The wastewater flows covered by this rule include some or all flows related to off-site waste receipts and on-site CWT wastewater generated as a result of CWT operations. The kinds of on-site CWT

wastewater generated at these facilities include, for example, the following: solubilization wastewater, emulsion breaking/gravity separation wastewater, used oil processing wastewater, treatment equipment washes, transport washes (tanker truck, drum, and roll-off boxes), laboratory-derived wastewater, air pollution control wastewater, landfill wastewater from on-site landfills, and contaminated storm water. Chapter 14 of the technical development document provides detailed discussion of CWT wastewaters.

The way EPA has expressed the applicability provisions of the final rule is to apply the provisions of this rule to all wastewater discharges to a receiving stream or the introduction of wastewater to a publicly owned treatment works from a facility that this regulation defines as a centralized waste treatment

facility unless specifically excluded. The following sections discuss the applicability of the CWT rule to various wastewater discharges associated with centralized waste treatment operations.

EPA received numerous comments on the 1995 proposal and 1996 Notice of Data Availability concerning the applicability of this rule to various operations. Consequently, EPA devoted significant discussion in the 1999 supplemental proposal to applicability issues. Again, in response, EPA received numerous comments on applicability issues. Many commenters were simply seeking clarification of the coverage of this rule to a specific operation. Table V.A-1 below provides a general summary of regulated and non-regulated CWT operations. EPA presents a detailed discussion of these operations in V.B through V.Z.

TABLE V.A-1.—EXAMPLES OF REGULATED AND NON-REGULATED CWT OPERATIONS

Centralized waste treatment activity	Regulated by this rule	Not regulated by this rule	For further information see
Those performed at federally owned facilities.	All federally owned CWT operations	None	V.E
POTWs	None	All	V.F
Thermal drying of POTW biosolids	None	All	V.H
Sanitary wastes or toilet wastes	None	All	V.Y
Food processing wastes	None	All	V.X
Manufacturing facilities	Those that accept off-site wastes for treatment and/or recovery that are not generated in a manufacturing process subject to the same limitations/standards as on-site generated waste and that the permit writer determines are not similar to, and compatible with treatment of, the on-site waste.	All others	V.B
Product stewardship	Those that accept waste materials from use of their products that are not similar to, and compatible with, treatment of waste generated on-site.	Those that accept back their unused products, shipping and storage containers with product residues, and off-specification products.	V.D
Petroleum refineries (SIC Code 2911) and petroleum distribution terminals (SIC Code 4612, 4613, 5171, 5172).	For off-site materials other than those listed in the next column, see discussion for manufacturing facilities.	Those that receive and manage off-site petroleum-containing materials generated by petroleum exploration, production, transportation, refining and marketing activities.	V.B
Pulp and paper off-site landfill leachates	Those that accept off-site landfill leachates for treatment and/or recovery that are not generated in a manufacturing process subject to the same limitations/standards as on-site generated waste and that the permit writer determines are not similar to, and compatible with, the on-site waste.	All others	V.B
Pipeline materials	Materials received via pipeline from waste consolidators or commingled with other covered CWT wastewaters.	All other piped materials and POTWs	V.C
Recycle/recovery activities	All unless specifically excluded elsewhere.		V.Q
Traditional solvent recovery	None	All	V.T
Fuel blenders	Those that generate a wastewater	"Dry" operations	V.T
Scrap metals recyclers	None	All	V.M
Silver recovery	Only included where wastewater generated from these activities is commingled with other covered wastes.	All others	V.R
Used oil filters & only absorbent recycling	Those that generate a wastewater	"Dry" operations	V.V
High Temperature Metals Recovery (HTMR).	Those that generate a wastewater	"Dry" operations	V.S

TABLE V.A-1.—EXAMPLES OF REGULATED AND NON-REGULATED CWT OPERATIONS—Continued

Centralized waste treatment activity	Regulated by this rule	Not regulated by this rule	For further information see
Used glycol recovery	All	None	V.Q
Re-refining	All	None	V.U
Solids, soils, and sludges	Those activities which generate a wastewater unless specifically excluded.	"Dry" operations	V.L
Stabilization/Solidification	Those that generate a wastewater	"Dry" operations	V.O
Transfer stations and recycling centers ...	None	All	V.N
Incineration activities	Only included when the wastewater generated from these activities is received from off-site and commingled with other covered wastewater.	All others	V.K
Transportation and/or transportation equipment cleaning.	Only included where wastewater generated from these activities is commingled with other covered waters.	All others	V.I
Landfills	Only included where wastewater generated from these activities is commingled with other covered waters.	All others	V.J
Grease trap/interceptor wastes	Those which contain petroleum based oils.	Those which contain animal or vegetable fats/oils.	V.W
Marine generated wastes	Off-loaded and subsequently sent to a CWT facility at a separate location and commingled with other covered wastewater.	All others	V.G
Waste, wastewater or used material re-use.	Those activities not listed in the next column or excluded elsewhere.	Not covered if the wastewater is accepted for use in place of potable water or if materials are accepted in place of virgin treatment chemicals.	V.P
Treatability, research and development, or analytical activities.	Only included where wastewater generated from these activities is commingled with other covered waters.	All others	V.Z

B. Manufacturing Facilities

Throughout the development of this rule, EPA has contemplated that the rule would apply to wastewater discharges from facilities that, while primarily engaged in other industrial operations, also may treat and/or treat for recovery or recycle off-site wastes or used materials. These facilities primarily treat wastes generated as a result of their own on-site manufacturing operations. Their wastewater discharges are, by and large, already subject to effluent guidelines and standards. (Some treatment operations, however, may be located at manufacturing facilities which are not subject to effluent guidelines and standards). All of these facilities also accept off-site generated wastes for treatment. In some instances, a facility under the same corporate ownership generates these off-site wastes. The facility treats these intra-company transfers on a non-commercial basis. In other instances, the off-site wastestreams originate from a company under a different ownership—an inter-company transfer. In some instances, the off-site wastes received at these industrial facilities are generated by a facility performing the same manufacturing operations, while in other instances, the off-site wastestreams are generated by facilities engaged in entirely unrelated

manufacturing operations. Some receive a constant wastestream from only a handful of customers and some receive a wide variety of wastestreams from hundreds of customers.

EPA received extensive comment concerning how the CWT rule should apply to facilities that provide waste treatment and/or recovery operations for off-site generated wastes, but whose primary business is something other than waste treatment or recovery. In general, commenters urged EPA to limit the scope of the regulation in one of several ways. Commenters suggested restricting the scope either to:

- Facilities whose sole purpose is the treatment of off-site wastes and wastewaters; or
- Facilities which only accept off-site wastes on a commercial basis; or
- Facilities which accept off-site wastes which are not produced as a result of industrial operations subject to the same effluent guidelines and standards as the on-site generated wastes or off-site wastes which are not compatible with the on-site generated wastes and the on-site wastewater treatment system; or
- Manufacturing facilities which accept off-site wastes in excess of a de minimis level.

In the supplemental proposal, EPA proposed subjecting centralized waste

treatment operations at manufacturing facilities to the provisions of the rule unless one of the following conditions was met:

- In the case of manufacturing facilities subject to national effluent limitations guidelines for existing sources, standards of performance for new sources, or pretreatment standards for new and existing sources (national effluent guidelines and standards), if the process or operation generating the wastes received from off-site for treatment is subject to the same national effluent guidelines and standards as the process or operation generating the on-site wastes; or
- In the case of manufacturing facilities not subject to existing national effluent guidelines and standards, if the process or operation generating the waste received from off-site is from the same industry (other than the waste treatment industry) and of a similar nature to the waste generated on-site.

After careful consideration of comments and further review of its database, EPA continues to regard this approach as appropriate, with some modifications. EPA has concluded that many manufacturing facilities, even though they are engaged primarily in another business, are also engaged in traditional CWT activities and, therefore, should be subject to this rule.

EPA has been unable to establish any direct correlation between the source of the off-site waste (intra-company or inter-company) and the similarity (or compatibility with) of the off-site waste to the on-site generated wastes that would support a blanket exclusion from this rule for intra-company waste treatment. EPA further concludes that all off-site wastewaters should be treated effectively irrespective of their volume, or their volume in relation to the volume of on-site generated waste and, thus, has rejected any exception for small volumes. As explained in the 1999 proposal, EPA's primary concern is that the effluent guidelines and standards currently in place for one industry may not ensure adequate treatment for wastes generated at another industry.

EPA has, however, concluded that there are circumstances where an off-site waste will receive adequate treatment at the treating facility even though the off-site waste may be generated by a manufacturing process that (if treated at the generating location) would be subject to a different set of effluent guidelines and standards than the effluent guidelines and standards applicable to the treating site. The record for this rule provides information and data on such facilities that support EPA's conclusion. An example is a pesticide formulating and packaging facility (PFPR), subject to 40 CFR 455 Subpart C, which sends its wastewaters off-site for treatment to a facility which manufactures the pesticide active ingredients. (The manufacturing facility is subject to a separate set of effluent guidelines and standards specific to pesticide manufacturers, 40 CFR 455 Subpart A and B). In this case, the same pollutants are likely to be present in the off-site and on-site generated wastewaters, even though the wastewaters are subject to different regulations. Therefore, the treating facility will need to use treatment appropriate for efficient removal of these pollutants. This situation would not be covered by this rule.

As a second example, consider a petroleum refinery that accepts off-site wastewaters. If the petroleum refinery (SIC Code 2911) accepts wastes generated off-site at petroleum distribution terminals (SIC Code 4612, 4613, 5171, and 5172), then the former is subject to effluent guidelines and standards for petroleum refineries (40 CFR 419), but the latter is not currently subject to any national effluent guidelines. However, the wastewaters generated at petroleum marketing terminals are based on materials

manufactured at the refineries, and therefore would likely reflect the same pollutant profile. This situation would not be covered by this rule.

A third example involves clean-up activities at manufacturing sites. As part of clean-up operations at its facility, one commenter (called facility A) noted that it accepts contaminated groundwater from a different manufacturing facility located next door (facility B). The contaminated groundwater site (while not located on facility A, the treating facility) was contaminated by the manufacturing process at the treating site (facility A) and not at the site where located (facility B). As such, the contaminated wastewater would be similar and compatible with the on-site generated wastewater at facility A. In this case, the CWT rule would not apply.

EPA received information on each of the examples provided in comment on the rule. The comments detail instances in which the off-site wastewaters, while not subject to the same national effluent guidelines and standards as the wastewater generated on-site, are similar to the on-site generated manufacturing wastewaters and compatible with the on-site treatment system. In these cases, EPA concluded that the application of the CWT rule may not result in increased environmental protection, but simply add an additional layer of complexity for the treating facility and the permit writer or control authority.

Furthermore, EPA determined there are other instances of off-site waste acceptance at manufacturing facilities in which the off-site wastes, while not from the same industrial category, are similar to the on-site generated manufacturing wastewaters and compatible with the manufacturing wastewater treatment system. Consequently, for purposes of this rule, EPA has decided that, where the dischargers establishes that the wastes being treated are of similar nature and compatible with treatment of the on-site wastes, the CWT limitations and standards will not apply to the resulting discharge. EPA concluded that, in those circumstances, the permit writer or control authority should instead apply the limitations or standards applicable to the treatment of on-site wastewater to wastewaters generated through treatment of the off-site waste. Under the approach adopted for the final rule, the permit writer or control authority will determine whether the off-site generated waste accepted for treatment and/or recovery at a manufacturing facility (whether subject to national effluent guidelines and standards or not)

and commingled for treatment in the on-site treatment system is similar to the on-site generated wastes and compatible with the on-site treatment system. If it is, then the discharge of the treated effluent should be subject to the applicable on-site limitations (or standards) even if the off-site wastes would be subject to a different set of national effluent guidelines and standards as the on-site generated wastes (or no national effluent guidelines and standards) if treated where generated. In the event that the permit writer or control authority makes this determination, the treating facility would be subject to the on-site limits only and not subject to the CWT guideline.

For this final rule, EPA has not rigidly defined when a waste is of similar character and the treatment of it is compatible with the treatment of the on-site wastes, believing that permit writers and control authorities are in the best position to determine this term. Permit writers and control authorities should compare the wastewaters at the manufacturing facility to the off-site generated wastewaters (constituents and concentrations) and the appropriateness of the treatment system to the off-site generated wastewaters on a case by case basis. The final guideline commits the decision that an off-site wastewater is similar and compatible (and thus whether CWT limitations or standards would apply) to the permit writer or control authority. A treating facility must submit information demonstrating to the permit writer or control authority that the off-site waste is similar and compatible. EPA cautions permit writers and control authorities that the judgment of "similar and compatible" should be made based only on the development of a full record on this issue. If the treating facility has not clearly established that the off-site wastewaters are similar to the on-site generated manufacturing wastewaters and compatible with the treatment system in the permit writer's or control authority's best judgment, the permit writer or control authority must apply the CWT limitations (or standards) to the treating facility.

Therefore, EPA has concluded that centralized waste treatment operations at manufacturing facilities will be subject to provisions of the rule unless one of the following conditions is met:

- In the case of a facility subject to national effluent limitation guidelines for existing sources, standards of performance for new sources, or pretreatment standards for new and existing sources, if the facility demonstrates that the wastes received

from off-site for treatment and/or recovery are generated in a process or operation that would be subject to the same national effluent guidelines and standards as the process or operation generating the on-site wastes; or

- In the case of a facility subject to national effluent guidelines and standards if the facility demonstrates that the waste received from off-site is similar in nature to the waste generated on-site and compatible with the on-site treatment system; or

- In the case of a facility not subject to national effluent limitations and standards, if the facility demonstrates that the waste received from off-site is similar in nature to the waste generated on-site and compatible with the on-site treatment system.

EPA contemplates that this approach would be implemented in the following manner. A facility that is currently subject to national effluent limitation guidelines or pretreatment standards receives wastewater from off-site for treatment. The wastewater is commingled for treatment with manufacturing wastewater generated on-site. If the off-site wastewater is subject to the same limitations or standards as the onsite wastewater (or would be if treated where generated) or if the off-site wastewater is similar to the onsite wastewater and compatible with the treatment system, the CWT limitations or standards would not apply to the discharge associated with the off-site wastewater flows. In that case, another guideline or standard applies. If, however, the off-site wastewater is not subject to the same national limitation guidelines or standards (or if none exist) and if the off-site wastewater is not similar to the onsite wastewater and compatible with the treatment system, that portion of the discharge associated with the off-site flow would be subject to CWT requirements. (Of course, the portion of the wastewater generated on-site remains subject to applicable limitations and standards for the facility. If the off-site and on-site wastewaters are commingled prior to discharge, the permit writer or control authority would use the "combined wastestream formula" or "building block approach" to determine limitations for the commingled wastestream).

Certain facilities that are subject to the CWT regulations because they accept wastes whose treatment is not compatible with the treatment of wastes generated on-site may nevertheless be subject to limitations and standards based on the otherwise applicable provisions of 40 CFR Subchapter N. Thus, the final regulations provide for

the permit writer or pretreatment control authority to develop "alternative limitations and standards" for certain facilities in a narrow set of circumstances. See *e.g.*, 40 CFR 437.10(b). Under this approach, which EPA discussed in the 1999 proposal, permit writers or control authorities could require manufacturing facilities that treat off-site wastes to meet all otherwise-applicable categorical limitations and standards for the industries from which the waste was generated. This approach would also determine limitations or standards for any commingled on-site and off-site wastewater using the "combined wastestream formula" or "building block approach." The permit writer or control authority would apply the categorical limitations or standards from the industries generating the wastewater, rather than the CWT limitations or standards, to the off-site portion of the commingled wastestream. The use of the combined wastestream formula and building block approaches for CWT wastes is discussed further in Section XIV.F of the 1999 proposal (64 FR 2342–2343). The permit writer (or pretreatment control authority) may establish alternative limitations and standards only when a facility receives continuous flows of process wastewaters with relatively consistent pollutant profiles from no more than five customers. EPA's information shows that, in practice, permit writers are currently following this approach for facilities that treat off-site waste for no more than five facilities. This approach is not appropriate for facilities that receive variable off-site wastewaters or that service more than a handful of customers.

After further consideration of the above described alternative and careful consideration of comments received on this alternative, EPA determined that the permit writer (or local pretreatment authority) should have the option in a limited set of circumstances of applying the applicable categorical limitations or standards to the off-site wastestreams. This is the approach described above. Thus, the final rule authorizes permit writers or control authorities (at their discretion) to subject the wastewater associated with the treatment of the off-site wastes to limitations or standards based on the categorical limitations or standards from the industries generating the wastewater, rather than applying the CWT limitations or standards to the off-site portion of the commingled wastestream. Consequently, the applicability provisions of Subparts A, B, C and D provide for such authority.

See 40 CFR 437.10(b), 437.20(b), 437.30(b) & 437.40(b).

C. Pipeline Transfers (Fixed Delivery Systems)

EPA did not propose to apply CWT limitations and standards to facilities that receive off-site wastes for treatment solely via an open or enclosed conduit (for example, pipeline, channels, ditches, trenches, *etc.*). EPA did not propose to include pipeline facilities because, based on information obtained by the Agency, facilities that receive all their wastes through a pipeline or trench (fixed delivery systems) from the original source of waste generation receive continuous flows of process wastewater with relatively consistent pollutant profiles. These wastewaters are traditional wastewaters from the applicable industrial category that generally remain constant from day to day in terms of the concentration and type of pollutant parameters. Unlike traditional CWT facilities, their customers and wastewater sources do not change and are limited by the physical and monetary constraints associated with pipelines. The preamble to the 1999 proposal provides additional detail on the characteristics of CWT facilities that accept waste for treatment through pipelines only (64 FR 2286–2287). The preamble also explained that permit writers were applying the "building block approach," in writing current discharge permits for pipeline facilities and that in all cases examined, the treating facility was required to comply with otherwise applicable effluent guidelines and standards.

EPA did not receive any information in response to the 1999 proposed rule that has convinced the Agency to change its treatment of pipeline facilities for purposes of this rule. Consequently, the scope of this final rule excludes wastes that are piped to waste treatment facilities. See 40 CFR 437.1(b)(3). These wastes will continue to be subject to otherwise applicable effluent guidelines and standards. In EPA's view, it is more appropriate for permit writers and control authorities to develop restrictions for treatment facilities that receive wastewater by pipeline on an individual basis by applying the "combined wastestream formula" or "building block" approach.

There are two exceptions to this approach. The first is for facilities that receive waste via conduit (that is, pipeline, trenches, ditches, *etc.*) from facilities that are acting merely as waste collection or consolidation centers that are not the original source of the waste. These wastewaters are subject to the CWT rule. The basis for EPA's exclusion

of waste treatment facilities receiving wastes by pipeline from the scope of the rule was that such facilities did not receive the same types of varying wastes as CWT facilities receiving wastes by truck or tanker. Pipeline facilities receive flows of wastes with consistent pollutant profiles. Waste consolidators, on the other hand, which send their flows to a treatment facility via pipeline are delivering wastes like those typically received by CWT facilities in tanks or trucks. See 40 CFR 437.1(b)(3). The second is for facilities that serve as both CWT facilities and pipeline facilities (i.e., receive waste from off-site via pipeline as well as some other mode of transportation such as trucks). If this type of facility commingles the trucked and piped waste prior to discharge, then both the trucked and piped wastewaters at these facilities are subject to the CWT rule. The basis for the pipeline exclusion no longer applies because the addition of hauled waste introduces variability in pollutant concentrations and characteristics that are not true for the piped wastes. See 40 CFR 437.1(b)(3). However, if such a facility discharges these wastewaters separately, then only the trucked off-site wastewater is subject to provisions of the CWT rule and the piped waste subject to limitations and standards based on the applicable 40 CFR Subchapter N limitations and standards. POTWs are not considered CWTs and are not subject to the limitations and standards of this rule. However, as discussed more fully in Section V.F, POTWs should not be receiving wastes from industrial users subject to national effluent guidelines and standards (either by pipeline or otherwise) that do not comply with applicable pretreatment standards.

D. Product Stewardship

As detailed in the proposed rule (64 FR 2287), many members of the manufacturing community have adopted "product stewardship" programs as an additional service for their customers to promote recycling and reuse of products and to reduce the potential for adverse environmental impacts from chemical products. Commenters defined "product stewardship" in this way: "Taking back spent, used, or unused products, shipping and storage containers with product residues, off-specification products and waste materials from use of products." Generally, whenever possible, these manufacturing plants recover and reuse materials from these products in chemical processes at their facilities. Manufacturing companies that cannot reuse the spent, used, or unused

materials treat these materials/wastewaters in their wastewater treatment plants. EPA's review of the comments suggests that, with few exceptions, the materials treated in the on-site wastewater treatment systems were produced at facilities subject to the same effluent limitations guidelines as the materials being manufactured on-site. In industry's view, such materials are inherently compatible with the treatment system.

In the proposal, EPA explained that it had decided it would treat wastewater generated from materials that are taken back for recycle or re-use under a product stewardship program in the same way it proposed to treat wastewater generated in treating any other off-site waste. If the materials received from off-site under the product stewardship program are produced at an industrial operation subject to the same limitations and standards in 40 CFR Subchapter N as the on-site generated manufacturing wastes, the treating facility would not be subject to CWT requirements with respect to the resulting wastewaters. Because EPA remained concerned that circumstances exist in which used materials or waste products may not be compatible with the otherwise existing treatment system, EPA did not propose a blanket exemption for product stewardship activities from the scope of this rulemaking. Under the proposal, wastewater from the treatment of used products or waste materials would be subject to the CWT rule if it were not produced at facilities subject to the same provisions of Subchapter N as wastewater from the treatment of the other on-site generated wastes.

EPA received numerous comments on this approach. Many commenters claimed that the proposed rule would deter product stewardship activities, and that EPA should not extend the rule to cover wastewater from certain product stewardship activities. Some commented that these materials are generally not "treated," but re-used or recovered, and for that reason they were fundamentally different from other wastes in the CWT industry. Others commented that while EPA's intent seemed to be appropriate, the language was much too restrictive. For example, commenters noted that when a product goes off-site to another manufacturing facility that is subject to different effluent limitation guidelines and standards, the product (while it remains unchanged) would then be subject to a different set of effluent limitations or standards. If the manufacturing facilities which originally produced the product took back the off-spec product from its

customer, the proposal as written, would require that the treating facility be subject to CWT even though the off-spec waste would clearly be the same as those generated on-site.

EPA applauds the efforts of manufacturing facilities to reduce pollution and the environmental impacts of their products and does not want to discourage these practices. Consequently, the final rule does not cover product stewardship activities in certain circumstances. Product stewardship activities at a manufacturing facility which involve taking back their unused products, shipping and storage containers with product residues, and off-spec products will not be subject to provisions of the CWT rule.

Certain other recovery activities may, however, remain subject to this rule. EPA is concerned about the treatment of spent, used or waste materials returned to the original manufacturer when it is treated with on-site wastewater. In some cases, wastewater from these recovery processes may not be compatible with the existing treatment system. The mere fact that these materials may be accepted for re-use or recycling rather than "treatment" does not ensure that resulting wastewaters would be inherently compatible with the treatment system. EPA is unable to see how such activities differ from waste recovery operations that the Agency has concluded should be subject to these guidelines. Here is an illustrative example. An inorganic chemical manufacturer produces industrial chemicals that one of its customers uses in the manufacture of printed circuit boards. The chemical manufacturer accepts spent etchants (waste materials from use of product) from its customer for recovery and re-use of certain metals in its inorganic chemical manufacturing process. (Note that CWT facilities not located at manufacturing sites also accept spent etchants). The recovery process generates a wastewater. Recovery may have introduced into the wastewater many pollutants that were not present in the wastewater generated in producing the inorganic chemical. These pollutants may not be compatible with, or effectively treated, in the treatment process at the inorganic chemical manufacturing facility. The same may be true if the accepting facility determined that spent etchant could not be effectively reused and recovered and directed the material to their wastewater treatment system.

Therefore, EPA has concluded that product stewardship activities that involve taking back spent, used or waste materials from use of products should,

as a general matter, be subject to provisions of this rule unless any of the exclusions established for manufacturing facilities as explained in V.B. would apply. See 40 CFR § 437.1(b)(2) & (4). Thus, those activities that involve used products or waste materials that are not subject to effluent guidelines or standards from the same category as the on-site generated wastes or that are not similar to the on-site generated manufacturing wastes and compatible with the treatment systems (as determined by the permit writer or control authority) are subject to today's rulemaking under 40 CFR § 437.1(b)(2). EPA concluded that this approach will not curtail product stewardship activities, in general, but will ensure that all wastes are treated effectively.

E. Federally Owned Facilities

Throughout development of this rule, EPA's database has included information on CWT facilities owned by the federal government. It has always been EPA's intention that federal facilities which accept wastes, wastewater, or used material from off-site for treatment and/or recovery of materials would be subject to provisions of this rule unless they meet the conditions under which the rule would not apply, *e.g.* treated off-site wastes subject to the same 40 CFR Subchapter N provisions as the federal facility.

EPA's database contains information on 23 federally owned facilities that operate treatment systems. EPA has determined that 15 of these facilities are not subject to provisions of the CWT rule because they do not accept off-site wastes. Of the remaining facilities, 6 are not subject to provisions of the CWT rule because they perform CWT activities to which the rule would not apply. Therefore, EPA has identified 1 federally owned CWT facility that is subject to this rule. EPA has included this facility in all of its analyses.

F. Publicly Owned Treatment Works (POTWs)

Comments to the 1995 and 1999 CWT proposals establish that large and small POTWs accept a large volume of hauled wastes. A special discharge survey conducted by the Association of Metropolitan Sewerage Agencies (AMSA) indicates that 42.5 percent of POTW respondents accept hauled industrial wastes. More recent comments suggest that this may underestimate the volume of hauled wastes POTWs receive.

A large quantity of the wastes trucked to POTWs is septage and chemical toilet wastes. EPA did not evaluate these wastes for regulation and they are not

subject to this rule. EPA would expect that POTWs would adequately treat these sanitary waste flows because EPA would expect septage and chemical toilet wastes to closely resemble sewage with respect to organic content.

POTWs also receive significant volumes of trucked industrial and commercial wastes. Examples of these include wastes subject to pretreatment standards under 40 CFR subchapter N, as well as wastes not subject to national effluent guidelines and standards. These wastes may include oil-water emulsions or mixtures, coolants, tank cleaning water, bilge water, restaurant grease trap wastes, groundwater remediation water, contaminated storm water run-off, interceptor wastewaters, and used glycols. CWT facilities also treat many of these wastes and discharges from these operations may be subject to the final CWT limits.

EPA received numerous comments on how the CWT rule should apply to POTWs. Commenters were largely divided on the applicability of the CWT rule to POTWs. All of the POTWs that commented on the proposal agreed that the CWT rule should not apply to POTWs. They stated that under the CWA, effluent guidelines and pretreatment standards do not apply to POTWs. Rather, as established by the CWA, POTWs are subject to secondary treatment and water quality standards. These commenters further stated that POTWs generally accept trucked wastes as a service to their community to insure that these wastes receive proper treatment. Commenting POTWs further cited that trucked wastes comprise a de minimis portion of the total volume of wastewater treated at their facilities.

Non-POTW commenters were, on the other hand, unanimously of the view that the CWT rule should apply to POTWs. These commenters asserted that POTWs and CWT facilities are competing for many of the same wastestreams, and therefore POTWs should be subject to the same standards as CWT facilities. These commenters stated that POTWs are actively competing for wastestreams not subject to national effluent guidelines and standards, and cautioned that EPA should be concerned that this hauled waste is being accepted with little or no documentation regarding the source, little or no monitoring of the shipments when they arrive, and no pretreatment before mixing with the normal POTW influent. They also expressed concern that POTWs often do not have equivalent treatment compared to CWT facilities and that pollutant reductions are often due to dilution rather than treatment. Finally, many CWT facilities

commented that by not including POTWs in the scope of the CWT rule, EPA might actually increase the discharge of pollutants to the nation's waters since waste generators will have an incentive to ship directly to POTWs thus skipping what would have been effective pretreatment at the CWT facility.

It is clear from reviewing the comments that many commenters may misunderstand the interaction between effluent guidelines and pretreatment standards, and they are consequently confused about how this guideline will affect POTW operations. The following discussion is intended as clarification. Under the CWA, all direct dischargers must comply with technology-based effluent guidelines and any more stringent limitations necessary to meet State water quality standards. In the case of certain pollutants and for certain categories and classes of direct dischargers, EPA promulgates guidelines that establish these technology-based limitations. In the case of POTWs, the CWA specifically identifies the technology—secondary treatment that is the basis for POTW effluent limitations.

In addition, the CWA also requires EPA to establish pretreatment standards for indirect dischargers—those introducing wastewater to a POTW either by pipe or sewer or by transporting the waste by truck or rail to the POTW. These standards are designed to prevent the discharges of pollutants that pass-through, interfere or are otherwise incompatible with POTW operations. The standards are technology-based and analogous to technology-based effluent limitations applicable to direct dischargers. Once EPA has established pretreatment standards, no indirect discharger may introduce wastewater to a POTW for which there are pretreatment standards except in compliance with the standard. The CWA specifically prohibits the owner or operator of any source from violating a pretreatment standard. See section 307(d) of the CWA. This prohibition applies whether the wastewater is discharged through a sewer system or sent to a POTW by truck or rail.

The CWA does authorize a POTW, in limited circumstances, to revise pretreatment standards for a discharger to take account of the POTW's actual removal of a particular pollutant. "Removal credits" may be available to a discharger generally under the following conditions. First, the granting of the removal credit by the POTW must not cause a violation of the POTW's permit limitations or conditions.

Second, the POTW's treatment of the pollutant must not result in a sewage sludge that cannot be used or disposed of in accordance with sewage sludge regulations promulgated pursuant to section 405 of the CWA. See section 307(b) of the CWA.

EPA has promulgated regulations at 40 CFR Part 403 (General Pretreatment Regulations for Existing and New Sources of Pollution) that establish pretreatment standards and requirements that apply to any source introducing pollutants from a non-domestic source into a POTW. These standards include a general prohibition on the introduction of any pollutant that might pass through or interfere as well as prohibitions on specific pollutants such as those that may create a fire or explosion hazard or corrosive structural damage. EPA has also promulgated national effluent pretreatment standards (like the pretreatment standards promulgated here today) for specific industry categories as separate regulations at 40 CFR subchapter N.

The regulations at 40 CFR Part 403 also require all POTWs with a design flow greater than 5 MGD per day to develop a pretreatment program. Moreover, EPA or a State may require a POTW with a design flow that is less than or equal to 5 MGD to develop a pretreatment program if warranted by circumstances in order to prevent pass through or interference. See 40 CFR 403.8(a). These pretreatment programs must require compliance with all applicable pretreatment standards and requirements by industrial users of the POTW. See 40 CFR 403.8(f)(ii). Furthermore, each POTW developing a pretreatment program must develop and enforce specific local limits to implement the general and specific prohibition against pass-through and interference. See 40 CFR 403.5(c). Thus, any POTW subject to the requirement to develop a pretreatment program that accepts waste that does not comply with a general or specific prohibition or with national effluent pretreatment standards is in violation of the regulations.

Consequently, following promulgation of today's rule, POTWs with pretreatment programs that receive wastestreams both subject to and not regulated by national effluent standards and limitations must ensure the wastestreams do not violate these requirements. In practice, with respect to the wastestreams discussed by commenters, this means that a POTW may not accept untreated wastestreams subject to national effluent guidelines and standards. These would include wastestreams subject to pretreatment standards in 40 CFR subchapter N (e.g.,

electroplating wastes). Moreover, a POTW may not accept certain other streams not subject to national guidelines and standards such as oil-water emulsions or mixtures if those streams contain pollutants that would pass through or interfere with POTW operation. Note that 40 CFR 403.5(b)(5) specifically prohibits the introduction into a POTW of petroleum oil that will cause pass-through or interference. Given EPA's conclusion here that oily wastewaters contain pollutants that will pass through POTWs, it is likely that many POTWs are accepting wastes for treatment that contain pollutants that will pass through.

EPA is concerned that wastestreams accepted at POTWs, both those subject to and those not regulated by national effluent guidelines and standards, receive proper treatment. In 1999, EPA's Office of Wastewater Management published the "Guidance Manual for the Control of Wastes Hauled to Publicly Owned Treatment Works" (EPA 833-B-98-003, September 1999). This document again stresses that national effluent pretreatment standards apply to waste generated by national effluent guidelines and standards (40 CFR parts 401 to 471), whether the waste is introduced to the POTW through the sewer system or hauled to the POTW. Moreover, EPA regulations require that POTWs must ensure pretreatment of wastes subject to national effluent standards received at the POTW regardless of the mode of transportation.

Similarly, because a POTW must ensure that no user is introducing pollutants into the POTW that would pass-through the POTW into the receiving waters or interfere with the POTW operation, EPA strongly recommends that each POTW should document and monitor all hauled wastestreams to ensure that necessary pretreatment steps have been performed. The guidance establishes a waste acceptance procedure that clearly resembles that generally performed at CWT facilities. Further, in the case of wastestreams not subject to national guidelines and standards, the POTW should also monitor the hauled wastestreams to ensure that pollutant reductions at the POTW will be achieved through treatment and not dilution.

Based on the types of hauled wastewater that commenters have indicated POTWs accept, EPA shares the concern of many commenters that pollutant reductions in these hauled wastewaters at POTWs are largely due to dilution. EPA reminds POTWs that wastewaters that contain significant quantities of metal pollutants,

significant quantities of petroleum-based oil and grease, or significant quantities of non-biodegradable organic constituents should be pretreated by the generating facility or an appropriate treatment facility prior to acceptance at the POTW. EPA further reminds POTWs that this remains true regardless of whether or not these wastewaters comprise a de minimis portion of the total volume of the wastewaters treated at their facility. EPA concluded that if POTWs monitor hauled wastes appropriately and additionally ensure that all hauled wastes not subject to national effluent guidelines and standards can be effectively treated with their biological treatment systems then many of the issues raised by non-POTW commenters will be alleviated.

EPA is aware of a POTW that plans to open a wastewater treatment system to operate in conjunction with its POTW operations. This facility would accept wastewaters subject to national guidelines and standards, treat them, and then discharge them to the POTW's treatment plant. The acceptance by a POTW of wastes subject to national effluent guidelines and standards that do not comply with pretreatment standards would seem to violate the requirements noted above unless the POTW has revised the applicable standards to take account of its removal of certain pollutants. EPA's regulations at 40 CFR § 403.7 describe the process for obtaining removal credits and identifying the pollutants for which removal credits may be available. Under the current regulations, removal credits are only available for a limited number of pollutants. The 1999 notice described the removal credits program and when and for what pollutants such credits might be available at 64 FR 2339-10. EPA would note that the new wastewater treatment system would itself be a POTW (or part of the POTW) and, thus, any wastewater introduced to it must meet all applicable pretreatment standards. However, because POTWs are already covered by the technology requirements (*i.e.*, secondary treatment) specified in the CWA (40 CFR 133), they are not considered CWT facilities and are not within the scope of today's rule.

G. Marine Generated Wastes

In the proposed rule (64 FR 2291), EPA defined marine waste as waste generated as part of the normal maintenance and operation of a ship, boat, or barge operating on inland, coastal or open waters. Such wastes may include ballast water, bilge water, and other wastes generated as part of routine ship operations. The proposal further explained that EPA considered

wastewater off-loaded from a ship as being generated on-site at the point where it is off-loaded provided that the waste is generated as part of the routine maintenance and operation of the ship on which it originated while at sea. The waste is not considered an off-site generated waste (and thus subject to CWT requirements) as long as it is treated and discharged at the ship servicing facility where it is off-loaded. Therefore, EPA proposed not to include these facilities as CWT facilities. The proposal further clarified that if marine generated wastes are off-loaded and subsequently sent to a CWT facility at a separate location and commingled with other covered wastewater, these facilities and their wastestreams would be subject to provisions of this rule.

After careful consideration of comments, EPA has not modified its approach for marine generated waste with one exception. For today's rule, EPA defines marine waste as waste generated as part of the normal maintenance and operation of a ship, boat, or barge operating on inland, coastal or open waters, or while berthed. See 40 CFR § 437.1(c)(2). In response to commenters' requests for clarification, EPA has changed the definition to clarify that wastes generated while ships are berthed are part of normal maintenance and operational activities and are thus "on-site." As a further point of clarification, waste generated while a ship is berthed is not an off-site generated waste so long as it is treated and discharged at the ship servicing facility where it is off-loaded. If, however, marine generated wastes are off-loaded and subsequently sent to a CWT facility at a separate location and commingled with other covered wastewater, these facilities and their wastestreams are subject to provisions of this rule.

H. Thermal Drying of POTW Biosolids

The thermal drying of POTW biosolids was not a focus of EPA's initial regulatory effort to develop this guideline. Consequently, EPA did not target thermal dryers during its data collection activities. However, commenters to the 1999 proposal provided information on thermal drying activities and requested EPA's views as to whether such operations would be subject to this rule. Thermal dryers accept off-site generated POTW biosolids (sludges that remain after wastewater treatment at a POTW) and treat these biosolids with a variety of technologies (e.g. rotary drum dryers) to form pellets. These biosolids can then be land applied. The thermal drying process generates two primary

wastewater streams: facility water wash down and blowdown from wet scrubbers. These wastewaters are discharged back to the POTW that produced the biosolids.

Commenters to the 1999 proposal requested that EPA not include these activities within the scope of this rule for the following reasons:

- The POTW and the thermal dryer form a closed loop system. POTWs are the sole source of off-site waste received by thermal dryers. All wastewaters generated from the treatment of these biosolids are returned to the generator (the POTW).
- All storage and processing areas at these facilities are enclosed. Therefore, this material poses very little or no threat to storm water.
- Thermal drying activities bear little resemblance to the other regulated activities. Mandated testing parameters and other requirements under the CWT rule have little applicability to biosolids processing.

EPA agrees with commenters that thermal drying of biosolids should not be subject to provisions of the CWT rule. Because the only source of off-site wastes received at these drying facilities is biosolids produced at the POTW, the wastewater being generated from thermal drying of these biosolids should contain the same pollutants being treated at the POTW. As a result, the wastewater should be completely compatible with the treatment system at the POTW and should not cause any pass-through or interference. Consequently, thermal drying of POTW biosolids is not subject to provisions of the CWT rule. See 40 CFR 437.1(b)(4).

I. Transporters and/or Transportation Equipment Cleaners

Facilities that treat wastewater that results from cleaning tanker trucks, rail tank cars, or barges may be subject to the provisions of this rule if not subject to the Transportation Equipment Cleaning (TEC) Point Source Category guidelines (40 CFR Part 442). Thus, for example, the CWT rule does not apply to discharges from wastewater treatment at facilities engaged exclusively in cleaning the interiors of transportation equipment covered by the TEC regulation. EPA promulgated these guidelines on August 14, 2000 at 65 FR 49666. The TEC regulation applies to facilities that solely accept tanks which have been previously emptied or that contain a small amount of product, called a "heel," typically accounting for less than one percent of the volume of the tank. A facility that accepts for cleaning a tank truck, rail tank car, or barge not "empty" for purposes of TEC

may be subject to the provisions established for the CWT rule.

There are some facilities that are engaged in traditional CWT activities and also engaged in traditional TEC activities. If the wastewaters from the two operations are commingled, under the approach adopted for TEC, the commingled wastewater flow from the transportation equipment cleaning activities would be subject to CWT limits. Therefore, a facility performing transportation equipment cleaning as well as other CWT services that commingles these wastes is a CWT facility and all of the wastewater discharges are subject to provisions of this rule. If, however, a facility is performing both operations and the wastestreams are not commingled (that is, transportation equipment cleaning process wastewater is treated in one system and CWT wastes are treated in a second, separate system), both the TEC rule and CWT rule apply to the respective wastewaters. See 40 CFR 437.1(b)(10).

As a further point of clarification, the CWT rule does apply to transportation equipment cleaning wastewater received from off-site. Transportation equipment cleaning wastes received from off-site that are treated at CWT facilities along with other off-site wastes are subject to provisions of this rule.

J. Landfill Wastewaters

EPA published effluent limitations guidelines for Landfills, (40 CFR Part 445) at 65 FR 3007, (January 19, 2000). There, EPA established limits for facilities which operate landfills subject to the provisions established in 40 CFR Parts 257, 258, 264, and 265. The final Landfills rule limitations do not apply to wastewater associated with landfills operated in conjunction with other industrial or commercial operations in most circumstances.

In the CWT industry, there are some facilities that are engaged both in CWT activities and in operating landfills. For the CWT final rule, EPA's approach to facilities which treat mixtures of CWT wastewater and landfill wastewater is consistent with that established for the landfill guideline. Therefore, a facility performing landfill activities as well as other CWT services that commingles the wastewater is a CWT facility only, and all of the wastewater discharges are subject to the provisions of this rule. If a facility is performing both operations and the wastestreams are not commingled (that is, landfill wastewater is treated in one treatment system and CWT wastewater is treated in a second, separate, treatment system), the provisions of the Landfill rule and CWT

rule apply to their respective wastewater.

Additionally, under the approach established in the Landfills rulemaking, CWT facilities which are dedicated to landfill wastewater only, whether they are located at a landfill site or not, are subject to the effluent limitations for Landfills. These dedicated landfill CWT facilities are not subject to provisions of the CWT rulemaking.

As a further point of clarification, landfill wastewater is not specifically excluded from provisions of this rule. Landfill wastewater that is treated at CWT facilities along with other covered off-site wastestreams are subject to provisions of this rule. Furthermore, a landfill that commingles for treatment its own landfill wastewater with other landfill wastewater only is subject to the Landfill limits in the circumstances described in V.B above.

K. Incineration Activities

In January of this year, EPA promulgated effluent guidelines and pretreatment standards for wastewater discharges from a limited segment of the waste combustion industry. 65 FR 4360 (January 27, 2000). This regulation, codified at 40 CFR Part 444, applies to the discharge from a "commercial hazardous waste combustor" (CHWC). CHWCs are commercial incinerators that treat or recover energy from hazardous industrial waste.

There may be certain industrial facilities (for whom EPA has established guidelines limitations or standards in 40 CFR subpart N) which are subject to the CWT regulation that also operate incinerators or CHWCs. For the CWT final rule, EPA has adopted the same approach it has followed for other industrial facilities subject to national limitations and standards. Where a facility treats CHWC (or other incinerator wastewater) with CWT wastewater, the permit writer (or local control authority) would establish discharge limitations (or pretreatment standards) by using a flow-weighted combination of the CHWC limitations/standards (or BPJ incinerator wastewater limitations/standards) and the CWT limitations/standards. Thus, an organic chemical facility with an on-site CHWC (or other incinerator) that is also a CWT would be subject to combined wastestream formula pretreatment standards or building block limitations based on all three 40 CFR subpart N regulations.

Additionally, a facility which only treats CHWC wastewater (or other incinerator wastewaters or waste that is similar in nature as determined by the permitting authority, see Section V.B),

whether located at a CHWC site or not, would be subject not to the CWT regulations but to the otherwise applicable limitations or standards (either CHWC or, in the case of non-CHWC incinerator wastewater, limitations or standards developed by the permit writer or local control authority). EPA notes, however, that it has not identified any CWT facilities that are dedicated to CHWC (or other incineration) wastewaters only.

Further, incineration wastewaters are not specifically excluded from provisions of this rule. Incineration wastewaters received from off-site that are treated at CWT facilities along with other covered off-site wastestreams are subject to CWT limitations and provisions of this rule.

L. Solids, Soils and Sludges

EPA did not distinguish in its information gathering efforts between those waste treatment and recovery facilities treating aqueous waste and those treating non-aqueous wastes or a combination of both. Thus, EPA's 308 Waste Treatment Industry Questionnaire and related CWT Detailed Monitoring Questionnaire (DMQ) asked for information on CWT operations without regard to the type of waste treated. EPA's sampling program also included facilities that accepted both aqueous and solid wastes for treatment and/or recovery. In fact, the facility that forms the technology basis for the metals subcategory limitations treats both liquid and solid wastes. A facility that accepts wastes from off-site for treatment and/or recovery that generates a wastewater is subject to the CWT rule regardless of whether the wastes are aqueous or non-aqueous. Therefore, wastewater generated in the treatment of solids received from off-site is subject to the CWT rule.

As a further point of clarification, the main concern in the treatment or recycling of off-site "solid wastes" is that pollutants contained in the solid waste may be transferred to a process or contact water resulting in a wastewater that may require treatment. Examples of such wastewaters include, but are not limited to:

- Entrained water directly removed through dewatering operations (for example, sludge dewatering);
- Contact water added to wash or leach contaminants from the waste material; and
- Storm water that comes in direct contact with waste material which contain liquids.

The treatment or recovery of solids that remain in solid form when contacted with water and which do not

leach any chemicals into the water are not subject to this rule. Examples of excluded solids recovery operations are the recycling of aluminum cans, glass and plastic bottles. As a further point of clarification, any wastewater generated at a municipal recycling center is not subject to provisions of this rule.

M. Scrap Metal Processors and Auto Salvage Operations

During development of this regulation, EPA did not examine facilities engaged in scrap metal processing or auto salvage operations as part of its study. EPA did not attempt to collect information on these types of operations. However, commenters to the 1999 proposal provided some information on these activities. Commenters noted that these operations often generate contaminated wastewaters as a secondary part of their operations. As described by commenters, wastewater is often produced when rainwater comes in contact with the scrap metal and/or automobiles during collection and storage. This rainwater then becomes contaminated with oily residue from the scrap metal and/or automobiles. Contaminated storm water is the only wastewater resulting from these operations.

Because contaminated storm water generated from centralized scrap metal processing or auto salvage operations would, as the regulatory language is specified, be subject to regulation, EPA considered whether it had a basis for regulating wastewaters from these operations. Other than the limited information supplied by commenters, EPA has very little data concerning these activities and the facilities that conduct these activities. As a result, EPA concluded that it should not include within the scope of the guideline wastewaters generated from centralized scrap metal processing or auto salvage at this time. EPA would expect that permit writers and control authorities would develop limitations or local limits to establish site-specific permit requirements for any centralized scrap metal processing or auto salvage operations generating and discharging a contaminated stormwater.

N. Transfer Stations

During the initial stages of development of this rule, EPA did not envision transfer stations as part of the centralized waste treatment industry. As such, EPA did not attempt to collect information on the operation of transfer stations. However, EPA received comment to the 1999 proposal asking

that EPA clarify its coverage of these facilities by this rule.

EPA has very little information on the operation of transfer stations. Based on comments, while transfer stations could fall within the definition of a CWT since they accept off-site industrial wastes, they do not perform any treatment or recovery of the off-site wastes. Transfer stations simply facilitate the distribution of wastes for disposal. Consequently, EPA has concluded that transfer stations should not be subject to provisions of the CWT rule.

O. Stabilization/Solidification

As explained in the 1999 proposal, EPA concluded that, by definition, stabilization/solidification operations are "dry" and do not produce any wastewater. As such, EPA did not propose to include stabilization/solidification processes in the CWT rule. At that time, EPA also explained that it was considering a subcategory for stabilization operations with a zero discharge requirement, and requested comment on this approach.

EPA received very little comment on stabilization/solidification and no new data from industry following the 1999 proposal. One commenter suggested EPA require stabilization/solidification operations to be zero discharge. Another suggested EPA use the same approach proposed for facilities handling used oil filters. A third commented that EPA should not promulgate a zero discharge requirement because, in the event that a wastewater is produced by stabilization/solidification operations, the facility would not have the option to treat the wastewater on-site.

EPA re-examined its database and concluded that while "solidification/stabilization" processes do not themselves produce any wastewater, there are often wastewaters associated with these processes. The major wastewater reported by questionnaire respondents associated with stabilization/solidification operations is equipment wash down. Further, the database shows that many of the wastes accepted from off-site for stabilization/solidification are the same or similar to wastes accepted for other covered CWT operations.

Consequently, EPA is not promulgating a subcategory for stabilization/solidification with a zero discharge requirement. EPA agrees with commenters that, in the event that there are wastewaters produced by or associated with these operations, facilities should have the option of choosing whether to treat the wastes on-site or through other means. If these operations produce a wastewater, then

the discharge of wastewater from these facilities should be subject to provisions of this rule. Therefore, "dry" stabilization/solidification operations themselves are not subject to provisions of the CWT rule. However, wastewater discharges from stabilization/solidification operations that are performed on waste received from off-site are subject to provisions of this rule. This approach is consistent with EPA's approach to fuel blending operations and used oil filter management.

P. Waste, Wastewater, or Used Material Re-Use

EPA recognizes that some facilities accept wastewater from off-site for re-use rather than treatment or recovery. The intent in accepting these off-site "treated" wastewaters is to replace potable water or more expensive pure water obtained from wells, surface waters, etc. Examples include, but are not limited to:

- The acceptance of wastewater from off-site for use in place of potable water in industrial processes;
- The use of secondary POTW effluents as non-contact cooling water; and
- The use of storm water in place of potable water at shared industrial facilities located in industrial parks.

Likewise, EPA is also aware that some facilities accept used materials such as spent pickle liquor for re-use as a treatment chemical in place of virgin treatment chemicals.

EPA applauds all pollution prevention activities, especially those that allow treated wastewater or spent chemicals to be re-used rather than discharged. EPA does not define this type of activity as treatment or recovery. Therefore, the acceptance of off-site wastewater or spent chemicals for re-use in the treatment system or other industrial process is not a CWT activity and is not subject to provisions of this rule.

Q. Recovery and Recycling Operations

Many CWT facilities perform recovery activities that lead to recycling of materials either at the recovering site or at another location. The purpose of these activities is to recycle product back into a use for which it was originally intended, not the treatment and disposal of wastewater streams. Examples of such activities include but are not limited to: used oil processing, used glycol recovery, fuel blending, metals recovery, and re-refining. Many commenters to both the 1995 proposal and the 1999 proposal noted that these activities should not be included under the scope of this rule because they are

not "treatment," but "recovery" activities.

EPA applauds efforts to reduce pollution and the ancillary adverse consequences to the environment associated with product disposal and does not want to discourage these practices. However, EPA also recognizes that while the intent of these activities is not treatment of a "wastewater," but rather recovery of a used or waste material, wastewater is usually generated from these recovery processes. Generally, the facility performing the recovery activity also performs on-site treatment of the resulting wastewater. EPA wants to ensure that these wastewaters receive appropriate treatment.

From the beginning of its data gathering activities associated with the development of this rule, EPA has included recycling and recovery activities along with wastewater treatment activities. In fact, EPA developed sections of the 308 Questionnaire to specifically target the collection of information on metals, solids, oils, and organics recovery activities. Many of the facilities visited and sampled by EPA perform recovery operations. Some of these facilities refer to themselves as "recyclers" and not "wastewater treatment facilities." EPA's sampling data show that in many instances the pollutants and concentrations of pollutants in wastewaters generated from recycling/recovery activities are very similar or more concentrated than wastewaters accepted for "treatment" only. In fact, many facilities that perform recovery operations combine the wastewater generated from the recovery operations with other off-site wastewater received for treatment. Consequently, EPA has concluded that recovery operations are included in the scope of this rule. Therefore, unless specifically stated elsewhere, facilities that recycle and recover off-site waste, wastewaters and/or used materials are considered "centralized waste treatment facilities" and are subject to provisions of this rule. However, if metals recovery operations are subject to the secondary metals provisions of 40 CFR 421, the Nonferrous Metals Manufacturing Point Source Category, then the provisions of this part do not apply. These secondary metals subcategories are Subpart C (Secondary Aluminum Smelting Subcategory), Subpart F (Secondary Copper Subcategory), Subpart L (Secondary Silver Subcategory), Subpart M (Secondary Lead Subcategory), Subpart P (Primary and Secondary Germanium and Gallium Subcategory), Subpart Q (Secondary Indium

Subcategory), Subpart R (Secondary Mercury Subcategory), Subpart T (Secondary Molybdenum and Vanadium Subcategory), Subpart V (Secondary Nickel Subcategory), Subpart X (Secondary Precious Metals Subcategory), Subpart Z (Secondary Tantalum Subcategory), Subpart AA (Secondary Tin Subcategory), Subpart AB (Primary and Secondary Titanium Subcategory), Subpart AC (Secondary Tungsten and Cobalt Subcategory), and Subpart AD (Secondary Uranium Subcategory).

R. Silver Recovery Operations From Used Photographic and X-Ray Materials

At the time of the 1999 proposal, EPA proposed not to include electrolytic plating/metallic replacement silver recovery operations of used photographic and x-ray materials within the scope of this rule. The Agency based its conclusion on the fundamental difference in technology used to recover silver at facilities devoted exclusively to treatment of photographic and x-ray wastes. However, for off-site wastes that are treated/recovered at these facilities through any other process and/or waste generated at these facilities as a result of any other centralized treatment/recovery process, the Agency proposed that these wastewaters would be subject to provisions of this rule.

The Agency received many comments to the 1999 proposal that supported EPA's decision to not include electrolytic plating/metallic replacement silver recovery operation of used photographic and x-ray materials within the scope of this rule. However, commenters additionally noted that while many of these facilities primarily use electrolytic plating followed by metallic replacement in silver recovery operations, there are other processes that are also utilized. Commenters further noted that new silver recovery technologies are emerging and being studied and developed on a regular basis. As such, commenters asked EPA to not include silver recovery operations from used photographic and x-ray materials regardless of the method used to recover the silver.

EPA agrees with commenters that facilities that are devoted exclusively to the centralized recovery of silver from photographic and x-ray wastes should not be covered by this rule, regardless of the type of process used to recover the silver. As such, facilities that exclusively perform centralized silver recovery from used photographic and x-ray wastes are not subject to provisions of this rule. EPA would expect that, as is the case now with wastewater discharges associated with this

operation, the control authority or permit writer would determine whether to apply the provisions of 40 CFR part 421, Subpart L (the Secondary Silver Subcategory of the Nonferrous Metals Manufacturing Regulation) or establish BPJ, site-specific permit requirements.

There are some facilities, however, which are engaged in traditional CWT activities and also engaged in centralized silver recovery from photographic and x-ray materials. If the wastewaters from the two operations are commingled, the commingled silver recovery wastewater flow would be subject to CWT limitations or standards. Therefore, a facility performing centralized silver recovery from used photographic and x-ray materials as well as some other covered CWT services that commingles these wastes are subject to provision of the CWT rule. All of the wastewater discharges are subject to provisions of this rule. If, however, a facility is performing both operations and the wastestreams are not commingled (that is, silver recovery wastewater is treated in one system and CWT wastes are treated in a second, separate system), the permit writer or control authority should apply the provision of 40 CFR part 421, if applicable, or continue to establish BPJ, site-specific permit requirements for the discharge associated with the silver recovery operations and apply the CWT rule to the wastewaters associated with the other covered CWT activities.

As a further point of clarification, wastewater generated as a result of centralized silver recovery operations are not specifically excluded from provisions of this rule. Silver recovery wastewaters that are treated at CWT facilities with other covered off-site wastestreams are subject to provisions of this rule.

S. High Temperature Metals Recovery

EPA is aware of three facilities in the U.S. that recover metal using a "high temperature metals recovery" process (HTMR). HTMR facilities recycle metal-bearing materials in a pyrometallurgical process that employs very high temperature furnaces. These facilities do not use the water-based precipitation/filtration technologies to recover metals from wastewater observed at metals subcategory facilities throughout the CWT industry. At the time of the proposal, EPA believed that all HTMR processes were "dry" (*i.e.*, did not produce a wastewater). Consequently, in the 1999 proposal, EPA proposed not to include facilities that perform high temperature metals recovery (HTMR) within the coverage of this rule. EPA further requested comment on whether

EPA should promulgate a zero discharge requirement for facilities that utilize the HTMR process.

Based on comment to the proposal, EPA has concluded that while most HTMR processes are dry, one of the three known HTMR facilities produces a wastewater (scrubber blowdown). As such, EPA has concluded that a zero discharge requirement for HTMR facilities is inappropriate and has not included it in the final CWT rule. However, upon further examination of the comments and its database, EPA has concluded that HTMR facilities that generate a wastewater should be included within the scope of the CWT rule. While the HTMR process is different from other recycling technologies studied by EPA for this rulemaking, EPA has concluded that the wastewater produced from HTMR operations contains many of the CWT metals subcategory pollutants of concern and that the concentration of these pollutants falls solidly within the range of wastewaters in the CWT metals subcategory. As such, while the HTMR process may be different from water-based precipitation technologies, the resulting wastewaters are similar (see DCN 33.2.1). Therefore, it is appropriate for EPA to establish limits for HTMR wastewaters using the metals subcategory technology basis and these limits will be achievable. EPA has revised all of its analysis to reflect the inclusion of these "non-dry" HTMR facilities within the scope of the CWT rule. However, if high temperature metals recovery operations are subject to any of the secondary metals provisions of 40 CFR 421, the Nonferrous Metals Manufacturing Point Source Category, then the provisions of this part do not apply. See Section V.Q for a list of the secondary metals subcategories.

T. Solvent Recycling/Fuel Blending

EPA studied the solvent recycling industry in the 1980s. EPA published its findings in the "Preliminary Data Summary for the Solvent Recycling Industry" (EPA 440/1-89/102) in September 1989 that describes this industry and its recycling processes. There, EPA has explained solvent recovery as "the recycling of spent solvents that are not the byproduct or waste product of a manufacturing process or cleaning operation located on the same site." Facilities generally recycle spent solvents in two main operations. Traditional solvent recovery involves pretreatment of the wastestream (in some cases) and separation of the solvent mixtures by specially constructed distillation columns. In most cases, traditional

solvent recovery is performed at organic chemical manufacturing facilities. As a result, wastewater discharges resulting from this process are subject to effluent limitations guidelines and standards for the organic chemicals industry (often abbreviated as OCPSF) (40 CFR part 414).

EPA is aware that there are a few facilities that accept solvents from other facilities for commercial solvent recovery operations. Some perform solvent recovery of spent or contaminated chemicals received from pharmaceutical and other chemical manufacturing companies. Some recycle spent solvents generated by parts washers and other cleaning devices operated by automotive shops, dry cleaners, and other small businesses. Because these commercial solvent recovery facilities are not located at an organic manufacturing facility, the provisions of 40 CFR 414, as written, do not apply to them.

Based on comments to the 1999 CWT proposal, EPA considered whether it should regulate commercial solvent recovery facilities under the provisions of this rule. EPA has determined, however, not to include these commercial solvent recovery operations within the scope of this rule at this time. Throughout the development of this rule, EPA has clearly stated that traditional solvent recovery operations would not be included within the scope of this rule. In developing its database to support this rule, while EPA did collect limited information on these activities, EPA intentionally excluded known solvent recoverers from its data collection activities. As such, EPA has only limited data on solvent recovery activities that are not already subject to OCPSF. It did not obtain information to characterize the wastewaters generated at such operations. Thus, EPA has no basis for determining whether or not such operations are sufficiently similar to the organic waste subcategory so that they may properly be regulated as organic wastestreams. Therefore, wastewaters resulting from traditional solvent recovery activities as defined above are not subject to these effluent guidelines.

For wastewaters associated with traditional solvent recovery activities located at organic chemical manufacturing facilities, permit writers (and local control authorities) will, of course, use the Organic Chemicals, Plastics, and Synthetic Fibers (OCPSF) guideline to establish discharge requirements. For commercial traditional solvent recovery activities (not located at an organic chemical manufacturing site), permit writers (and

local control authorities) should carefully examine the wastewater to see if it also contains pollutants regulated by the OCPSF guidelines when the permit writer establishes case-by-case limitations under NPDES regulations at 40 CFR 125.3 or the control authority establishes local limits under the General Pretreatment Regulations at 40 CFR 403.5. Permit writers or local control authorities must include technology-based limits for any toxic pollutant which is or may be discharged at a level greater than the level which can be achieved by treatment requirements appropriate to the permittee, or any pollutant which may pass through or interfere with POTW operations. (See 40 CFR 122.44(e), 125.3. See also 40 CFR 403.5).

Fuel blending is a type of solvent recovery. Fuel blending is the process of mixing wastes for the purpose of regenerating a fuel for reuse. At the time of the 1995 proposal, EPA did not include fuel-blending operations within the scope of the CWT rule because EPA believed the fuel blending process was "dry" (that is, no wastewaters were produced). Based on comments to the original proposal and the Notice of Data Availability and its review of data it has obtained, EPA has reconfirmed its conclusion that true fuel blenders do not generate any process wastewaters and are, therefore, zero dischargers. EPA is concerned, however, that the term "fuel blending" may be loosely applied to any process where recovered hydrocarbons are combined as a fuel product. Such operations occur at nearly all used oil and fuel recovery facilities.

EPA has, therefore, not included "dry" fuel blending operations within the scope of the CWT rule. In the event that wastewater is generated at a CWT fuel blending facility, the discharge of wastewaters associated with these operations is subject to this rule.

U. Re-Refining

When EPA initially proposed guidelines and standards for CWT facilities, the regulations would have limited discharges from used oil reprocessors/reclaimers, but did not specifically include or exclude discharges from used oil re-refiners. During review of information received on the 1995 proposal and assessment of the information collected, the Agency, at one point, considered limiting the scope of this regulation to reprocessors/reclaimers only because it was not clear whether re-refiners actually generated wastewater. However, further data gathering efforts have revealed that re-refiners may generate wastewater and

that the principal sources of re-refining wastewaters are essentially the same as for reprocessors/reclaimers. Consequently, the final guidelines will apply to re-refining wastewater.

EPA studied the used oil reclamation and re-refining industry in the 1980s. In September 1989, EPA published the "Preliminary Data Summary for the Used Oil Reclamation and Re-Refining Industry" (EPA 440/1-89/014) that describes this industry and the processes utilized. This document generally characterizes the industry in terms of the types of equipment used to process the used oil. Minor processors (reclaimers) generally separate water and solids from the used oil using simple settling technology, primarily in-line filtering, and gravity settling with or without heat addition. Major processors (reclaimers) generally use various combinations of more sophisticated technology including screen filtration, heated settling, centrifugation, and light fraction distillation primarily to remove water. Re-refiners generally use the most sophisticated systems that include, in addition to the previous technologies, a vacuum distillation step to separate the oil into different components.

Today's final rule applies to the process wastewater discharges from used oil re-refining operations. The principal sources of wastewater include oil-water gravity separation (often accompanied by chemical/thermal emulsion breaking) and dehydration unit operations (including light distillation and the first stage of vacuum distillation). EPA has, to date, identified two re-refining facilities.

V. Used Oil Filter and Oily Absorbent Recycling

EPA did not obtain information on used oil filter or oily-absorbent (oil soaked or contaminated disposable rags, paper, or pads) recycling through the Waste Treatment Industry Questionnaire. However, in response to the September 1996 Notice of Data Availability and the 1999 proposal, EPA received comments from facilities which recycle used oil filters and oily absorbents. In addition, EPA also visited several used oil reprocessors that recycle used oil filters or oily absorbents as part of their operations.

Used oil filter and oily absorbent recycling processes range from simple crushing and draining of entrained oil to more involved processes where filters or absorbent materials are shredded and the metal and filter material are separated. Generally, the resulting used oil is recycled, the separated metal product is sold to a smelter, and the

separated filter material is sold as a solid fuel. Based on information collected during EPA's site visits and comments on the 1999 proposal, wastewater may be generated during all phases of the recycling activity including collection activities, plant maintenance, and air pollution control. EPA notes, however, that based on its observations, many of these activities are "dry" and do not produce associated wastewaters. In fact, at the time of the 1999 proposal, EPA believed these activities were largely "dry" and requested comment on whether EPA should promulgate a zero discharge requirement for facilities performing used oil filter recovery.

As detailed above, based on comment on the proposal, EPA has learned that not all used oil filter and absorbent recycling activities are dry. Consequently, EPA has decided that it should not adopt a zero discharge requirement for these activities. Upon further examination of the comments and its database, EPA has concluded that it should include used oil filter and absorbent recovery facilities that generate a wastewater within the scope of the CWT rule. While EPA does not have data specific to used oil filter recovery on the characteristics of these wastewaters, these wastewaters are often combined with other covered CWT wastewaters for treatment. Further, since the material being recovered is primarily used oil, EPA has concluded that any resulting wastewaters will be similar (in terms of constituents and concentration) to wastewaters generated from used oil recovery. As a result, EPA has concluded that these operations should be regulated as are other centralized used oil recovery activities. Where information is available to EPA on these operations, EPA has revised its analysis to reflect the inclusion of these "non-dry" used oil filter and absorbent facilities within the scope of the CWT rule.

W. Grease Trap/Interceptor Wastes

EPA received comments suggesting that the scope of the CWT rule should not include grease, sand, and oil interceptor wastes. Some of these wastes are from non-industrial sources and some are from industrial sources. Some are treated at central locations designed to treat grease trap/interceptor wastes exclusively and some of these wastes are treated at traditional CWT facilities with traditional CWT wastes. Examples of the types of customers which generate these grease trap/interceptor wastes include, but are not limited to auto and truck maintenance and repair

shops; auto body and parts shops; car washes; gas stations; commercial bottling facilities; food and produce distribution shops; restaurants; and tire shops.

Throughout the development of this rule, EPA has directed its efforts to CWT operations that treat and/or recover off-site industrial wastes and not to food-related wastes. Grease trap/interceptor wastes are defined as animal or vegetable fats/oils from grease traps or interceptors generated by facilities engaged in food service activities. Such facilities include, but are not limited to restaurants, cafeterias, caterers, commercial bottling facilities, and food and distribution shops. EPA has concluded that these wastes are fundamentally different from the types of wastes examined for this rule and are outside the scope of this rule. Grease trap/interceptor wastes should not contain any hazardous chemicals or materials that would prevent the fats/oils from being recovered and recycled.

Wastewater discharges from the centralized treatment of wastes produced from oil interceptors, however, which are designed to collect petroleum-based oils, sand, etc. from industrial type processes, are a different case and EPA has determined that this wastewater is properly subject to this rule. Examples of facilities that produce oil interceptor waste include, but are not limited to, auto and truck maintenance and repair shops; auto body and parts shops; car washes; and gas stations. EPA collected data on the types and concentrations of pollutants in oil interceptor wastes through comments and EPA sampling. The data show, that like other CWT wastes, the concentration of pollutants can vary greatly from one wastestream to another. EPA's sampling data show that these materials can be very similar in nature and concentration to other wastes covered by this rule. Consequently, EPA has determined these wastes should be included within the scope of this rule.

X. Food Processing Wastes

During development of this rule, EPA did not collect information from facilities engaged in centralized waste treatment of food processing wastes. As detailed in V.W, EPA envisioned that this rule would be limited to the treatment and/or recovery of off-site industrial wastes. While food processing may be an "industrial" activity, these wastes do not contain heavy metals, concentrated organics, or petroleum based oils. In terms of contaminants of concern, these wastes are similar to those generated by cafeterias, restaurants, etc. Consequently, the final

guidelines will not apply to animal and vegetable fats/oils wastewaters at CWT facilities, specifically those generated by food processors/manufacturers.

Y. Sanitary Wastes and/or Chemical Toilet Wastes

The provisions of the CWT rule, as previously explained, will not cover sanitary wastes (such as septage), nor will they cover chemical toilet wastes. EPA expects that permit writers and control authorities would develop BPJ limitations or local limits to establish site-specific permit requirements for any commercial sanitary waste treatment facility.

Similarly, sanitary wastes or chemical toilet wastes received from off-site and treated at an industrial facility or a CWT facility are not subject to the provisions of the CWT rule. If these wastes are mixed with industrial wastes, EPA would expect that, as is the case now with ancillary sanitary waste flows mixed for treatment at facilities subject to national effluent guidelines and standards, the permit writer would establish BPJ, site-specific permit requirements.

Z. Treatability, Research and Development, and Analytical Studies

During the initial stages of development of this rule, EPA did not envision regulation of facilities which accept off-site wastes for treatability studies, research and development, or chemical or physical analysis. As such, EPA did not attempt to collect information on these activities. However, EPA received comment to its proposals asking that EPA clarify its coverage of these activities by this rule.

EPA has very little information on these activities. Based on comments, these activities, arguably, would fall within the definition of Centralized Waste Treatment since they accept off-site wastes. The purpose of these activities is not treatment or recovery, but rather the evaluation of different treatment techniques. Consequently, EPA has concluded that treatability, research and development or analytical activities should not be subject to provisions of the CWT rule.

Permit writers and local authorities should use their Best Professional Judgment (BPJ) and local limits authority to establish limitations and standards for these wastestreams. Under EPA's regulations, permit writers or local control authorities must include technology-based limits either for any toxic pollutant which is or may be discharged at a level greater than the level which can be achieved by treatment requirements appropriate to

the permittee or for any pollutant which may pass through or interfere with POTW operations. (See 40 CFR 122.44(e), 125.3.) See also 40 CFR 403.5. EPA would expect that, in some cases, wastewater associated with these activities might look very much like the wastestreams regulated under this rule. In those circumstances, permit writers (and local control authorities) may want to consider the technical development document developed for the CWT guideline when the permit writer establishes case-by-case limitations under NPDES regulations at 40 CFR 125.3 or the control authority establishes local limits under the General Pretreatment Regulations at 40 CFR 403.5.

EPA notes that if a CWT facility accepts off-site wastes for treatability, research and development, or analytical activities, and commingles any resulting wastewaters with other covered wastewaters prior to discharge, these wastewaters would be subject to provisions of this rule.

VI. Subcategorization

EPA developed different limitations and standards for the CWT operations depending on the type of waste received for treatment or recovery. EPA remains convinced this is the most appropriate basis for subcategorizing the CWT industry. EPA has determined that there are four subcategories appropriate for the CWT industry:

- Subcategory A: Facilities that treat or recover metal from metal-bearing waste, wastewater, or used material received from off-site ("metals subcategory");
- Subcategory B: Facilities that treat or recover oil from oily waste, wastewater, or used material received from off-site ("oils subcategory");
- Subcategory C: Facilities that treat or recover organics from organic waste, wastewater, or used material received from off-site ("organics subcategory"); and
- Subcategory D: Facilities that treat or recover some combination of metal-bearing, oily, or organic waste, wastewater, or used material received from off-site ("multiple wastestream subcategory").

For a detailed explanation of EPA's subcategorization methodology and factors considered as the basis for today's subcategorization, see the 1999 proposal (64 FR 2300–2301) and Chapter 5 of the Final Technical Development Document.

VII. Industry Description

As detailed in Section V above, the universe of CWT facilities in the United

States is broad. The development of this industry is largely a result of the adoption of the increased pollution control measures required by the CWA and RCRA. The 1999 proposal (64 FR 2293–2294) and Chapter 4 of the technical development document provide a detailed description of the development of this industry and its operation. EPA's 1999 proposal (64 FR 2301–2302) and Chapter 5 of the Final Technical Development Document also provide detailed descriptions of operations at facilities by subcategory.

EPA now estimates that there are 223 CWT facilities. Changes in the estimate of the total number of CWT facilities since the proposal reflect facilities that were included or excluded because of scope changes/clarifications. EPA is aware that CWT facilities have entered or left the centralized waste treatment market. This is expected in a service industry. Even so, EPA is comfortable that its estimate of facilities is reasonable and has not adjusted it, other than to account for scope changes/clarifications. Of these 223 CWT facilities, approximately 14 discharge directly to surface waters of the U.S., 151 discharge indirectly to POTWs, and 58 are zero or alternative dischargers. The zero or alternative discharge methods include (1) wastewater is disposed of by alternate means such as deep well injection or incineration; (2) wastewater is sent off-site for treatment, generally to another CWT; (3) wastewater is evaporated; and (4) no wastewater is generated. There are 62, 178, and 32 facilities in the metals, oils, and organics subcategories, respectively. Thirty-seven facilities accept wastes from multiple subcategories and could be subject to the multiple wastestream subcategory.

VIII. The Final Regulation

For a detailed discussion of all technology options considered in the development of today's final rule, see the proposal (64 FR 2305–2315) and Chapter 9 of the technical development document.

A. Best Practicable Control Technology (BPT)

1. Subcategory A—Metals Subcategory

EPA is establishing BPT limitations for the metals subcategory for 19 pollutants, including cyanide. The technology basis for these BPT limitations is metals option 4: primary precipitation, liquid-solid separation, secondary precipitation, clarification, and sand filtration. This is the same technology that was the basis for the 1999 proposed limitations. Under

option 4, the treater varies pH levels and treatment chemicals in order to promote optimal removal of the wide range of metal pollutants found in CWT metals wastewaters. Different metals are preferentially removed with different treatment chemicals and different pH levels. Generally, BPT limitations based on option 4 will require some facilities to more carefully control their treatment systems, increase the quantities of treatment chemicals they use, perform an additional precipitation step, and add a clarification and sand filtration step. In the case of complex cyanide, metal-bearing streams, EPA's limitations require cyanide removal prior to metals treatment. EPA based the cyanide limitations on cyanide option 2 treatment, which is alkaline chlorination in a two-step process.

The Agency concluded that this treatment system represented the best practicable technology currently available and should be the basis for the BPT metals limitations for the following reasons. First, the option 4 technology is one that is readily applicable to all facilities that are treating metal-bearing wastestreams. It is based on a technology including two-stage chemical precipitation that is currently used at approximately 25 percent of the facilities in this subcategory. Second, the adoption of this level of control would represent a significant reduction in pollutants discharged into the environment by facilities in this subcategory. Option 4 would annually remove approximately 4.1 million pounds of TSS and metals now discharged to the Nation's waters. Third, the Agency assessed the total cost of water pollution controls likely to be incurred for option 4 in relation to the effluent reduction benefits and determined these costs were reasonable—\$0.40 per pound (\$1997). In the 1999 proposal, EPA explained why it rejected the other options it considered for BPT. See 64 FR 2280 at 2306.

Although EPA is not changing the technology basis from that proposed, EPA is revising all of the BPT metals subcategory limitations. This is due to changes in the statistical methodology used to calculate pollutant long-term averages and limitations as detailed in Section IV.H above.

The Agency used chemical precipitation treatment technology performance data from the Metal Finishing regulation (40 CFR Part 433) to establish direct discharge limitations for TSS because the facility from which the option 4 limitations were derived is an indirect discharger and the treatment system is not necessarily designed for

optimum removal of conventional parameters, due to the lack of stringent local limits for these parameters. EPA has concluded that the transfer of this data is appropriate given the absence of adequate treatment technology for this pollutant at the only otherwise well-operated BPT CWT facility examined by EPA. Based on a review of the data, EPA concluded that similar wastes (in terms of TSS concentrations) are being treated at both metal finishing and centralized waste treatment facilities, and that the use of the metal finishing data to derive TSS limits for this subcategory is warranted. Because the technology basis for the transferred limitations includes clarification rather than sand filtration, the Agency also included a clarification step prior to sand filtration (which the option 4 facility does not have) in the technology basis for option 4 for facilities subject to BPT. Therefore, because the technology basis for CWT is based on primary chemical precipitation, primary clarification, secondary chemical precipitation, secondary clarification, and sand filtration and the technology basis for Metal Finishing is based on primary precipitation and clarification only, EPA concluded that CWT facilities will perform similarly (or better) when treating TSS in wastes in this subcategory.

BPT limitations established by option 4 (except TSS) are based on data from a single, well-operated system. Generally, for purposes of defining BPT effluent limitations, EPA looks at the performance of the best treatment technology and calculates limitations from some level of average performance measured at facilities that employ this "best" treatment technology. In reviewing technologies currently in use in this subcategory, however, EPA found that facilities generally utilize a single stage chemical precipitation step—a technology which does not achieve adequate metals removals for the wastestreams observed at these operations. EPA did identify facilities that utilize additional metals wastewater treatment, generally secondary chemical precipitation, but without the final multimedia filtration step. Also, EPA found that only the BPT model facility accepts a full spectrum of waste, often with extremely high metals concentrations and provides, therefore, a suitable basis to determine the performance that a well-designed and operated system can achieve for a wide range of raw waste concentrations. Consequently, EPA is adopting BPT limitations based on performance data from this facility. For further discussion,

see the 1999 proposal at 64 FR 2280–2357.

Cyanide Subset. EPA is adopting BPT limitations for the metals subcategory for cyanide bearing streams. The presence of high cyanide concentrations detrimentally affects the performance of metal precipitation processes due to the formation of metal-cyanide complexes. Effective treatment of such wastes typically requires a cyanide destruction step prior to any metal precipitation steps. Consequently, in the case of metal streams which contain concentrated cyanide complexes, EPA based BPT limitations on an additional treatment step to destroy cyanide before metals precipitation: alkaline chlorination in a two-step process (cyanide option 2). This is the same technology that was the basis for the 1999 proposed limitations. In the first step, cyanide is oxidized to cyanate in a pH range of 9 to 11. The second step oxidizes cyanate to carbon dioxide and nitrogen at a controlled pH of 8.5.

There are several reasons supporting the selection of limitations based on cyanide option 2, as explained in detail in the 1999 proposal at 64 FR 2309. First, the facility achieving cyanide option 2 removals accepts a full spectrum of cyanide waste. Consequently, the treatment used by the cyanide option 2 facility can be readily applied to all facilities in the subset of this subcategory. Second, adoption of this level of control would represent a significant reduction in pollutants discharged into the environment by facilities in this subset. Finally, the Agency assessed the total cost for cyanide option 2 in relation to the effluent reduction benefits and determined these costs were economically reasonable.

2. Subcategory B—Oils Subcategory

The Agency is today adopting BPT limitations for the oils subcategory for 22 pollutants. The technology basis for the BPT limitations is oils option 9: emulsion breaking/gravity separation, secondary gravity separation and dissolved air flotation. This is the same technology that was the basis for the 1999 proposed limitations. EPA's data indicate that all oils treatment facilities currently utilize some form of emulsion breaking and/or gravity separation system. Secondary gravity separation involves using a series of tanks to separate the oil and water and then skimming the oily component off. The resulting water moves to the next step. The gravity separation steps are then followed by dissolved air flotation (DAF). DAF separates solid or liquid particles from a liquid phase by

introducing air bubbles into the liquid phase. The bubbles attach to the particles and rise to the top of the mixture. Often, chemicals are added to increase the removal of metal constituents. BPT limitations based on this option will likely require some facilities to more carefully control their treatment systems, perform additional gravity separation steps, or install and operate a DAF system. For oils streams with relatively high concentrations of metals, these limitations will also require some facilities to use increased quantities of treatment chemicals to enhance the removal of metals.

EPA developed the final limitations for this option using sampling data from facilities both with and without the secondary gravity separation step. EPA's data show that the secondary gravity separation step may not always be necessary to meet the final limitations, depending on the level of treatment in the initial gravity-separation/emulsion-breaking step. EPA's data show there is a wide range of pollutants being discharged from this initial treatment step. EPA concluded that if many of the facilities optimize treatment at this level, the secondary gravity separation step may not be required. However, EPA estimated the costs to comply with the limitations with the secondary gravity separation step included to ensure this technology option's economic achievability.

The Agency is today adopting BPT limitations for the oils subcategory based on Option 9, emulsion breaking/gravity separation, secondary gravity separation and dissolved air flotation for two reasons. First, the adoption of this level of control would represent a significant reduction in pollutants discharged into the environment by facilities in this subcategory. Second, the Agency assessed the total costs of water pollution controls likely to be incurred for this option in relation to the effluent reduction benefits and determined these costs were reasonable at \$0.63/lb (\$1997). In the 1999 proposal, EPA explained why it rejected the other options it considered for BPT for this subcategory. See 64 FR 2280 at 2309–11.

EPA believes it is important to note that BPT limitations for conventional parameters established by Option 9 are based on data from a single, well-operated, indirect-discharging system. Generally, for purposes of defining BPT effluent limitations, EPA looks at the performance of the best treatment technology and calculates limitations from some level of average performance measured at facilities that employ this "best" treatment technology. The

facilities sampled as the technology basis for this subcategory, however, were not required to optimize their oil and grease or TSS removals because they discharge to POTWs. Current POTW/local permit limitations for oil and grease in this subcategory range from 100 mg/L to 2,000 mg/L and for TSS from 250 mg/L to 10,000 mg/L. Many have no oil and grease or TSS limits at all. EPA concluded that only one of the systems in this subcategory for which EPA has data was designed to remove oil and grease and TSS effectively. EPA concluded that the oil and grease and TSS removals are uniformly inadequate at the other facilities included in the BPT limitations calculations for other parameters. Consequently, EPA based the oil and grease and TSS limitations on data from a single facility.

3. Subcategory C—Organics Subcategory

The Agency is today adopting BPT limitations for the organics subcategory for 17 pollutants. The technology basis for the BPT limitations is organics option 4: equalization and biological treatment. Biological treatment for this option is in the form of a sequential batch reactor. This is the same technology that was the basis for the 1999 proposed limitations. The preamble to the proposal provided further explanation of EPA's decision (64 FR 2311–12).

The Agency concluded that this treatment system represented the best practicable technology currently available and should be the basis for the BPT organics limitations for several reasons. The technology is already used at the four direct discharging facilities that treat organic wastes and results in the removal of 28,700 lbs annually of conventional pollutants (at baseline). Moreover, because the treatment is in place, the cost of compliance with the limitations will obviously be reasonable.

Unlike the other BPT limitations adopted today, the adoption of limitations based on option 4 will not, in all probability, result in any significant change in the quantity of pollutants discharged into the environment by facilities in this subcategory. As noted, EPA's data suggests that all direct discharging facilities in this subcategory currently employ equalization and biological treatment systems, and EPA assumed that all those facilities will be able to meet the BPT limitations without additional capital or operating costs. If any facilities were to incur increased operating costs associated with the limits, EPA concluded these increases are negligible and has not quantified

them. Many of these facilities are not currently required to monitor for organic parameters or are only required to monitor a couple of times a year. Thus, the estimated costs for complying with BPT limitations for this subcategory are associated with additional monitoring only. The Agency determined the additional monitoring is warranted, and will promote more effective and consistent treatment at these facilities. In the 1999 proposal, EPA explained why it rejected the other options it considered for BPT for this subcategory. See 64 FR 2280 at 2311–12.

The selected BPT option is based on the performance of a single indirect discharging facility. While EPA identified four direct discharging organics subcategory facilities that utilize biological treatment, EPA did not use data from these facilities to establish limitations because they commingle organics subcategory wastewaters with other CWT subcategory wastewaters or wastewaters subject to other national effluent guidelines and standards. Many facilities that are treating wastes that will be subject to effluent limitations for the organics subcategory also operate other industrial processes that generate much larger amounts of wastewater than the quantity of off-site generated organic waste receipts. The off-site generated organic waste receipts are directly mixed with the wastewater from the other industrial processes for treatment. Therefore, identifying facilities to sample for limitations development was difficult because the waste received for treatment and treatment unit effectiveness could not be properly characterized for off-site generated waste. The treatment system on which EPA based option 4 was one of the few facilities identified which treated organic waste receipts separately from other on-site industrial wastewater.

The Agency used biological treatment performance data from the Thermosetting Resin Subcategory of the OCPSF regulation to establish direct discharge limitations for BOD₅ and TSS because the facility from which Option 4 limitations were derived is an indirect discharger and the treatment system is not operated to effectively remove conventional pollutants. EPA has concluded that the transfer of this data is appropriate given the absence of adequate treatment technology for these pollutants at the only otherwise well-operated BPT CWT facility in this subcategory that the Agency was able to evaluate. Moreover, EPA concluded that the biological treatment systems at CWT facilities will perform similarly to those at OCPSF facilities. EPA based this conclusion on its review of the NPDES

permits for the four direct discharging facilities in this subcategory. Two of these facilities are located at manufacturing facilities that commingle their wastewater for treatment and are already subject to OCPSF. The other two facilities have conventional pollutant limits which are lower than those adopted today. EPA has concluded that all of these facilities should be able to comply with the transferred limitations without incurring additional costs. Likewise, EPA has not estimated any additional pollutant removals associated with this data transfer.

4. Subcategory D—Multiple Wastestream Subcategory

The Agency is today adopting BPT limitations for the multiple wastestream subcategory for up to 38 pollutants. EPA developed four sets of limitations for each of the possible combinations of the three subcategories of wastestreams: oils and metals, oils and organics, metals and organics, and oils, metals and organics. The multiple wastestream subcategory limitations were derived by combining BPT pollutant limitations from up to all three subcategories selecting the most stringent values where they overlap.³ Therefore, the technology basis for the multiple wastestream subcategory limitations reflects the technology basis for the applicable subcategories as detailed in VIII.A.1–3.

As detailed in IV.F, multiple wastestream subcategory limitations are only available to CWT facilities which accept waste in multiple subcategories. These facilities must certify as well as demonstrate that their treatment system obtains equivalent removals to those which are the basis for the separate subcategory limits. The multiple wastestream subcategory allows the facility to monitor for compliance just prior to discharge rather than directly following treatment of a each subcategory's wastestream. For multiple subcategory facilities, this option simplifies implementation and reduces monitoring costs. EPA has, however, estimated additional burden associated with the certification process in "National Pollutant Discharge Elimination System (NPDES)/ Compliance Assessment/Certification Information" ICR (No.1427.05) for direct dischargers and "National Pretreatment Program (40 CFR part 403)" ICR (No. 0002.08) for indirect dischargers.

EPA has determined these limitations are also best practicable technology

³ EPA selected the most stringent maximum monthly average limitations and its corresponding maximum daily limitation.

limitations for facilities that operate in one or more CWT categories for the following reasons. EPA has concluded that, for multiple subcategory facilities, the limitations adopted in this subcategory in combination with the certification process will provide pollutant removals equal to or greater than those projected if the facility elects to comply with the individual subcategory limitations. Further, analysis shows that the costs for multiple subcategory facilities to comply with the multiple wastestream subcategory limitations are generally equal to or less than the costs associated with complying with each applicable subcategory's limitations individually. Because EPA determined that costs of complying with the individual subcategory limits are achievable and costs of complying with the multiple subcategory limits are no greater, EPA concluded that the multiple subcategory wastestream limits are economically achievable.

B. Best Conventional Pollutant Control Technology (BCT)

In today's rule, EPA adopts BCT limitations equivalent to BPT for all subcategories. In deciding whether to adopt different BCT limits, EPA considered whether there are technologies that achieve greater removals of conventional pollutants than adopted for BPT, and whether those technologies are cost-reasonable under the standards established by the CWA, and implemented through regulation. EPA generally refers to the decision criteria as the "BCT Cost Test." For all four subcategories, EPA identified no technologies that can achieve greater removals of conventional pollutants than those that are the basis for BPT that are also cost-reasonable under the BCT Cost Test. Accordingly, EPA is adopting BCT effluent limitations equal to the BPT effluent limitations. For additional information on the results of the BCT Cost Test, refer to Section X.F.

C. Best Available Technology Economically Achievable (BAT)

EPA today is adopting BAT effluent limitations for all subcategories of the CWT industry based on the same technologies selected as the basis for BPT for each subcategory. The BAT limitations are the same as the BPT limitations for priority and non-conventional pollutants. As described in the BPT discussion, in general, the adoption of this level of control will represent a significant reduction in pollutants discharged into the environment by facilities in this

industry. Additionally, EPA has evaluated the economic impacts associated with compliance and found the technologies to be economically achievable. The economic analysis is discussed in Section X.G.

With the exception of the metals subcategory, EPA has not identified any more stringent treatment technology option different from those evaluated for BPT that might represent best available technology economically achievable for this industry.

For the metals subcategory, EPA did consider as BAT technology a treatment technology that it had evaluated for the 1999 proposal, option 3, based on the use of selective metals precipitation. However, as detailed in the proposal (64 FR 2307–2308, 2312), there is little additional toxic removal associated with option 3 while the costs to the industry for are four times greater than the cost of the BPT option, option 4.⁴

EPA has concluded that it should not adopt BAT limitations based on Option 3 for several reasons. First, the option 3 technology may not be the best "available" technology for existing metals subcategory facilities because physical constraints may prevent its use at certain facilities. Currently, only one facility in the metals subcategory is employing selective metals precipitation, which requires the separation and holding of wastestreams in numerous treatment tanks. EPA is aware that some facilities do not have, and may not be able to obtain, sufficient space to install the additional treatment tanks that would be needed for selective metals precipitation. Second, while the removals associated with option 4 are not as great as those calculated for option 3, achievement of limitations based on the option 4 technology will still represent a significant advance in removals for the industry over those obtained from conventional precipitation technology. Given these factors, EPA has concluded it should adopt BAT limitations based on the option 4 technology.

For the oils and organics subcategories, as detailed in the proposal (64 FR 2312–2313), EPA has evaluated treatment technologies for BAT limitations, which theoretically should provide greater removal of pollutants of concern. For example, EPA identified an add-on treatment technology to technologies considered for BPT—carbon adsorption—that should have further increased removals of pollutants of concern. However,

⁴ EPA's data show that option 3 would remove approximately 6% more additional toxic pound-equivalents than option 4.

EPA's data show increases rather than decreases in concentrations of specific pollutants of concern. EPA has found that the treatment performance of activated carbon is sometimes unreliable due to the competitive adsorption and desorption of pollutants that have different affinities for adsorption on activated carbon. Also, pH changes of the wastewater going through the carbon adsorption system may cause stable metal complexes to dissolve and thus cause an increase in some metal concentrations through the adsorption system. Consequently, EPA is not adopting BAT limitations based on this technology.

D. New Source Performance Standards (NSPS)

As previously noted, under Section 306 of the Act, EPA must propose and promulgate Federal standards of performance for categories of new sources. Section 306(e) provides that, after the effective date of the standards of performance, the owner or operator of a new source may not operate the source in violation of any applicable standard of performance. The statute defines "standard of performance" as a standard for the control of the discharge of pollutants which reflects the greatest degree of effluent reduction achievable through application of the best available demonstrated control technologies, processes, operating methods or other alternatives, including, where practicable, a standard permitting no discharge of pollutants. See Section 306(a)(1) of the CWA, 33 U.S.C. 1316(a)(1). Congress envisioned that new treatment systems could meet tighter controls than existing sources because of the opportunity to incorporate the most efficient processes and treatment systems into plant design. See general discussion of legislative history in *American Iron and Steel Institute v. EPA*, 526 F.2d 1027, 1057–59 (3rd Cir. 1975). In establishing these standards, Congress directed EPA to consider the cost of achieving the effluent reduction and any non-water quality environmental impacts and energy requirements. As the legislative history of the CWA makes clear, consideration of cost in establishing new source standards is given less weight than in establishing BAT limitations because pollution control alternatives are available to new sources that would not be available to existing sources. See Legis. Hist. (Sen. Muskie statement of House-Senate Conference Report on 1972 Act).

For the oils and the organics subcategory, EPA is promulgating NSPS that would control the same

conventional, priority, and non-conventional pollutants as the BPT effluent limitations. The technologies used to control pollutants at existing facilities are fully applicable to new facilities. Therefore, EPA is promulgating NSPS oils and organics subcategory limitations that are identical to BPT/BCT/BAT.

For the metals subcategory, however, EPA is promulgating NSPS effluent limitations based on a technology which is different from that used to establish BPT/BCT/BAT limitations. EPA is promulgating NSPS for the metals subcategory based on the NSPS technology proposed in 1999—selective metals precipitation, liquid-solid separation, secondary precipitation, liquid-solid separation, and tertiary precipitation and clarification. This technology (option 3) provides the most stringent controls attainable through the application of demonstrated technology. EPA has concluded that this technology is the best demonstrated controlled technology for removing metals from the metal wastestreams typically treated in the CWT industry. Additionally, EPA has concluded that there is no barrier to entry for new sources to install, operate, and maintain treatment systems that will achieve discharge levels associated with these option 3 technologies. See X.I for a more detailed discussion of EPA's barrier to entry analysis.

An additional critical factor in EPA's decision is that new facilities will not face the same constraints on using selective metals precipitation that existing facilities may. Thus, new facilities in configuring their operation will have the opportunity to provide sufficient space to operate the multiple tanks associated with the option 3 technology.

EPA's determination to establish new source limitations based on option 3 is also tied to its conclusion that facilities using this technology have the technical capability to recover and reuse metals, whereas facilities employing technologies to comply with option 4 limitations do not generally have the capability to reuse the metals and will dispose of metal-bearing sludges in landfills. EPA's analysis shows that in the event that a new facility elects to recover and re-use metals rather than simply treating the wastes, the start-up costs for the option 3 technology may actually be less than the start-up costs for the option 4 technology. This is because of the significant reduction in RCRA permitting costs associated with recycling activities versus wastewater treatment activities. Furthermore, EPA has examined the market for re-use of metals and has concluded that these

markets exist. Consequently, EPA has concluded that metals re-use with option 3 is viable. As such, this technology selection promotes the objectives of both the Clean Water Act and the Pollution Prevention Act. While EPA has concluded there is no barrier to entry associated with the option 3 technology, EPA recognizes that a CWT metals recycling facility will be required to be somewhat more selective about the waste receipts it accepts than a CWT treatment facility. However, EPA's data show that the vast majority of metal-bearing wastewaters accepted at CWT facilities are not dilute. In EPA's view, this is because generating facilities elect to treat dilute metal-bearing wastestreams on-site because of the ease in treating these wastes and the costs associated with the transport and treatment of these dilute wastes off-site. Also, there is a large amount of capacity available at existing CWT metals subcategory facilities. Consequently, EPA has concluded that existing CWT metals subcategory facilities already provide adequate capacity for dilute metal-bearing wastestreams in the event that the frequency of dilute wastes being transferred off-site for treatment increases. Finally, EPA notes that new CWT metals subcategory facilities are not required to install the option 3 technology or to recover metals. However, EPA's economic analyses show that new sources should carefully consider recycling as an alternative to wastewater treatment.

The Agency used performance data from the CWT metals subcategory BAT limitations data set to promulgate NSPS limitations for oil and grease because the facility from which the NSPS limitations were derived did not have oil and grease in its influent at treatable levels during EPA's sampling episodes. EPA has concluded that transfer of this data is appropriate given that the technology basis for NSPS includes selective metals precipitation and an additional precipitation step. As such, EPA has every reason to conclude that facilities employing the NSPS technology could achieve the limitations, given the fact that the oil and grease limitations are based on performance at a facility employing fewer treatment steps.

As was the case for BPT/BAT, the technology basis for the multiple wastestream subcategory new source limitations reflects the technology basis for the applicable subcategories.

E. Pretreatment Standards for Existing Sources (PSES)

Section 307(b) of the Clean Water Act requires EPA to promulgate

pretreatment standards for pollutants that are not susceptible to treatment by POTWs or which would interfere with the operation of POTWs. EPA looks at a number of factors in deciding whether a pollutant is not susceptible to treatment at a POTW or would interfere with POTW operations—the predicate to establishment of pretreatment standards. First, EPA assesses the pollutant removals achieved by directly discharging CWT facilities using BAT treatment. Second, for CWT facilities that are indirect dischargers, EPA estimates the quantity of pollutants likely to be discharged to receiving waters after POTW removals. Third, EPA studies whether any of the pollutants introduced to POTWs by CWT facilities interfere with or are otherwise incompatible with POTW operations. In some cases, EPA also looks at the costs, other economic impacts, likely effluent reduction benefits, and treatment systems currently in-place at CWT facilities.

As noted above, among the factors EPA considers before establishing pretreatment standards is whether the pollutants discharged by an industry pass through a POTW or interfere with the POTW operation or sludge disposal practices. One of the tools traditionally used by EPA in evaluating whether pollutants pass through a POTW, is a comparison of the percentage of a pollutant removed by POTWs with the percentage of the pollutant removed by discharging facilities applying BAT. In most cases, EPA has concluded that a pollutant passes through the POTW when the median percentage removed nationwide by representative POTWs (those meeting secondary treatment requirements) is less than the median percentage removed by facilities complying with BAT effluent limitations guidelines for that pollutant. For a full explanation of how EPA performs its removal analysis, see Chapter 7 of the Technical Development Document. Based on EPA's evaluation of pass-through potential, 16 of the 19 BAT pollutants regulated by the metals subcategory, 14 of the 22 BAT pollutants regulated by the oils subcategory, 5 of the 17 BAT pollutants regulated by the organics subcategory, and up to 27 of the 38 potential BAT pollutants regulated by the multiple wastestream subcategory would pass through. EPA has accordingly adopted PSES for these pollutants. The BAT pollutants in each subcategory that were determined to pass-through are listed in Tables 7-6 through 7-8 in the TDD.

For the metal and organics subcategories, the Agency today is promulgating pretreatment standards for

existing sources (PSES) based on the same technologies as adopted for BPT and BAT.⁵ EPA has determined that the technology that forms the basis for PSES for this final rule is economically achievable for both subcategories. These standards will apply to existing facilities in the metals and organics subcategories of the CWT industry that introduce wastewater to publicly-owned treatment works (POTWs). These standards will prevent pass-through of pollutants from POTWs into receiving streams and also help control contamination of POTW sludge. Today's pretreatment standards represent a national baseline for treatment of CWT wastewaters. Local authorities may establish stricter limitations (based on site-specific water quality concerns or other local factors) where necessary.

For the oils subcategory, EPA proposed to base PSES on option 8 even though option 9 (the BAT technology) achieved greater removals. Option 8 is the same technology as option 9, but does not include the secondary gravity separation step. At that time, the economic analysis showed that the additional costs associated with option 9 resulted in higher economic impacts for the subcategory. In particular, EPA expressed concerns about the economic impacts of the more expensive technology for small businesses in the oils subcategory. Furthermore, EPA estimated that pollutant removals (in pound-equivalents) for option 9 were only one percent higher than the removals for option 8.

Following proposal, EPA finalized its estimates of costs, loadings reductions, and economic impacts, and then re-examined its technology selection for PSES in the oils subcategory. As part of this examination, EPA carefully considered the impacts of both option 8 and option 9 and the differences between them. EPA also looked at subsets of the oils facilities, including the set of small businesses. Based on an evaluation of all factors, EPA has not changed the technology basis from the 1999 proposal and today sets PSES standards for the oils subcategory based on option 8.

The Agency's economic analysis is discussed in detail in Section X of this preamble and Chapter 5 of the final EA. Briefly, in evaluating economic impacts, EPA looks at a variety of impacts to facilities and firms (in particular, small businesses). For this industry, EPA determined that the most relevant

economic impacts are on CWT processes and facilities. Waste industries such as the CWT industry are difficult to model economically; EPA's first attempts to model CWT operations as part of a larger facility greatly overestimated closures (see Section 7.2 of the 1995 EA and 64 FR 2326). EPA therefore decided to examine the impacts on the CWT operations and, in particular, the profitability of individual CWT processes and facilities (note that a CWT "facility" is all of the CWT processes at a given facility and does not include the non-CWT operations at a given facility).

EPA estimates that option 8 will cost \$8.2 million per year while option 9 would cost \$11.9 million per year. As discussed in Section X.H, based on these costs EPA projects 10 process closures (4.7 percent of indirect oils processes) and 12 facility closures (9.4 percent of indirect oils facilities) associated with option 8. EPA projects 15 process closures (7.0 percent of indirect oils processes) and 12 facility closures associated with option 9. The incremental economic impact of option 9 relative to option 8 for oils indirect dischargers is thus five process closures. For small businesses, however, EPA projects two process closures (2.1 percent of indirect oils processes owned by small businesses) and eight facility closures (14.0 percent of indirect oils facilities owned by small businesses) for option 8. EPA projects seven process closures (7.4 percent of indirect oils processes owned by small businesses) and eight facility closures for option 9. Thus, small businesses represent a significant share of facility closures and all of the additional process closures associated with moving from option 8 to option 9. However, EPA estimates lower additional pollutant removals between option 8 and option 9 than estimated in 1999. Today, EPA estimates an incremental pollutant reduction of only 2,644 pound-equivalents between option 8 and option 9, compared to 3,658 pound equivalents estimated at the 1999 proposal (see Section IV.J for a discussion of changes in estimated pollutant reductions). EPA has determined that achieving these slight additional pound-equivalent removals does not warrant imposition of the additional cost and impacts of option 9. All of these reasons support the selection of option 8 as the PSES technology basis. Therefore, EPA is promulgating PSES standards for the oils subcategory technology based on option 8.

In determining economic achievability for indirect dischargers in the oils subcategory, EPA acknowledges

that its estimates of the impacts are not trivial (e.g., an almost 10% facility closure rate). However, EPA has determined that the standards are economically achievable for the oils subcategory as a whole. EPA has concluded that, in the circumstances of this industry, the costs reflect appropriate levels for PSES control for a number of reasons. First, costs are high because a significant number of facilities in the oils subcategory will require major upgrades to their in-place treatment. The information collected for this rulemaking shows that many of the facilities with the larger impacts have little effective treatment in place. Second, this rule represents the first time EPA has established limitations and standards for this industry, so some economic impact may be expected. (*American Iron and Steel Institute v. EPA*, 526 F.2d 1027,1052 (3rd Cir. 1975)).

As was the case for BPT/BAT, the technology basis for pretreatment standards for the multiple wastestream subcategory reflect the technology bases for the applicable subcategories.

F. Pretreatment Standards for New Sources (PSNS)

EPA is today establishing pretreatment standards for new sources that are equal to NSPS for priority and non-conventional pollutants for the oils and organics subcategories. Since the pass-through analysis remains unchanged, for these subcategories, the Agency is establishing PSNS for the same priority and non-conventional pollutants as are being established for PSES. EPA considered the cost of the PSNS technology for new oils and organics facilities. EPA concluded that such costs are not so great as to present a barrier to entry, as demonstrated by the fact that currently operating facilities are using these technologies. The Agency considered energy requirements and other non-water quality environmental impacts and found no basis for any different standards than the selected PSNS.

For the metals subcategory, however, EPA is establishing PSNS based on a different technology than that proposed in 1999. At that time, EPA proposed to base PSNS on the option 3 technology. For the final rule, however, EPA based the pretreatment standards for new sources on the option 4 technology. EPA concluded the additional removals projected with the option 3 technology for indirect dischargers do not justify the selection of option 3. This is because, unlike in the case of direct dischargers, a significant share of the additional pollutant removals associated

⁵ For the metals subcategory, the technology basis for PSES does not include the second clarification step since this step was only included to meet the transferred TSS limitations that apply to direct dischargers only.

with option 3 for indirect dischargers will occur at the POTW anyway.

As was the case for PSES, the technology basis for the multiple wastestream subcategory new source limitations reflects the technology basis for the applicable subcategories.

IX. Compliance Cost and Pollutant Reduction Estimates

A. Regulatory Costs

The Agency estimated the cost for CWT facilities to achieve each of the effluent limitations and standards promulgated today. Chapter 11 of the

Final Technical Development Document provides information on the methodologies used to estimate these costs. More detailed information, including the cost curves for all treatment technologies considered as the basis for today's rule, are located in the "Detailed Costing Document for Final Effluent Limitations Guidelines and Standards for the Centralized Waste Treatment Industry." This section summarizes these estimated costs. All cost estimates in this section are expressed in terms of 1997 dollars. The cost components reported in this section represent estimates of the investment

cost of purchasing and installing equipment, the annual operating and maintenance costs associated with that equipment, land costs associated with equipment, and additional costs for discharge monitoring.

1. BPT Costs

Table IX.B-1 summarizes, by subcategory, the total capital expenditures, and annual O&M costs for implementing BPT (on a pre-tax, annualized basis). The total capital expenditures for BPT are estimated to be \$5.32 million with annual O&M costs of \$3.75 million.

TABLE IX.B-1.—COST OF IMPLEMENTING BPT REGULATIONS

[In 1997 dollars]

Subcategory	Number of facilities ¹	Total capital and land costs	Annual O&M costs	Pre-tax annualized costs
Metals Treatment and Recovery	9	4,069,600	3,103,200	3,544,900
Oils Treatment and Recovery	5	1,168,100	432,100	542,400
Organics Treatment	4	80,000	215,800	221,900
Multiple wastestream Subcategory ²	3	1,836,200	3,618,300	4,357,000
Total for All Subcategories ³	14	5,317,700	3,751,100	4,309,200

¹ There are 14 direct dischargers. Because some direct dischargers include operations in more than one subcategory, the sum of the facilities with operations in any one subcategory exceeds the total number of facilities.

² This estimate assumes that all facilities that accept waste in multiple subcategories elect to comply with the single Subcategory limitations.

³ This total assumes that all facilities that accept waste in multiple subcategories elect to comply with each set of limitations separately.

2. BCT/BAT Costs

The costs of compliance for implementing BCT/BAT are identical to the cost of compliance with BPT because the technology used to develop

BCT/BAT limitations is identical to BPT.

3. PSES Costs

The Agency estimated the cost for implementing PSES applying the same assumptions and methodology used to

estimate the cost of implementing BPT. Table IX.B-2 summarizes, by subcategory, the capital expenditures and annual O&M costs for implementing PSES. The total capital expenditures for PSES are estimated to be \$52.6 million with annual O&M costs of \$25.5 million.

TABLE IX.B-2.—COST OF IMPLEMENTING PSES REGULATIONS

[In 1997 dollars]

Subcategory	Number of facilities ¹	Total capital and land costs	Annual O&M costs	Pre-tax annualized
Metals Treatment and Recovery	44	11,111,100	10,242,100	11,449,600
Oils Treatment and Recovery	127	23,834,000	12,484,400	14,797,600
Organics Treatment	16	17,709,200	2,766,200	4,592,800
Multiple wastestream Subcategory ²	24	44,576,100	20,392,700	24,875,900
Total for All Subcategories ³	151	52,654,300	25,792,700	30,840,000

¹ There are 151 indirect dischargers. Because some indirect dischargers include operations in more than one subcategory, the sum of the facilities with operations in any one subcategory exceeds the total number of facilities.

² This estimate assumes that all facilities that accept waste in multiple subcategories elect to comply with the single waste subcategory limitations.

³ This total assumes that all facilities that accept waste in multiple subcategories elect to comply with each set of limitations separately.

B. Pollutant Reductions

The Agency estimated pollutant reductions for CWT activities achieving each of the effluent limitations and standards promulgated today. This section summarizes these estimated reductions and Chapter 12 of the technical development document discusses the methodology in detail. For multiple subcategory facilities, EPA

estimated pollutant reductions assuming facilities will elect to comply with each subcategory's limitations separately. Table IX.C-1 summarizes, by subcategory, the reduction in discharge of pollutants for implementing BPT/BAT. For multiple subcategory facilities which elect to comply with the multiple wastestream subcategory limitations, EPA estimates pollutant removals will

be equal to or greater than those presented here.

1. Conventional Pollutant Reductions

The Agency estimates that this regulation will reduce BOD₅ discharges by approximately 5.0 million pounds per year, TSS discharges by approximately 4.4 million pounds per year, and oil and grease discharges by

approximately 0.3 million pounds per year.

2. Priority and Non-Conventional Pollutant Reductions

Today's rule will reduce discharges of priority and non-conventional pollutants. Because EPA has

promulgated BAT limitations equivalent to BPT, EPA estimates pollutant reductions associated with BPT and BAT will be equal.

a. Direct Discharge Facilities (BPT/BAT). The estimated reductions in priority and non-conventional pollutants directly discharged in treated

final effluent resulting from implementation of BPT/BAT are listed in Table IX.C-1. The Agency estimates that promulgated BPT/BAT regulations will reduce direct discharges of priority and non-conventional pollutants by approximately 2.7 million pounds per year.

TABLE IX.C-1—REDUCTION IN DIRECT DISCHARGE OF PRIORITY AND NON-CONVENTIONAL POLLUTANTS AFTER IMPLEMENTATION OF BPT/BAT REGULATIONS

Subcategory	Priority metal and organics compounds lbs/year	Non-priority metal and organic compounds lbs/year	Total metal and organic compounds lbs/year	Total lbs-equivalent/year
Metals Treatment and Recovery	981,200	1,708,600	2,689,800	377,800
Oils Treatment and Recovery	2,100	23,100	25,200	1,800
Organics Treatment ¹	0	0	0	0
Total Removals for all Subcategories	983,300	1,731,700	2,715,000	379,600

¹ EPA estimates there will be no additional removal of organic compounds for the organics subcategory, because all facilities had the treatment-in-place for removal of organic compounds.

b. PSES Effluent Discharges to POTWs. Table IX.C-2 lists the estimated reductions in priority and non-conventional pollutants indirectly discharged to POTWs resulting from implementation of PSES. The Agency estimates that promulgated PSES

regulations will reduce indirect facility discharge to POTWs by 1.9 million pounds per year. These figures are not adjusted for pollutant removals expected from POTWs, and thus do not reflect reductions in discharges to waters of the U.S. Estimated reductions

in pollutants discharged indirectly to surface waters are provided on a subcategory basis in Tables 12-10 through 12-13 of the technical development document.

TABLE IX.C-2—REDUCTION IN DISCHARGES TO POTWS OF PRIORITY AND NON-CONVENTIONAL POLLUTANTS AFTER IMPLEMENTATION OF PSES REGULATIONS

Subcategory	Priority metal and organics compounds lbs/year	Non-priority metal and organic compounds lbs/year	Total metal and organic compounds lbs/year	Total lbs-equivalent/year
Metals Treatment and Recovery	61,897	419,667	481,564	37,539
Oils Treatment and Recovery	82,359	752,429	834,788	50,803
Organics Treatment	163,664	447,620	611,283	19,876
Total Removals for All Subcategories	307,920	1,619,716	1,925,543	108,218

X. Economic Analyses

A. Introduction

EPA's economic analysis for this regulation assesses the costs and a variety of impacts. The record for the final rule contains the detailed results of this analysis. This section reviews that analysis. A report titled "Economic Analysis of Final Effluent Limitations Guidelines and Standards for the Centralized Waste Treatment Industry" (hereinafter "final EA") summarizes the results of that assessment. The EA estimates the economic and financial costs of compliance with the final regulation on individual process lines, facilities and companies. The EA also considers impacts on new sources. Community impacts, foreign trade

impacts, market impacts, and an "environmental justice" analysis are also presented there. The EA also includes a Regulatory Flexibility Analysis detailing the effects on small CWT businesses. The results of a cost-effectiveness analysis are in a report titled "Cost-Effectiveness Analysis of Final Effluent Limitations Guidelines and Standards for the CWT Industry." EPA has used the same methodology for estimating compliance costs and impacts of the final rule as it used for the 1999 proposal except for adjustments to costs discussed under section IV.I above.

B. Annualized Compliance Cost Estimate

As discussed previously, EPA identified 223 CWT facilities, including 14 direct dischargers, 151 indirect dischargers, and 58 zero discharge facilities. EPA calculated the economic impact on each of the facilities based on the cost of compliance using the selected technology basis for the final limitations and standards. For direct dischargers, EPA calculated impacts for compliance with the selected BPT/BCT/BAT; for indirect dischargers, EPA calculated impacts for compliance with PSES. As detailed previously in Section VIII, EPA based the final limitations on metals option 4, oils option 9, and organics option 4 and the final standards on metals option 4, oils

option 8, and organics option 4. EPA conservatively assigned costs to a facility with processes in multiple subcategories for meeting the limits or standards in each subcategory although an alternative costing scheme was also applied.

The technologies that are the basis for today's final rule are estimated to have a total pre-tax annualized cost of \$35.1 million (unlike the costs presented in Section IX.B, these costs are annualized to represent the yearly cost of compliance). Table X.B-1 presents the total annualized costs for BPT/BCT/BAT and PSES in 1997 dollars for the entire CWT industry. This table differentiates between pre-tax annualized costs and post-tax annualized costs. The pre-tax annualized costs are the engineering estimates of annualized control costs, but the post-tax costs more accurately reflect the costs businesses will incur. For that reason, post-tax costs are used in the economic impact analysis. Pre-tax costs, however, more accurately reflect the total cost to society of the rule and are used in the cost-effectiveness analysis and elsewhere.

TABLE X.B-1—TOTAL ANNUALIZED COSTS
(1997)

	Pre-tax costs (\$ million)	Post-tax costs (\$ million)
BPT/BCT/BAT Costs (Direct Dischargers)	4.31	2.68
PSES Costs (Indirect Dischargers)	30.8	17.1
Total Costs	35.1	19.8

C. Economic Description of the CWT Industry and Baseline Conditions

The 1999 proposal and Chapter 2 of the Final EA detail the current economic conditions in the industry and the data sources used in determining these conditions. This section updates the information presented at the time of the 1999 proposal.

EPA now estimates that there are 223 CWT facilities. EPA includes 211 CWT facilities in its economic baseline,⁶ 207 facilities are commercial, accepting waste generated by other facilities and/or generators for treatment and/or recovery for a fee. Three facilities are non-commercial facilities that accept waste from off-site for treatment and/or

recovery exclusively from facilities under the same ownership, and one is owned by the Federal government and is treated as noncommercial. Some facilities perform both commercial and non-commercial operations. For the purposes of this analysis, a facility's commercial status refers only to the operations subject to today's final rule and not other operations at that facility. That is, a facility that performs non-commercial CWT operations along with other non-CWT commercial operations would still be considered a non-commercial facility.

The 167 companies owning CWT facilities range from large, multi-facility companies to small companies that operate only a single facility. Company-level sales information is available or estimated for 208 facilities. Company level profit information is available for 144 facilities. One hundred and nine companies own these 144 facilities. EPA currently estimates that 82 companies owning CWT facilities (including zero discharge facilities) are small businesses (for the purposes of this analysis, EPA has defined small businesses as companies with less than \$6 million in annual revenues—see Section X.M). Sixty-three small companies own two direct discharging facilities and 61 indirect discharging facilities.

D. Economic Impact and Closure Methodology

1. Overview of Economic Impact Methodology

There are no differences between the economic methodology used for the 1999 proposal and the current methodology. Standard economic and financial analysis methods are used to assess the economic effects of the proposed regulation. These methods incorporate an integrated view of CWT facilities, the companies that own these facilities, the markets the facilities serve, and the communities where they are located.

CWT facilities are divided into two groups: commercial (those that charge a fee for their services) and noncommercial (those that handle intra-company waste). Impacts on commercial CWT facilities are estimated based on the results of a market model that allows facilities to adjust operations in response to changes in operating costs. The market model predicts adjustments in market prices and quantities and facility-level changes in revenues and employment. (EPA also performed sensitivity analysis in which prices do not adjust.) After the markets and facilities have responded to the regulation, facilities are assumed to

close CWT treatment operations (or processes) for which operating costs (including compliance costs) exceed operating revenues. Because non-commercial CWT facilities do not operate in the markets defined by the model, impacts on these facilities are estimated at the company level, assuming that the firm must absorb the full cost of compliance. For a detailed description of the economic methodology see the 1999 proposal (64 FR 2324) and Chapter 5 of the Final EA.

In the economic analysis, EPA examines impacts on commercial CWT facilities in terms of closures, but focuses on potential closures of CWT processes by examining the costs and revenues of each waste treatment or recovery operation with the regulation in effect. (This isolates the analysis to examine only CWT operations and not overall facility operations). If with-regulation costs of the operation exceed revenues, then the model predicts (assumes) that the operation shuts down. This is called a "process closure." If all the CWT treatment processes at a facility are estimated to shut down, this is called a "facility closure." This does not mean that if a CWT facility with other non-CWT operations experiences a facility closure that the entire facility shuts down; other operations at a facility are not included in the economic modeling, only CWT operations. Employment losses are calculated from process closures, facility closures, and from reductions in waste treated by process lines that do not close. In all cases, the reduction in employment is calculated as a percentage decrease of the facility's total CWT employment proportionate to the percentage reduction in waste treated (this does not account for any possible increases in employment due to the regulations).

EPA notes that its model for the 1999 proposal and the final rule, unlike the market model used for the 1995 proposal, does not assume that wastewater from processes or facilities that close will be transferred to another facility in the market. Although the model assumes the price increase caused by increased compliance costs forces the total quantity of waste treated in the market to decline (the amount of this decline is governed by the elasticity of demand for a market), some of the waste previously treated at a facility that closes will be treated at other facilities. By assuming that all changes in quantity occur at the highest-priced facilities and that waste is not sent to other facilities, EPA is assuming an all-or-nothing impact. The model may overstate impacts at those facilities that could

⁶ Twelve zero dischargers were identified after proposal for which EPA does not have adequate data to perform modeling. They are therefore not included in the economic baseline.

accept waste from another facility that closes. Conversely, the model may understate impacts at those facilities that cannot raise their price as much as projected. (EPA solicited comments on this issue and on appropriate ways to model this transfer but received none, so no changes were made to the methodology.)

Changes in facility revenues and costs result in changes in the revenues and costs of the companies owning the facilities, and thus changes in company profits. Increased borrowing and changes in the assets owned by the companies, together with changes in profits, result in changes in overall company financial health. EPA evaluates company-level impacts by examining changes in company profit margins and returns-to-assets test. These results are presented separately for small businesses. For small businesses, EPA also evaluates the economic impacts using a cost-to-sales test, comparing company compliance costs to baseline sales (unadjusted for cost pass-through).

Finally, the communities where the CWT facilities are located may be affected. Obviously, if facilities cut back operations, employment and income may fall, sending ripple effects throughout the local community. On the other hand, there may be increased employment associated with operating the pollution controls associated with the regulation, resulting in increased community employment and income. Facility-level changes in employment are used to calculate total employment changes. At the same time, for the communities in which CWT facilities

are located, water quality may be expected to improve.

2. Comments on Economic Methodology

During the SBAR Panel consideration of the 1999 proposal, the Small Business Administration (SBA) expressed concern that EPA's economic methodology understates impacts. In particular, SBA questioned the elasticity of demand assumption used by the Agency, which affects the extent to which facilities will be able to pass on cost increases to their customers. As discussed in the final EA and this notice, the elasticity of demand (which varies depending on the number of facilities in each market) is based on economic reasoning that the Agency determines to be sound and reflects the limited empirical evidence available in the literature. In response to SBA's comment (but prior to the 1999 proposal), EPA reexamined the literature and attempted to contact waste generators to obtain further information on their responsiveness to the price of CWT services. EPA identified several additional empirical studies that support the elasticity parameters used in the EA. The Agency has not been successful, however, in eliciting information from waste generators. In the 1999 proposal, EPA solicited comment on the elasticity parameter and requested data that EPA could use to calculate the parameter, but received neither. EPA is therefore not altering its choice of parameters. For a complete discussion of the elasticity parameters used in this analysis, see Appendix E of the proposal EA.

In Appendix E to the proposal EA, EPA presents a sensitivity analysis that assumes that CWT facilities are unable to pass costs to their customers. In this analysis, impacts on direct dischargers are unchanged, but impacts on indirect dischargers increase from 13 to 16 facility closures and from 16 to 29 process closures.

E. Costs and Economic Impacts of BPT

For BPT, EPA evaluates treatment options first by calculating pre-tax total annualized costs and total pollutant removals in pounds. The ratios of the costs to the removals for each option considered for the final rule are presented in Table X.E-1. (EPA is no longer considering two options considered in the 1999 proposal: metals option 2 and organics option 3. See 64 FR 2308 and 64 FR 2312.) In all cases throughout section X, estimated costs and impacts for facilities with operations in multiple operations are presented assuming that the facilities comply with the limits for each subcategory separately, rather than with the limits for the multiple wastestream subcategory. See section VIII.A.4)

EPA based the selected BPT options for the metals, oils, and organics subcategories on option 4, option 9, and option 4, respectively. As detailed in Section VIII.A.3, all direct dischargers in the organics subcategory employ the BPT technology basis. As such, other than monitoring costs, EPA assigned no compliance costs to these facilities nor did it estimate incremental pollutant removals.

TABLE X.E-1.—BPT COST ANALYSIS

Option	Pre-tax total annualized costs (\$1997 million)	Conventional pollutant removals (million lbs)	Average cost reasonableness (1997 \$/lb)
Metals Subcategory—9 Facilities			
4	\$3.54	8.77	\$0.40
3	14.8	9.33	1.59
Oils Subcategory—5 Facilities			
9 ¹	0.542	0.865	0.63
Organics Subcategory—4 Facilities			
4	0.222	0	n/a

¹ Since all direct discharging oils facilities already have treatment-in-place equivalent to secondary gravity separation, EPA did not consider the Option 8 technology.

Table X.E-2 presents the economic impact results for the selected BPT options. Options in the Metals and Organics subcategories more stringent

than promulgated BPT are evaluated in Sections X.F and X.G. Impacts are presented for process closures, facility closures, and employment losses.

Process closures are a direct output of the market model. EPA concludes that a facility will close if all of the processes at a facility close.

TABLE X.E-2.—ECONOMIC IMPACTS OF BPT OPTIONS

Option	Post-tax total annualized costs (\$1997 M)	Process closures	Facility closures	Total employment losses
Metals Subcategory—9 Facilities				
4	\$2.19	1	1	39
Oils Subcategory—5 Facilities				
9 ¹	0.348	2	0	8
Organics Subcategory—4 Facilities				
4	0.138	2	0	0

¹ Since all direct discharging oils facilities already have treatment-in-place equivalent to secondary gravity separation, EPA did not consider the Option 8 technology.

EPA projects that the selected BPT regulations will result in only one process closure and one facility closure in the metals subcategory; two process closures, but no facility closures, in the oils subcategory; and only 2 process closures, but no facility closures, in the organics subcategory. The summed job losses for the BPT options are 47. (There

are no job losses associated with the organics subcategory even though there are two process closures because job losses are proportional to flow. The organics flow at the facilities with the process closures is so low compared to the facility flow that there are no proportional job losses.)

Many facilities in the CWT industry have operations in more than one subcategory. EPA therefore evaluated the impacts of a combined BPT option on all direct dischargers. The combined impacts of this option are presented in Table X.E-3.

TABLE X.E-3.—ECONOMIC IMPACTS OF COMBINED BPT OPTION

Option	Post-tax total annualized costs (\$1997 M)	Process closures	Facility closures	Total employment losses
All Direct Dischargers—14 Facilities				
Combined	\$2.68	3	2	47

EPA projects that the final BPT regulations will result in three process closures, two facility closures, and a total employment loss of 47 jobs. The totals for the individual subcategories shown in Table X.E-2 do not add to the totals shown in Table X.E-3 because a facility may have operations in more than one subcategory. For example, a closure is counted when all of the processes at a given facility close, and a process closure is counted when one, but not all, of the processes close. Therefore, for facilities with process closures in more than one subcategory, the analysis of the combined option can show a lower number of process closures and a higher number of facility closures.

F. Results of BCT Cost Test

In July 1986, EPA explained how it developed its methodology for setting effluent limitations based on BCT (51 FR 24974). EPA evaluates the

reasonableness of BCT candidate technologies—those that remove more conventional pollutants than BPT—by applying a two-part cost test: a POTW test and an industry cost-effectiveness test.

EPA first calculates the cost per pound of conventional pollutant removed by industrial dischargers in upgrading from BPT to a BCT candidate technology, and then compares this cost to the cost per pound of conventional pollutants removed in upgrading POTWs to advanced secondary treatment. The upgrade cost to industry must be less than the POTW benchmark of \$0.25 per pound (in 1976 dollars) (*i.e.* “the POTW test”). In the industry cost-effectiveness test, the ratio of the incremental BPT to BCT cost divided by the BPT cost for the industry must be less than 1.29 (that is, the cost increase must be less than 29 percent).

Table X.F-1 presents the calculations for the BCT cost test for the metals

subcategory. For option 3 (the only more stringent option considered for the metals subcategory in the final rule), the table presents costs and conventional pollutant removals and compares them to the BPT baseline, option 4. For a candidate BCT option to pass the POTW test, the ratio of costs to removals for that option must be less than \$0.71 (\$1997) per pound. Option 3's ratio is \$20.11, well above the benchmark of \$0.71, so it fails the POTW test. This option therefore does not pass the BCT cost test and it is not necessary to perform the industry cost-effectiveness test. Thus, BCT is set equal to BPT.

For the final CWT rule, EPA did not consider any technologies for the oils and organics subcategories that are more stringent than the selected BPT technology basis. As such, EPA did not perform a BCT cost test for these subcategories and set BCT equal to BPT.

TABLE X.F-1.—BCT COST TEST CALCULATIONS
[Metals Subcategory]

Option	Pre-tax total annualized costs (\$1997 M)	Conventional pollutant removals (M lbs)	Ratio of costs to removals for BCT candidate (\$/ lb)	Does the BCT candidate pass POTW test?
4 (BPT)	\$3.54	8.77	n/a	n/a
3 (BCT Candidate)	14.8	9.33	\$20.11	no

G. Costs and Economic Impacts of BAT Options

EPA also evaluated options more stringent than BPT in the metals subcategory for BAT (in the oils and organics subcategories, EPA set BPT

equal to the most stringent option that it considered for the final rule). This is metals option 3. For a given technology to be the basis for BAT limitations it must be economically achievable. EPA is today adopting BAT limitations

equivalent to BPT for all subcategories; economic impacts are, therefore, equivalent to those presented in Section X.E for the final BPT limits. Table X.G-1 presents the economic impact results for the options considered for BAT.

TABLE X.G-1.—ECONOMIC IMPACTS OF BAT OPTIONS

Option	Post-tax total annualized costs (\$1997 M)	Process closures	Facility closures	Total employment losses
Metals Subcategory—8 Facilities				
4	\$2.19	1	1	39
3	9.01	1	1	40
Oils Subcategory—5 Facilities				
9 ¹	0.348	2	0	8
Organics Subcategory—4 Facilities				
3	0.263	2	0	0

¹ Since all direct discharging oils facilities already have treatment-in-place equivalent to secondary gravity separation, EPA did not consider the option 8 technology.

EPA projects (see Table X.E-3) that the selected BAT regulations will result in three process closures, two facility closures and 47 job losses. The projected closure impacts for the rejected metals option are equivalent to the impacts for the selected option, although there are slightly more employment losses for the rejected metals options. However, as discussed in Section VIII.C, EPA did not select this option for BAT.

H. Costs and Economic Impacts of PSES Options

In addition to evaluating impacts to direct dischargers for BPT/BCT/BAT, EPA evaluated the impacts to indirect dischargers for complying with PSES. For the metals and organics subcategory, EPA is selecting the same options for PSES that were selected for BPT/BAT: metals option 4 and organics option 4. For the oils subcategory, EPA selected oils option 8 for PSES. The impacts of the PSES options are presented in Table

X.H-1. Impacts are presented for process closures, facility closures, and employment losses. Process closures are a direct output of the market model; facility closures are designated if all of the processes at a facility close. Employment losses are calculated from process closures, facility closures, and from reductions in waste treated by process lines that do not close. In all cases, the reduction in employment is calculated as a decrease of the facility's total CWT employment proportionate to the reduction in waste treated.

TABLE X.H-1.—IMPACTS OF PSES OPTIONS

Option	Post-tax total annualized costs (\$1997 M)	Process closures	Facility closures	Total employment losses
Metals Subcategory—47 Facilities				
4	\$6.25	6	0	152
3	26.8	9	1	289
Oils Subcategory—127 Facilities				
8	8.23	10	12	224

TABLE X.H-1.—IMPACTS OF PSES OPTIONS—Continued

Option	Post-tax total annualized costs (\$1997 M)	Process closures	Facility closures	Total employment losses
9	11.9	15	12	233
Organics Subcategory—16 Facilities				
4	2.67	7	0	30

In the metals subcategory, EPA projects that Option 4, the selected PSES technology basis, will result in six process closures, no facility closures, and 152 job losses. For the oils subcategory, EPA projects that option 8, the selected PSES technology basis, results in 10 process closures, 12 facility closures, and 224 job losses. For the organics subcategory, EPA projects that Option 4 results in seven process

closures and no facility closures, with 30 job losses.

Many facilities in the CWT industry have operations in more than one subcategory. EPA therefore evaluated the impacts of a combined PSES option on all indirect dischargers. This option consists of metals option 4, oils option 8, and organics option 4. The projected impacts of the combined option are presented in Table X.H-2. The impacts of the selected PSES options shown in

Table X.H-1 do not add to the impacts shown in Table X.H-2 because a facility closure is counted if all of the processes at a given facility close while a process closure is counted if one, but not all, processes close. Therefore, in the combined options, the number of process closures can go down while facility closures go up if processes in different subcategories close. The employment losses also do not add up because of rounding.

TABLE X.H-2.—ECONOMIC IMPACTS OF COMBINED PSES OPTION

Option	Post-tax total annualized costs (\$1997 M)	Process closures	Facility closures	Total employment losses
All Indirect Discharges—151 Facilities				
Combined	\$17.1	15	15	414

I. Economic Impacts for New Sources

EPA is establishing NSPS limitations equivalent to the limitations that are established for BPT/BCT/BAT for both the organics and oils subcategories. These limitations are economically achievable because, in general, EPA concludes that new sources will be able to comply at costs that are similar to, or less than, the costs for existing sources. They may be able to comply at lower cost since new sources can apply control technologies more efficiently than sources that need to retrofit for those technologies. Therefore, NSPS limitations will not present a barrier to entry for new facilities in these subcategories.

For the metals subcategory, EPA is establishing NSPS limitations based on the option 3 technology. EPA's analysis shows that the start-up costs for the option 3 technology for new sources may be less than the start-up costs for the option 4 technology. Consequently, EPA has concluded that compliance with limitations based on this option would not constitute a barrier to entry for new direct discharging metals subcategory sources. EPA also investigated the extent of the market for

recycling or reuse of the metals-rich sludge generated by option 3 to determine if a market exists for these materials (since promoting recycling was part of the justification for option 3). EPA has determined that there is a wide market for a number of metals that could be recycled through this process, though as discussed previously, EPA recognizes that there are some metal bearing wastestreams that may not be suitable for recycling because of the low concentrations of metals. Also, for some metals, such as aluminum, there are no current markets for recycling.

EPA is setting PSNS equal to PSES limitations for existing sources for the metals and organics subcategories. Given EPA's finding of economic achievability for PSES in those two subcategories, EPA also finds that the PSNS regulation will be economically achievable and will not constitute a barrier to entry for new sources.

For the oils subcategory, EPA is establishing pretreatment standards for new sources that are equal to NSPS for priority and non-conventional pollutants. EPA concluded there is no barrier to entry for new indirect discharging facilities in the oils

subcategory because existing oils indirect dischargers are using the technology.

J. Firm Level Impacts

Complying with the selected effluent limitations guidelines and standards affects the revenues and profitability of firms owning CWT facilities. In Section 6.1.4 of the Final EA, the Agency examines two financial ratios to assess the magnitude of these impacts: firm profit margin (profit/revenues) and return on assets or ROA (profit/total assets). Baseline values are compared to post-regulation values that are determined by calculating changes in profits based on output from the market model. EPA does not have complete data for all firms, but the two measures decline for more than half of the firms for which EPA has data. EPA also examined these measures by size categories, including a category for small businesses. For most size categories, median profit margin and median ROA decline or stay approximately the same (although for some size categories the medians may increase). EPA has profit data on 56 small firms and asset data for 26 small

firms; profit margin declines for 33 of the 56 firms and ROA declines for 15 of the 26 firms. As discussed more fully in the EA, these results are dependent on the assumptions used in the market model and the market in which EPA placed the facilities.

K. Community Impacts

EPA estimated impacts on communities in which CWT facilities were located by estimating the overall change in employment in the community as a result of the CWT rule. EPA estimated the change in employment at each CWT facility associated with reductions in the quantity of waste treated at facilities incurring economic impacts. Then, EPA applied state-specific direct-effect employment multipliers to estimate the total change in employment. Most of the change in employment will occur in the community where the CWT facility is located. Thus, EPA estimated the change in community employment as a result of the rule by assigning all of the change in employment to the community. Table X.K-1 shows a distribution of the estimated changes in community employment resulting from the economic impacts of the regulation. Community employment losses range from zero to 213 full time equivalents. Even the largest reduction in employment represents only 0.7 percent of the baseline employment in that community. Thus, the Agency expects the negative employment impacts of the regulation to be extremely small. In fact, EPA estimates that most facilities that do not close or scale back their CWT operations will have to hire from one to three additional workers to comply with the regulation (although this is not taken into account in Table X.K-1). Taking these impacts into effect, almost all of these facilities will experience increases in employment due to the regulation. The overall impact of the regulation on community employment may, therefore, be either positive or negative.

TABLE X.K-1.—ESTIMATED COMMUNITY EMPLOYMENT IMPACTS OF THE CWT REGULATION¹

Reductions in community employment as a result of process and facility closures	Number of communities
Greater than 50 full time equivalents	5
20 to 50	11
1 to 20	14
0 to 1	12
Zero	100

¹ Does not account for employment gains associated with compliance.

The Agency also examined the distribution of benefits across communities with different socioeconomic and ethnic characteristics. Pursuant to Executive Order 12898, EPA must, to the greatest extent practicable and permitted by law, make achieving environmental justice part of its mission. Environmental justice concerns arise when disadvantaged or minority communities experience disproportionately high and adverse human health or environmental impacts. CWT facilities are frequently located in industrial areas; as such, the communities frequently have higher minority populations and greater poverty than the rest of their state or the nation as a whole. Reductions in pollutant exposures to these populations would, benefit such communities, but they may bear a disproportionate share of the costs of attaining these reductions. Table X.K-2 characterizes the communities in which CWT facilities are located.

TABLE X.K-2.—SOCIOECONOMIC PROFILE OF COMMUNITIES IN WHICH CWT FACILITIES ARE LOCATED

Percentage	Number of communities
Percent of the Population that are Non-Caucasian (National Percentage=16.8%)	
Less than 10	32
10 to 20	17
20 to 30	35
30 to 50	39
over 50	23
Percent of the Population With Incomes Below Poverty Level (National Percentage=13.5)	
Less than 7	19
7 to 13	33
13 to 20	56
20 to 30	31
over 30	7

Using the most recent census data, in 1990, the nation as a whole had a population that was 16.8 percent non-Caucasian. Of the communities in which CWT facilities were located, on the other hand, 38 percent had populations that were at least 30 percent minority, and 54 percent of communities had populations whose minority percentage exceeded that of the state in which they were located by more than five percentage points. In 1990, 13.5 percent of the U.S. population had incomes below the poverty level, 22 percent of communities with CWT facilities had at least 20 percent of their residents in poverty, and 33 percent had percentages

of the population in poverty that exceeded by at least 5 percentage points the percentage of the population in poverty for the states in which they were located. Thus, environmental justice is a concern for these communities. The costs of the rule fall disproportionately on facilities in minority and low-income communities. Benefits may also accrue to these communities as a result of this rule, but a large share of benefits are likely to accrue to communities downstream from the CWT or POTW, which may not be the same community.

L. Foreign Trade Impacts

The EA does not project any foreign trade impacts as a result of the effluent limitations guidelines and standards. Many of the affected CWT facilities treat waste that is considered hazardous under RCRA and international trade in CWT services for treatment of hazardous wastes is virtually nonexistent. Furthermore, there is very little, if any, international trade in treatment of non-hazardous CWT wastes.

M. Small Business Analysis

The Agency prepared a final regulatory flexibility analysis to assess the impacts on small businesses owning CWT facilities. No small governmental jurisdictions or small organizations own and/or operate CWT facilities. For purposes of this analysis, EPA defines small CWT businesses as those having sales less than \$6 million—the Small Business Administration definition of a small business for SIC code 4953, Refuse Systems. This is the SIC code that most CWT facilities listed in their questionnaire responses (see final EA Chapter 3). Two small companies own facilities that discharge directly. There are 61 small companies that own facilities that discharge indirectly. (The total number of small companies includes applying weights to some of the facilities). EPA evaluated the impact on small CWT companies using a cost-to-sales test, which compares baseline sales to compliance costs (adjusted for inflation so that the costs and sales are expressed in the same year's dollars). This assessment does not account for any ability of the companies to pass any increase in operating costs through to their customers. EPA recognizes that for many industries, costs-to-sales ratios in excess of one percent may correspond to much higher ratios of cost to pre-compliance profits, and, thus, serve as a signal for additional analysis. EPA sought to identify those small business that would experience costs in excess of one percent of sales and those experiencing costs exceeding three

percent of sales. However, EPA does not believe that the cost-to-sales ratio is a particularly precise measure of economic impact for this industry.

The two small companies that own direct discharging facilities, both in the oils subcategory, have cost-to-sales ratios of over three percent. Results of the cost-to-sales test for the PSES

options are presented in Table X.M-1 for the number of facilities with estimated costs exceeding one percent and three percent of sales.

TABLE X.M-1.—RESULTS OF COST-TO-SALES TEST FOR PSES OPTIONS FOR SMALL BUSINESSES

Option	# of small companies with cost/sales > 1%	# of small companies with cost/sales > 3%
Metals Subcategory—4 Small Businesses		
4	4	2
3	4	4
Oils Subcategory—57 Small Businesses		
8	47	25
9	53	36
Organics Subcategory—2 Small Businesses		
4	2	1

As can be seen from Table X.M-1, the bulk of the small businesses are in the oils subcategory. Oils option 8 has 47 firms (82 percent of the small businesses) with cost-to-sales ratios in excess of 1 percent and 25 firms (44 percent of the small businesses) with cost-to-sales ratios in excess of 3 percent (without adjustment for pass-through of costs). On the other hand, oils option 9

has 53 firms (93 percent of the small businesses) with cost-to-sales ratios in excess of 1 percent and 36 firms (63 percent of the small businesses) with cost-to-sales ratios in excess of 3 percent (without adjustment for pass-through of costs).

Many of the facilities owned by small businesses operate processes in more than one subcategory so, as with the

economic impact analyses presented earlier in this section, cost-to-sales test results are presented for combined PSES options. In order to be consistent with the 1999 proposal, there are two combined options: one based on oils option 8 and one based on oils option 9. These results are presented in Table X.M-2.

TABLE X.M-2.—RESULTS OF COST-TO-SALES TEST FOR COMBINED PSES OPTIONS FOR SMALL BUSINESSES

Combined option	# of small companies with cost/sales > 1%	# of small companies with cost/sales > 3%
Indirect Dischargers—61 Small Businesses		
w/Oils Option 8	51	28
w/Oils Option 9	57	38

The PSES combined option with Oils Option 8 has 51 firms (84 percent of small businesses) with cost-to-sales ratios in excess of 1 percent and 28 firms (46 percent of small businesses) with cost-to-sales ratios in excess of 3 percent. On the other hand, the combined option with Oils Option 9 has 57 firms (93 percent of small businesses) with cost-to-sales ratios in excess of 1 percent and 38 firms (62 percent of small businesses) with cost-to-sales ratios in excess of 3 percent.

EPA convened a Small Business Advocacy Review (SBAR) Panel during the development of this rule and also considered several regulatory alternatives to provide relief for small businesses. These alternatives are summarized below, and are discussed in

other sections of the preamble along with EPA's conclusions (See Sections IV.A-IV.E).

EPA examined several criteria for establishing an exclusion for small businesses such as the volume of wastewater flow, employment, or annual revenues. The objective was to minimize the impacts on small businesses, still achieve the environmental benefits, and stay responsive to the Clean Water Act. EPA is defining small CWT businesses according to the SBA size definition of \$6 million in annual revenue, but considered other criteria that would be easier to implement in practice, such as wastewater flow. To target relief to small businesses, EPA examined the

correlation between these criteria and the size definition.

Because most CWT facilities have similar numbers of employees regardless of their size (*i.e.*, revenue), EPA first eliminated employment as a basis for establishing a small business exclusion. While EPA also found no correlation between annual volume of wastewater and the size of a facility, EPA retained this criterion in the 1999 proposal due to the anticipated ease in implementing an exclusion based on this criterion. However, if an exclusion based on volume of wastewater had ultimately been selected, the regulation would have excluded both small and large businesses.

EPA evaluated three alternatives based on wastewater flow and size as

potential bases for limiting the scope of the regulation to: (i) Indirect dischargers with flows greater than 3.5 million gallons per year (MGY), or (ii and iii) indirect dischargers that manage non-hazardous wastes only with flows greater than either 3.5 MGY or 7.5 MGY. EPA also considered limiting the applicability of the proposed regulation to indirect dischargers not owned by small businesses without any specific reference to flow (referred to as "no smalls", below). The justification for

EPA's consideration of these particular exclusion alternatives is included in the record in materials submitted to the SBAR Panel.

For each alternative, EPA estimated the projected economic impacts, both in absolute terms and in relative terms (that is, whether the impacts were higher, proportionately, for small businesses). The economic impacts that EPA considered for small companies include process closures, facility closures, employment losses, and the cost-to-sales test. Table X.M-3 shows

the results of the facility-level analyses (if current facility receipts do not change) and the results of the analyses for the selected options for comparison purposes for all indirect dischargers. Table X.M-4 shows the results of the cost-to-sales test, which are company-level impacts for small companies that own indirect dischargers. Preliminary versions of these results were provided to the small entity representatives (SERs) who provided advice to the SBAR Panel.

TABLE X.M.-3.—IMPACTS OF PSES OPTIONS WITH LIMITED SCOPE

Option	Post-tax total annualized costs (\$1997 M)	Process closures (small/large)	Facility closures (small/large)	Total employment losses
All Indirect Dischargers—151 Facilities				
Combined Option w/ Oils 8	\$20.83	4/11	8/7	414
reduced monitoring	17.87	4/11	7/7	420
>3.5 MGY, non-hazardous	17.14	7/10	2/5	221
>3.5 MGY	14.89	5/9	0/1	80
>7.5 MGY, non-hazardous	15.49	7/10	2/5	213
"No smalls"	13.21	0/10	0/8	256

TABLE X.M-4.—RESULTS OF COST-TO-SALES TEST FOR SMALL BUSINESSES FOR PSES OPTIONS WITH LIMITED SCOPE

Option	Cost/sales > 1%	Cost/sales > 3%
Indirect Dischargers—61 Small Businesses		
Combined Option w/Oils Option 8	57	38
Reduced monitoring	35	14
>3.5 MGY, non-hazardous	30	19
>3.5 MGY	24	14
>7.5 MGY, non-hazardous	23	17
"No smalls"	0	0

These results are roughly consistent with the magnitude of impacts presented for the same options in the 1999 proposal (see 64 FR 2332) with the exception of the reduced monitoring option. At the time of the 1999 proposal, EPA estimated that the reduced monitoring option resulted in 5 small and 11 large process closures, 4 small and 7 large facility closures, and 286 job losses. Now, EPA estimates that the reduced monitoring option would result in 4 small and 11 large process closures, 7 small and 7 large facility closures, and 420 job losses.

Some SBAR Panel members and SERs argued that these results supported excluding small businesses from the regulation. As described in the Panel's final report, these Panel members and SERs believed that the "lost" pollutant reductions associated with excluding small businesses would not be environmentally significant. Based on analysis available at the time of the

Panel, limiting the applicability to exclude all oils facilities owned by small businesses would have reduced removals by 12 percent. Excluding indirect dischargers with flows under 3.5 MGY would have reduced removals by 6 percent. They also suggested that these facilities provide an important "safety valve" for an affordable and effective treatment alternative for industrial facilities that would otherwise find it prohibitively expensive to comply with industry-specific national effluent guidelines and standards.

Other SERs opposed this approach. These SERs argued that excluding small businesses from the scope of this rule would adversely impact the image of the industry. One of these SERs preferred reduced monitoring and also suggested that small businesses might be granted additional time to comply with the new standards, rather than excluding those businesses within the scope of the rule.

EPA expressed concern that the absence of national effluent guidelines and standards for CWT facilities has been a major "loophole" in a national program to control industrial pollution, allowing wastes to be treated off-site less effectively than would be required of the same wastes if treated on-site. One of EPA's primary concerns with any of the alternatives that limit the scope of the rule is that the limited scope encourages such a loophole. If a segment of the industry is not subject to national regulation, these companies might quickly expand, leading to much greater discharges within a few years. This tendency would be limited by the flow or size cut-off itself unless more concentrated wastes are funneled through plants below the cut-off. In addition, as demonstrated by the survey responses and public comments, almost all CWT facilities have substantial amounts of unused capacity. Because

this industry is extremely competitive, by limiting the scope of the CWT rule, EPA could actually be encouraging ineffective treatment while discouraging effective treatment.

N. Cost-Effectiveness Analysis

EPA also conducted an analysis of the cost-effectiveness of the alternative treatment technology options that were considered. The report, "Cost-Effectiveness Analysis of Final Effluent Limitations Guidelines and Standards for the CWT Industry" (hereinafter, "Cost-Effectiveness Report"), describes the methodology, data, and results; the report is included in the record of this rulemaking. The results of this cost-effectiveness analysis are expressed in terms of the costs (in 1981 dollars) per pound-equivalent removed, where

pounds-equivalent removed for a particular pollutant is determined by multiplying the number of pounds of a pollutant removed by each option by a toxic weighting factor. The toxic weighting factors account for the differences in toxicity among pollutants and are derived using ambient water quality criteria. Cost effectiveness results are presented in 1981 dollars as a reporting convention. Cost-effectiveness is calculated as the ratio of pre-tax annualized costs of an option to the annual pounds-equivalent removed by that option, and can be expressed as the average or incremental cost-effectiveness for an option.

Average cost-effectiveness can be thought of as the "increment" between no regulation and the selected option for any given rule. For direct dischargers,

the technologies used as the basis for BPT/BCT/BAT in all subcategories have an average cost-effectiveness ratio of \$6.77/lb-equivalent. For indirect dischargers, the technologies used as the basis for PSES in all subcategories have an average cost-effectiveness ratio of \$175/lb-equivalent. These results incorporate all subcategories with their selected options.

Incremental cost-effectiveness is the appropriate measure for comparing one regulatory option to another regulatory option for the same subcategory. Cost-effectiveness results by subcategory and option are presented for direct dischargers in Table X.N-1 and indirect dischargers in Table X.N-2. The options are listed in order of increasing removals.

TABLE X.N-1.—BPT/BCT/BAT COST-EFFECTIVENESS ANALYSIS

Option	Pre-tax total annualized costs (\$1981 M)	Removals (lbs-eq)	Average cost effectiveness (1981 \$/lb-eq)	Incremental cost effectiveness (1981 \$/lb-eq)
Metals Subcategory—9 Facilities				
4	\$2.15	384,416	\$6.00	
3	9.00	401,426	22.00	\$403
Oils Subcategory—5 Facilities				
9 ^a	0.329	1,771	186	n/a
Organics Subcategory—4 Facilities				
4	0.135	0		

^a Since all direct discharging oils facilities already have treatment-in-place equivalent to secondary gravity separation, EPA did not consider the option 8 technology.

TABLE X.N-2.—PSES COST-EFFECTIVENESS ANALYSIS

Option	Pre-tax total annualized costs (\$1981 M)	Removals (lbs-eq)	Average cost effectiveness (1981 \$/lb-eq)	Incremental cost effectiveness (1981 \$/lb-eq)
Metals Subcategory—42 Facilities				
4	\$6.95	39,211	\$176	
3	26.9	48,008	561	\$2,323
Oils Subcategory—123 Facilities				
8	8.98	48,148	187	
9	12.8	50,792	252	1,442
Organics Subcategory—15 Facilities				
4	2.79	19,814	141	

XI. Water Quality Analysis and Environmental Benefits

EPA evaluated the environmental benefits of controlling the discharges of

104⁷ priority and non-conventional pollutants from centralized waste treatment facilities to surface waters and

⁷ EPA accounted for a total of 161 pollutant of concern analytes. However, ambient water quality criteria or toxicity profiles are established for only 104 analytes.

POTWs in national analyses of direct and indirect discharges. Discharges of these pollutants into freshwater and estuarine ecosystems may alter aquatic habitats, adversely affect aquatic biota, and adversely impact human health through the consumption of

contaminated fish and drinking water. Furthermore, these pollutants may also interfere with POTW operations in terms of inhibition of activated sludge or biological treatment and contamination of sewage sludges, thereby limiting the method of disposal and thereby raising its costs. All of these pollutants have at least one toxic effect (human health carcinogen and/or systemic toxicant or aquatic toxicant). In addition, many of these pollutants bioaccumulate in aquatic organisms and persist in the environment.

EPA has updated its analysis to reflect changes to the National Ambient Water Quality Criteria made after the 1999 CWT proposal was issued. National Ambient Water Quality Criteria have been updated for 63 of the analytes modeled in the water quality benefits analysis. In some cases, water criteria for aquatic organisms were completely removed, while for others, criteria for human health were made more stringent.

The Agency did not evaluate the effects of conventional pollutants since the analysis focused on priority and non-conventional pollutants. However, the discharge of a conventional pollutant such as total suspended solids (TSS) can have adverse effects on the environment. For example, habitat degradation can result from increased suspended particulate matter that reduces light penetration, and thus primary productivity, or from accumulation of sludge particles that alter benthic spawning grounds and feeding habitats.

Of a total of 223 CWT facilities, for the purposes of the water quality and benefits analysis, EPA evaluated 12 direct dischargers and 101 indirect dischargers. Facilities not evaluated include zero dischargers (58) and those with insufficient data (2 direct and 50 indirect facilities) to conduct the water quality analysis. To estimate benefits from the improvements in water quality, in-stream concentration estimates are modeled and then compared to both aquatic life and human health ambient water quality criteria (AWQC) or toxic effect levels. The analyses were first performed on a subcategory-specific basis. The subcategory-specific analyses, however, consider only impacts of discharges from individual subcategories, and therefore, underestimate overall water quality impacts for facilities that treat wastes in more than one subcategory. At least 15 percent of facilities in the CWT industry accept wastes in multiple subcategories. In order to evaluate overall benefits of the final technologies, EPA also analyzed water quality and POTW

impacts for multiple subcategory combinations.

EPA expects a variety of human health, environmental, and economic benefits to result from these projected reductions in effluent loadings (see "Environmental Assessment of the Final Effluent Guidelines for the Centralized Waste Treatment Industry," (Environmental Assessment)). In particular, the assessment addresses the following benefit categories: (a) Human health benefits due to reductions in excess cancer risk; (b) human health benefits due to reductions in lead exposure; (c) human health benefits due to reductions in non-carcinogenic hazard (systemic); (d) ecological and recreational benefits due to improved water quality with respect to toxic pollutants; and (e) benefits to POTWs from reductions in interference, pass through, and biosolid contamination, and elimination of some of the efforts associated with establishing local pretreatment limits.

A. Reduced Human Health Cancer Risk

EPA expects that reduced loadings to surface waters associated with the final rule will reduce cancer incidences by approximately 0.03 per year with estimated monetized benefits of \$0.076 to \$0.412 million (\$1997) per year. These estimated benefits are attributable to reducing the cancer risks associated with consuming contaminated fish tissue. EPA developed these benefit estimates by applying an existing estimate of the value of a statistical life to the estimated number of excess cancer cases avoided. The estimated range of the value of a statistical life used in this analysis is \$2.3 million to 12.4 million (\$1997).

B. Reduced Lead Health Risk

EPA solicited comment on, and updated its methodology used to estimate lead health risks due to ingestion of lead-contaminated fish tissues by recreational and subsistence anglers. For the proposed rule EPA used the 7Q10 flow (lowest seven day flow which reoccurs every ten years), although the harmonic mean flow would have been more appropriate to estimate the human health effects due to consumption of lead contaminated fish tissues. As a result, EPA's calculated benefit at the time of proposal for the reduction of lead discharges into the environment was overestimated.

For the final rule, EPA used the harmonic-mean flow to estimate human health effects due to consumption of lead contaminated fish tissue. Under the final treatment levels, the ingestion of lead-contaminated fish tissues by

recreational and subsistence anglers would be reduced at 10 water bodies. Because elevated blood lead levels can cause intellectual impairment in exposed children 0 to 6 years of age, benefits to the at-risk child populations are quantified by estimating the reduced potential IQ point loss. Benefits to adults are quantified by estimating the reduced risk for cardiovascular diseases including hypertension, coronary heart disease, and strokes (the benefits of reduced heart disease and strokes include both fatal and non-fatal cases). The benefits are quantified and monetized using methodologies developed in the Retrospective Analysis of the Clean Air Act (Final Report to Congress on Benefits and Costs of the Clean Air Act, 1970 to 1990; EPA 410-R-97-002). EPA estimates that this final regulation will reduce cases of these adverse health effects; the total benefit for these reductions would range from approximately \$0.488 million to \$1.59 million.

C. Reduced Noncarcinogenic Human Health Hazard

Exposure to toxic substances poses risk of systemic and other effects to humans, including effects on the circulatory, respiratory or digestive systems, and neurological and developmental effects. This final rule is expected to generate human health benefits by reducing exposure to these substances, thus reducing the hazards of these associated effects. EPA expects that reduced loadings to surface waters would reduce the number of persons potentially exposed to non-cancer effects due to consumption of contaminated fish tissue by 1880 people. Presently EPA does not have methodology for monetizing these benefits.

D. Improved Ecological Conditions and Recreational Activity

EPA expects this final rule to generate environmental benefits by improving water quality. There are a wide range of benefits associated with the maintenance and improvement of water quality. These benefits include use values (e.g., recreational fishing), ecological values (e.g., preservation of habitat), and passive use values. For example, water pollution might affect the quality of the fish and wildlife habitat provided by water resources, thus affecting the species using these resources. This in turn might affect the quality and value of recreational experiences of users, such as anglers fishing in the effected streams. EPA has estimated the value of the recreational

fishing benefits and intrinsic benefits resulting from this final rule.

EPA estimates that the annual monetized recreational benefits to anglers associated with the expected changes in water quality range from \$1.23 million to \$3.49 million (\$1997). EPA evaluates these recreational benefits, applying a model that considers the increase in value of a "contaminant-free fishery" to recreational anglers resulting from the elimination of all pollutant concentrations in excess of AWQC at 5 of the 43 receiving water locations. EPA's modeling projects that discharges from CWT facilities are responsible for 252 AWQC violations at 43 receiving water locations and that the rule would eliminate all violations at 5 of these locations. Note these results are derived from computer modeling only. The monetized value of impaired recreational fishing opportunity is estimated by first calculating the baseline value of the receiving stream using a value per-person-day of recreational fishing, and the number of person-days fished on the receiving stream. The value of improving water quality in this fishery, based on the increase in value to anglers of achieving contaminant-free fishing, is then calculated. However, adding these benefits to the cancer and lead toxicity reduction benefits calculated above may result in double counting. Presumably reduced incidence of adverse health effects is one of the factors anglers considered when valuing a "contaminant free fishery."

In addition, EPA estimates that the annual monetized intrinsic benefits to the general public, as a result of the same improvements in water quality, range from at least \$0.62 million to \$1.75 million (\$1997). These intrinsic benefits are estimated as half of the recreational benefits and may be either underestimated or overestimated.

E. Improved POTW Operations

EPA considers two potential sources of benefits to POTWs from this final regulation: (1) Reductions in the likelihood of interference, pass through, and biosolid contamination problems; and (2) reductions in costs potentially incurred by POTWs in analyzing toxic pollutants and determining whether to, and the appropriate level at which to, set local limits. Although the benefits from reducing these effects at POTWs might be substantial, EPA is unable to quantify them.

First, regarding potential interference, pass through and biosolid contamination, this final rule is expected to help reduce these problems

by reducing pollutant loadings in the industry's effluent and reducing shock releases. Anecdotal evidence from POTW operators and sampling results indicate that such effects can occur. EPA also expects the final rule to improve the biosolid quality of 3900 metric tons, permitting the use of less expensive disposal mechanisms. The estimated monetized benefits for improving biosolid quality range from \$0.14 million to \$0.85.

Finally, reducing the pollutant load to local POTWs may eliminate some of the efforts associated with establishing local pollutant limits. Local limits are sometimes required to protect against pass through and interference, and to protect worker health and safety. Several POTWs indicated that establishment of more effective national pretreatment standards will reduce the time and effort required to establish local limits.

F. Other Benefits Not Quantified

The above benefit analyses focus mainly on identified compounds with quantifiable toxic or carcinogenic effects. This potentially leads to an underestimation of benefits, since some pollutant characterizations are not explicitly considered. While the analysis does include a general estimate for non-use benefits, it is possible that some potential effects of reductions in certain pollutants were not fully captured in the monetized estimates. For example, the analyses do not include the benefits associated with reducing the particulate load (measured as TSS), or the oxygen demand (measured as BOD₅ and COD) of the effluents. TSS loads can degrade ecological habitat by reducing light penetration and primary productivity, and from accumulation of solid particles that alter benthic spawning grounds and feeding habitats. BOD₅ and COD loads can deplete oxygen levels, which can produce mortality or other adverse effects in fish, as well as reduce biological diversity.

G. Summary of Benefits

EPA estimates that the annual monetized benefits resulting from this final rule are in the range from \$2.56 million to \$8.09 million (\$1997). Table XI.G-1 summarizes these benefits, by category. The range reflects the uncertainty in evaluating the effects of this final rule and in placing a dollar value on these effects. As indicated in Table XI.G-1, these monetized benefits ranges do not explicitly reflect some potential benefit categories, including aspects of improved ecological conditions from improvements in water

quality; and improved POTW operations.

At the same time, there may be a certain amount of double counting in the benefits categories that have been monetized, for example, between the health and recreational benefits. Therefore the reported benefits may understate or overestimate the total benefits of this final rule.

TABLE XI.G-1.—POTENTIAL ECONOMIC BENEFITS

Benefit category	Millions of 1997 dollars per year
Reduced Cancer Risk	0.076–0.412
Reduced Lead Health Risk	0.49–1.59
Reduced Non-Carcinogenic Hazard.	Unquantified
Improved Recreation Value ...	1.23–3.49
Improved Intrinsic Value (including ecological conditions).	0.62–1.75*
Reduced Biosolid Contamination at POTW.	0.14–0.85
Potentially Improved POTW Operation (inhibition).	Unquantified
Total Monetized Benefits	2.56–8.09

*May not fully capture all ecological effects.

XII. Non-Water Quality Environmental Impacts

The elimination or reduction of one form of pollution may create or aggravate other environmental problems. Therefore, Sections 304(b) and 306 of the Act require EPA to consider non-water quality environmental impacts of effluent limitations guidelines and standards. Accordingly, EPA has considered the effect of these regulations on air pollution, waste treatment residual generation, and energy consumption.

A. Air Pollution

CWT facilities generate wastewater that contain significant concentrations of organic compounds, some of which are also on the list of Hazardous Air Pollutants (HAP) in title 3 of the Clean Air Act Amendments (CAAA) of 1990. These wastewaters often pass through a series of collection and treatment units that are open to the atmosphere and allow wastewater containing organic compounds to contact ambient air. Atmospheric exposure of the organic-containing wastewater may result in significant volatilization of both volatile organic compounds (VOC), which contribute to the formation of ambient ozone, and HAP from the wastewater.

As discussed in 1999 proposal, EPA considered including air stripping in the technology basis for today's limitations and standards, but rejected it because it

would not have resulted in significantly different limitations. Because this rule would not allow any less stringent control of VOCs than is currently in place at most CWT facilities, EPA does not project any net increase in air emissions from volatilization of organic pollutants due to today's final action. As such, no adverse air impacts are expected to occur as a result of today's regulations.

Although this rule does not require the use of air stripping with emissions control to control the emission of volatile pollutants, EPA encourages all facilities which accept waste containing volatile pollutants to incorporate air stripping with overhead recovery or destruction into their wastewater treatment systems. Additionally, EPA also notes that CWT sources of hazardous air pollutants are subject to maximum achievable control technology (MACT) as promulgated for off-site waste and recovery operations on July 1, 1996 (61 FR 34140) at 40 CFR Part 63.

Finally, EPA notes that the increased energy requirements discussed below may result in increased emissions of combustion byproducts associated with energy production. Given the relatively small projected increases in energy use, however, EPA does not anticipate that this effect would be significant.

B. Solid Waste

Solid waste will be generated due to a number of the treatment technologies selected as the basis for today's rule. These wastes include sludge from biological treatment systems, chemical precipitation and clarification systems, and gravity separation and dissolved air flotation systems. EPA estimated costs for off-site disposal in Subtitle C and D landfills of the solid wastes generated due to the implementation of the technologies discussed above. These costs were included in the economic evaluation of the selected technologies.

The precipitation and subsequent separation selected as the technology basis for the metals subcategory will produce a metal-rich filter cake which requires disposal. EPA estimates that metals subcategory facilities will generate annually 3.7 million gallons of filter cake. Dissolved air flotation and additional gravity separation steps selected as the technology basis⁸ for the oils subcategory will also produce a metal-rich filter press cake that requires disposal. EPA estimates that oils subcategory facilities will generate

approximately 23 million gallons of filter press cake annually. Finally, the biological treatment system selected as the technology basis for the organics subcategory will also produce a sludge that requires disposal. EPA estimates that 4.3 million gallons of sludge will be generated annually by the organics subcategory facilities.

EPA has concluded that the disposal of these filter cakes and/or sludges will not have an adverse effect on the environment or result in the release of pollutants in the filter cake to other media. EPA made this conclusion for two reasons. First, EPA estimates that the additional solid wastes disposed in landfills as a result of this regulation will be less than 0.19% of the annual tonnage of waste currently disposed in landfills. Second, the disposal of these wastes into controlled Subtitle C and D landfills is strictly regulated by the RCRA program.

C. Energy Requirements

EPA estimates that the attainment of BPT, BCT, BAT, and PSES will increase energy consumption by a small increment over present industry use. With the exception of the oils subcategory, the projected increase in energy consumption is primarily due to the incorporation of components such as power pumps, mixers, blowers, and controls. For the metals subcategory, EPA projects an increased energy usage of 3.5 million kilowatt hours per year and, for the organics subcategory, an increased energy usage of 0.5 million-kilowatt hours per year. For the oils subcategory, however, the main energy requirement in today's rule is for the operation of dissolved air flotation units. Dissolved air flotation units require air sparging to help separate the wastestream. For the oils subcategory, EPA projects an increased energy usage of 3.4 million kilowatt hours per year. Overall, an increase of 7.5 million kilowatt-hours per year would be required for today's regulation which equates to 4210 barrels of oil per day. In 1996, the United States consumed 18.3 million barrels of oil per day.

XIII. Regulatory Implementation

The purpose of this section is to provide assistance and direction to permit writers, control authorities, and CWT facilities to aid in their implementation of this regulation. This section also discusses the relationship of upset and bypass provisions and variances and modifications to the final limitations and standards.

A. Implementation of the Limitations and Standards

1. Introduction

Effluent limitations and pretreatment standards act as a primary mechanism to control the discharges of pollutants to waters of the United States. These limitations and standards are applied to individual facilities through NPDES permits and local limits developed for POTWs issued by the EPA or authorized States under Section 402 of the Act and local pretreatment programs under Section 307 of the Act.

In specific cases, the NPDES permitting authority or local POTW may elect to establish technology-based permit limits or local limits for pollutants not covered by this regulation. In addition, if State water quality standards or other provisions of State or Federal law require limits on pollutants not covered by this regulation (or require more stringent limits or standards on covered pollutants to achieve compliance), the permitting authority must apply those limitations or standards.

2. Compliance Dates

New and reissued Federal and State NPDES permits to direct dischargers must include the effluent limitations promulgated today. Existing indirect dischargers must comply with today's pretreatment standards no later than December 22, 2003. New direct and indirect discharging sources must comply with applicable limitations and standards on the date the new sources begin operations. As a further point of clarification, new direct and indirect sources are those that began construction of CWT operations after August 28, 2000.

3. Applicability

EPA provided detailed information on the applicability of this rule to various operations in Section V. EPA also provided examples of regulated and non-regulated CWT operations in Table V.A-1. Also see 40 CFR 437.1. Permit writers and pretreatment authorities should closely examine all CWT operations to determine if they should be subject to provisions of this rule.

4. Subcategorization Determination

Each CWT facility subject to this rule will need to make an initial determination of which subcategories are applicable. Multiple subcategory facilities will need to choose to comply with each of the applicable subcategory limitations or standards separately (directly following treatment of each subcategory's waste) or to certify

⁸ The technology basis for indirect discharges in the oils subcategory does not include additional gravity separation steps. See Section VIII.E.

equivalent treatment and comply with one of the four sets of limitations or standards in the multiple wastestream subcategory. The following sections provide guidance on a facility's subcategorization determination as well as implementation of the rule for multiple subcategory facilities. In addition, this section provides a procedure that should assist CWT facilities in determining into which category particular waste receipts might fall.

EPA determined that the paperwork and analyses currently performed at CWT facilities, as part of their waste acceptance procedures, provide CWT facilities with sufficient information for them to determine into which of the subcategories their treated waste would fall. EPA based its recommended subcategorization determination procedure on information generally obtained during these waste acceptance and confirmation procedures. In EPA's view, permit writers and local pretreatment authorities should not (because they need not) require additional monitoring or paperwork solely for the purpose of subcategory determinations, unless the CWT facility's waste acceptance procedures are inadequate. EPA concluded that if CWT facilities follow EPA's recommendations, they should easily classify their wastes. Permit writers and local authorities, in these circumstances, would only need to satisfy themselves that the facility made a good-faith effort to determine the category of wastes treated. In most cases, as detailed below, EPA determined that the subcategory determination can be made on the type of waste receipt, e.g., metal-bearing sludge, used oil, or landfill leachate. Certainly, in EPA's estimation, all CWT facilities should, at a minimum, collect adequate information from the generator on the type of waste received at the CWT facility because this is the minimum information required by CWT facilities to treat off-site wastes effectively.

To determine an existing facility's subcategory classification(s), the facility should review data for a period of one year on its incoming wastes (that is, at the point where the shipment is received at the facility). The facility should first use Table XIII.A-1 below to classify each of its waste receipts into a subcategory for that one-year period.

TABLE XIII.A-1—WASTE RECEIPT CLASSIFICATION

Metals Subcategory:
Spent electroplating baths and/or sludges

TABLE XIII.A-1—WASTE RECEIPT CLASSIFICATION—Continued

Metal finishing rinse water and sludges
Chromate wastes
Air pollution control blow down water and sludges
Spent anodizing solutions
Incineration wastewaters
Waste liquid mercury
Cyanide-containing wastes
Waste acids and bases with or without metals
Cleaning, rinsing, and surface preparation solutions from electroplating or phosphating operations
Vibratory deburring wastewater
Alkaline and acid solutions used to clean metal parts or equipment
Oils Subcategory:
Used oils
Oil-water emulsions or mixtures
Lubricants
Coolants
Contaminated groundwater clean-up from petroleum sources
Used petroleum products
Oil spill clean-up
Bilge water
Rinse/wash waters from petroleum sources
Interceptor wastes
Off-specification fuels
Underground storage remediation waste
Tank clean-out from petroleum or oily sources
Non-contact used glycols
Aqueous and oil mixtures from parts cleaning operations
Wastewater from oil bearing paint washes
Organics Subcategory:
Landfill leachate
Contaminated groundwater clean-up from non-petroleum sources
Solvent-bearing wastes
Off-specification organic product
Still bottoms
Byproduct waste glycol
Wastewater from paint washes
Wastewater from adhesives and/or epoxies formulation
Wastewater from organic chemical product operations
Tank clean-out from organic, non-petroleum sources

If the CWT facility receives the wastes listed above, the subcategory determination may be made solely from this information. If, however, the wastes are unknown or not listed above, EPA recommends that the facility use the following hierarchy to determine how to characterize the wastes it is treating, so as to identify the appropriate regulatory subcategory.

(1) If the waste receipt contains oil and grease at or in excess of 100 mg/L, the waste receipt should be classified in the oils subcategory;

(2) If the waste receipt contains oil and grease <100 mg/L, and has any of the pollutants listed below in concentrations in excess of the values

listed below, the waste receipt should be classified in the metals subcategory.

Cadmium: 0.2 mg/L
Chromium: 8.9 mg/L
Copper: 4.9 mg/L
Nickel: 37.5 mg/L

(3) If the waste receipt contains oil and grease < 100 mg/L, and does not have concentrations of cadmium, chromium, copper, or nickel above any of the values listed above, the waste receipt should be classified in the organics subcategory.

Once a facility's subcategory determination has been made, in EPA's view, the facility would not need to repeat this annual determination process unnecessarily. However, if a CWT facility alters its operation to accept wastes from another subcategory (or to no longer accept waste from a subcategory), the facility should notify the appropriate permit writer or pretreatment authority and the subcategory determination should be revisited. EPA notes that current permit regulations require notification to the permitting authority when significant changes occur. EPA also recommends that the subcategory determination be reevaluated whenever the permit is reissued, though this would not necessarily require complete characterization of a subsequent year's waste receipts if there were no indication that the make-up of the facility's receipts had significantly changed.

For new CWT facilities, the facility should estimate the percentage of waste receipts expected in each subcategory. Alternatively, the facility could compare the treatment technologies being installed to the selected treatment technologies for each subcategory. After the initial year of operation, the permit writer or pretreatment authority should reassess the facility's subcategory determination and follow the procedure outlined for existing facilities.

5. Implementation for Facilities in Multiple CWT Subcategories

EPA estimates that many facilities in the CWT industry accept wastes in two or more of the individual subcategories adopted for regulation here. In other words, the facilities actively accept a variety of waste types. This situation is different from the case in which metal-bearing wastestreams may include low-level organic pollutants or that oily wastes may include low-level metal pollutants due to the origin of the wastestream accepted for treatment.

As promulgated today, multiple subcategory facilities may comply with this rule in one of two ways: (1)

Facilities may elect to comply with the limitations or standards for each applicable subcategory directly following treatment (before commingling with different subcategory wastes); or (2) facilities may certify equivalent treatment and comply with one of the four sets of limitations or standards for the multiple wastestream subcategory. Each of these options is discussed further below.

a. Comply with Limitations or Standards for Subcategory A, B, and/or C. In implementing this rule for multiple subcategory facilities in this manner, the permit writer or pretreatment control authority needs to ensure that the CWT facility has an optimal waste management program. First, the permit writer or control authority should verify that the CWT facility is identifying and segregating wastestreams appropriately since segregation of similar wastestreams is the first step in obtaining optimal mass removals of pollutants from industrial wastes. Next, the permit writer or control authority should verify that the CWT facility is employing treatment technologies designed to treat all off-site waste receipts effectively. Finally, the permit writer or control authority should establish compliance monitoring for each applicable subcategory directly following treatment of the each subcategory's waste stream. As a further point of clarification, the permit writer or control authority should not allow CWT facilities to commingle wastestreams from different subcategories prior to monitoring for compliance with each subcategory's limitations or standards.

b. Comply with Limitations or Standards for Subcategory D. First, facilities which desire this option would submit an initial request to their permit writer or local control authority certifying that their treatment train includes all applicable equivalent treatment systems. This initial certification would include, at a minimum, the applicable subcategories (*i.e.*, metals, oils, organics), a listing of and descriptions of the treatment technologies and operating conditions used to treat wastes in each subcategory, and the justification for making an equivalent treatment determination (see § 437.40 of the final rule). For example, a direct discharging facility which accepts metals subcategory and oils subcategory wastewaters could show that their treatment train includes two-stage oil/water separation, two-stage chemical precipitation, and dissolved air flotation operated in a similar manner to that costed by EPA. Since these are the treatment technologies

selected as the basis for this rule, the equivalent treatment determination could be established. However, EPA is not defining "equivalent treatment" as specific treatment technologies or the technology bases, but rather as a "wastewater treatment system that is demonstrated in literature, treatability tests, or self-monitoring data to remove a similar level of the appropriate pollutants as the applicable treatment technology selected as the basis for the applicable regulations".⁹ EPA is leaving the decision as to whether a particular treatment train is "equivalent treatment" to the permit writer's or local control authority's best professional judgment. However, the requesting facility is responsible for providing the permit writer or local control authority with enough information and/or data to make the equivalent treatment determination. This initial certification statement must be signed by the responsible corporate officer as defined in 40 CFR 403.12(1) or 40 CFR 122.22. If the permit writer or local control authority determines that equivalent treatment is demonstrated, then the permit writers of local control authority will issue discharge requirements based on one of the four subsets of limitations or standards promulgated for the multiple wastestream subcategory.

Next, the facility shall submit an annual certification statement which indicates that the treatment technologies are being utilized in the manner set forth in their original certification or a justification to allow modification of the practices listed in its initial certification (see § 437.41 of the final rule). If the information contained in the initial certification statement is still applicable, a facility shall simply state that in a letter to the permitting authority or local control authority, and the letter shall constitute the periodic statement. However, if the facility has modified its treatment system in any way, it shall submit the revised information in a manner similar to the initial certification. Once again, the permit writer or local control authority would be expected to use BEJ/BPJ in reviewing any modifications.

Finally, the facility shall be required to maintain on-site compliance paperwork. The on-site compliance paperwork should include information from the initial and periodic certifications, but must also include: (1) The supporting documentation for any modifications that have been made to the treatment system; (2) a method for

demonstrating that the treatment system is well operated and maintained; and (3) a discussion of the rationale for choosing the method of demonstration. Proper operation and maintenance of a system includes a qualified person to operate the system, use of correct treatment chemicals in appropriate quantities, and operation of the system within the stated design parameters. For example, a facility may operate dissolved air flotation. The method for demonstrating the dissolved air flotation system is well operated can be as simple as maintaining records on the temperature and pH, the chemicals added (including quantity), the duration of treatment, recycle ratio, and physical characteristics of the wastewater before and after dissolved air flotation. Alternatively, the facility could monitor for selected parameters for the purpose of demonstrating effective treatment. This could include any pollutant or a combination of pollutants.

Control authorities, at any time after entering into an individual control mechanism, or permitting authorities, or any time after issuing, reissuing, or modifying the NPDES permit, could inspect the CWT facility to confirm that the listed practices are being employed, that the treatment system is well operated and maintained, and that the necessary paperwork provides sufficient justification for any modifications.

6. Implementation for Metals Subcategory Facilities With Cyanide Subset

Whenever a CWT facility accepts a waste receipt that contains more than 136 mg/L of total cyanide, the CWT facility must monitor for cyanide when the wastewater exits the cyanide destruction process rather than after mixing with other process wastewater. Alternatively, the facility may monitor for compliance after mixing if the cyanide limitations are adjusted using the "building block approach" or "combined wastestream formula," assuming the cyanide limitations do not fall below the minimum analytical detection limit.

7. Implementation for CWT Facilities Subject to Multiple Effluent Limitations Guidelines or Pretreatment Standards

For determination of effluent limits where there are multiple categories, the effluent guidelines are applied using a flow-weighted combination of the appropriate guideline for each category (*i.e.*, "the building block approach"). Where a facility treats a CWT wastestream and process wastewater from other non-CWT industrial operations, the effluent guidelines

⁹ The pollutant removals for each treatment technology selected as the basis are listed in Tables 7.6 through 7.9 in the TDD.

would be applied by using a flow-weighted combination of the BPT/BAT limitations for the CWT and the other non-CWT industrial operation to derive the appropriate limitations. Similarly, for indirect dischargers, under these circumstances, the pretreatment standards would be applied using the "combined wastestream formula" as defined in 40 CFR 403.6(e). The only exceptions to this are for facilities also subject to effluent guidelines for Landfills (40 CFR 445) and effluent limitations guidelines and pretreatment standards for Transportation Equipment Cleaning (40 CFR 442). The interaction between these categories and the CWT rule are detailed in Section V. J and V.I, respectively.

8. Internal Monitoring Requirements

Working in conjunction with the effluent guidelines and pretreatment standards are the monitoring conditions set out in the NPDES or POTW discharge permit. An integral part of monitoring conditions is the point at which a facility must demonstrate compliance. The point at which a sample is collected can have a dramatic effect on the monitoring results for that facility. Therefore, as detailed elsewhere in the implementation section, it may be necessary to require internal monitoring points in order to assure compliance. Authority to address internal wastestreams is provided in 40 CFR 122.44(i)(1)(iii), 122.45(h), and 40 CFR 403.6(e)(2) and (4). Permit writers or local control authorities may establish additional internal monitoring points to the extent consistent with EPA's regulations.

B. Upset and Bypass Provisions

A "bypass" is an intentional diversion of wastestreams from any portion of a treatment facility. An "upset" is an exceptional incident in which there is unintentional and temporary noncompliance with technology-based permit effluent limitations because of factors beyond the reasonable control of the permittee. EPA's regulations concerning bypasses and upsets for direct dischargers are set forth at 40 CFR 122.41(m) and (n) and for indirect dischargers at 40 CFR 403.16 and 403.17.

C. Variances and Modifications

Upon the promulgation of these regulations, all new and reissued Federal and State NPDES permits issued to direct dischargers in the CWT Industry must include the effluent limitations. In addition, the indirect dischargers must comply with the

pretreatment standards within three years of issuance.

1. Fundamentally Different Factors (FDF) Variances

The CWA requires application of the effluent limitations established pursuant to Section 301 or the pretreatment standards of section 307 to all direct and indirect dischargers. However, the statute provides for the modification of these national requirements in a limited number of circumstances. Moreover, the Agency has established administrative mechanisms to provide an opportunity for relief from the application of national effluent limitations guidelines and pretreatment standards for categories of existing sources for priority, conventional, and non-conventional pollutants.

EPA will develop effluent limitations or standards different from the otherwise applicable requirements if an individual existing discharging facility is fundamentally different with respect to factors considered in establishing the limitations or standards applicable to the individual facility. Such a modification is known as a "fundamentally different factors" (FDF) variance.

Early on, EPA, by regulation, provided for FDF modifications from BPT effluent limitations, BAT limitations for priority and non-conventional pollutants, and BCT limitations for conventional pollutants for direct dischargers. For indirect dischargers, EPA provided for FDF modifications from pretreatment standards for existing facilities. FDF variances for priority pollutants were challenged judicially and ultimately sustained by the Supreme Court (*Chemical Manufacturers Ass'n v. NRDC*, 479 U.S. 116 (1985)).

Subsequently, in the Water Quality Act of 1987, Congress added new Section 301(n) of the Act explicitly to authorize modification of the otherwise applicable BAT effluent limitations or national effluent pretreatment standards for existing sources if a facility is fundamentally different with respect to the factors specified in Section 304 (other than costs) from those considered by EPA in establishing the effluent limitations or pretreatment standards. Section 301(n) also defined the conditions under which EPA may establish alternative requirements. Under Section 301(n), an application for approval of FDF variance must be based solely on (1) information submitted during the rulemaking raising the factors that are fundamentally different, or (2) information the applicant did not have an opportunity to submit. The

alternate limitation or standard must be no less stringent than justified by the difference, and not result in markedly more adverse non-water quality environmental impacts than the national limitation or standard.

EPA regulations at 40 CFR 125 Subpart D, authorizing the Regional Administrators to establish alternative limitations and standards, further detail the substantive criteria used to evaluate FDF variance requests for existing direct dischargers.

Thus, 40 CFR 125.31(d) identifies six factors (for example, volume of process wastewater, age, and size of a discharger's facility) that may be considered in determining if a facility is fundamentally different. The Agency must determine whether, on the basis of one or more of these factors, the facility in question is fundamentally different from the facilities and factors considered by the EPA in developing the nationally applicable effluent guidelines. The regulation also lists four other factors (for example, infeasibility of installation within the time allowed or a discharger's ability to pay) that may not provide a basis for an FDF variance. In addition, under 40 CFR 125.31(b)(3), a request for limitations less stringent than the national limitation may be approved only if compliance with the national limitations would result in either (a) a removal cost wholly out of proportion to the removal cost considered during development of the national limitations, or (b) a non-water quality environmental impact (including energy requirements) fundamentally more adverse than the impact considered during development of the national limits. EPA regulations provide for an FDF variance for existing indirect dischargers at 40 CFR 403.13. The conditions for approval of a request to modify applicable pretreatment standards and factors considered are the same as those for direct dischargers.

The legislative history of Section 301(n) underscores the necessity for the FDF variance applicant to establish eligibility for the variance. EPA's regulations at 40 CFR 125.32(b)(1) are explicit in imposing this burden upon the applicant. The applicant must show that the factors relating to the discharge controlled by the applicant's permit which are claimed to be fundamentally different are, in fact, fundamentally different from those factors considered by the EPA in establishing the applicable guidelines. The pretreatment regulations incorporate a similar requirement at 40 CFR 403.13(h)(9).

An FDF variance is not available to a new source subject to NSPS or PSNS.

2. Water Quality Variances

Section 301(g) of the CWA authorizes a variance from BAT effluent guidelines for certain non-conventional pollutants due to localized environmental factors. These pollutants include ammonia, chlorine, color, iron, and total phenols.

3. Permit Modifications

Even after EPA (or an authorized State) has issued a final permit to a direct discharger, the permit may still be modified under certain conditions. (When a permit modification is under consideration, however, all other permit conditions remain in effect.) A permit modification may be triggered in several circumstances. These could include a regulatory inspection or information submitted by the permittee that reveals the need for modification. Any interested person may request a permit modification. There are two classifications of modifications: major and minor. From a procedural standpoint, they differ primarily with respect to the public notice requirements. Major modifications require public notice while minor modifications do not. Virtually any modification that results in less stringent conditions is treated as a major modification, with provisions for public notice and comment. Conditions that would necessitate a major modification of a permit are described in 40 CFR 122.62. Minor modifications are generally non-substantive changes. The conditions for minor modification are described in 40 CFR 122.63.

XIV. Related Acts of Congress, Executive Orders, and Agency Initiatives

A. Executive Order 12866: Regulatory Planning and Review

Under Executive Order 12866 [58 **Federal Register** 51735, (October 4, 1993)], the Agency must determine whether a regulatory action is "significant" and therefore subject to Office of Management and Budget (OMB) review and the requirements of the Executive Order. The Order defines "significant regulatory action" as one that is likely to result in a rule that may:

(1) Have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities;

(2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

Pursuant to the terms of Executive Order 12866, it has been determined that this rule is a "significant regulatory action." Consequently, EPA submitted this action to OMB for review. Changes made in response to OMB suggestions or recommendations will be documented in the public record.

B. Regulatory Flexibility Act (RFA), as Amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), 5 U.S.C. 601 et seq.

1. Background

The RFA generally requires an agency to prepare a regulatory flexibility analysis for any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act or any other statute unless the Agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small organizations and small governmental jurisdictions.

For purposes of assessing the impact of today's rule on small entities, small entity is defined as (1) a small business with gross revenue under \$6 million (based on Small Business Administration size standards); (2) a small governmental jurisdiction that is a government of a city, county, town, school district or special district with a population less than 50,000; and (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.

In accordance with section 603 of the RFA, EPA prepared an initial regulatory flexibility analysis (IRFA) for the proposed rule and convened a Small Business Advocacy Review (SBAR) Panel to obtain advice and recommendations of representatives of affected small entities in accordance with section 609(b) of the RFA. See 64 FR 2298–2300, 2332–33 (January 13, 1999). A detailed discussion of the SBAR Panel's advice and recommendations can be found in the Panel Report which is available in the docket for this rule (DCN 21.5.1). The 1999 proposal provides a summary of the Panel's recommendation. See 64 FR 2298–2300.

2. Summary of Final Regulatory Flexibility Analysis

As required by section 604 of the RFA, EPA also prepared a final regulatory flexibility analysis (FRFA) for today's rule. The FRFA addresses the issues raised by public comments on the IRFA, which was part of the proposal of this rule. The FRFA is available for review in the docket (in Section 8 of the Final EA) and is summarized below.

a. *Need for and Objectives of the Regulation.* A detailed discussion of the need for the regulation is presented in Section V of the 1999 preamble (64 FR 2293–2295). A summary may also be found in Section 9.1.2 of the Final EA. A detailed discussion of the objectives and legal basis for the rule is presented in Sections I and II of this preamble and Chapter 1 of the final development document. Very briefly, the Clean Water Act requires EPA to establish effluent limitations guidelines and standards to control pollutant discharges to the nation's waters. The CWT industry is not currently subject to national standards that provide for an adequate level of control.

b. *Significant Comments on the IRFA.* The significant comments on the IRFA all addressed the following regulatory alternatives: exemptions for small businesses, exemptions based on flow cutoffs, reduced monitoring frequency for small businesses, and the use of an indicator parameter for compliance monitoring. These alternatives are discussed more fully in Section 8.3.6 of the EA and Section IV of this preamble.

Most commenters who discussed the small business exemptions, the flow cutoffs, and the reduced monitoring alternatives were opposed to them. Many commenters argued that size and flow were not necessarily related to the environmental impact of the facility. Others asserted that company revenue was a difficult basis for implementing an exemption. Other commenters noted that exempted facilities would have lower operating costs; they could, therefore, capture more market share which would lead to more untreated wastes going to a POTW. With respect to reduced monitoring, commenters stated that permit writers and control authorities should continue to establish monitoring frequencies on a case-by-case basis, taking into account the probable impact of the discharge to surface waters or a POTW, compliance history of the facility, and other relevant factors.

Many commenters responded on the subject of indicator parameters, with essentially an equivalent number opposing and favoring the use of an

indicator parameter for compliance monitoring for indirect discharging oils subcategory facilities. Commenters that did not support the use of oil and grease (either SGT-HEM or HEM) as indicator parameters raised a number of technical concerns. Commenters that supported their use cited the decreased analytical costs and the wide range of organic compounds that can be measured with these analyses.

EPA shared the concerns of some of these commenters. In the final rule, EPA is not adopting any of these alternatives, but is taking steps to minimize the impacts on small businesses (see XIV.B.2.e). See Section IV of this preamble for more information on the comments, EPA's responses to those comments, and EPA's justification for final decisions on these options. EPA's detailed responses to comments, and the comments themselves, are contained in the Comment Response Document in response categories SBREFA, Small Business, and Indicator Parameters.

c. Description and Estimation of Number of Small Entities to Which the Regulation Will Apply. The small entities subject to this rule are small businesses. There are no nonprofit organizations or small governmental operations that operate CWT facilities. For purposes of assessing the impacts of today's rule on small businesses, EPA relied on the SBA size standard for SIC code 4953, "Refuse Systems," and applied that standard to companies owning CWT facilities. For this SIC code, SBA defines a small business as one receiving less than \$6 million/year, averaged over the most recent three fiscal years.

The CWT industry is composed of an estimated 167 companies (as discussed in Section 3, this number is scaled up to reflect the total number of CWT companies). Small companies make up approximately half of all companies in the CWT industry (an estimated 82 of 167). All of these small companies, except for one, operate single CWT facilities. One company in the analysis operates two facilities. Sixty-three small companies own discharging facilities (61 own indirect dischargers and 2 own direct dischargers) that are subject to the requirements of this rule. Fifty-nine of these small companies are in the oil treatment/recovery business. The number of employees at each of these companies ranges from 2 to 115, with a median of 18. Fifty-three out of the 63 companies have costs greater than one percent of sales; 30 out of the 63 companies have costs greater than three percent of sales. Section X.M provides more detail on the impacts to small businesses.

d. Description of the Reporting, Recordkeeping, and Other Compliance Requirements. For almost all of the small businesses subject to the final CWT rule, this regulation does not contain any specific new requirements for monitoring, recordkeeping, or reporting. Regulations for the existing NPDES and national pretreatment programs already contain minimum requirements; and permit writers and control authorities establish the monitoring regime for individual facilities. Consequently, for almost all of the CWT facilities owned by small businesses, there are similarly no new professional skills required to meet any new requirements.

However, for CWT facilities that accept waste in more than one CWT subcategory that elect to comply with the multiple wastestream subcategory limitations or standards, the final rule does include new requirements for monitoring, recordkeeping, and reporting. These requirements and the multiple wastestream subcategory are described in Sections IV.F and XIII.A.5 of the final preamble. See also § 437.41. EPA concluded that CWT facilities already have the professional skills to meet these new requirements. Based on the information in EPA's database, only two CWT facilities owned by small businesses may be subject to these new requirements.

e. Steps Taken to Minimize Significant Impacts on Small Entities. EPA went to some length to explore and analyze a variety of regulatory alternatives to minimize impacts on small businesses. Today's notice includes extensive discussions of the alternatives, EPA's analysis of those alternatives, and the rationale for EPA's decisions. EPA selected the least expensive option that was considered for the final rule as the technology basis for the standards and limitations for existing sources. Furthermore, EPA selected oils option 8 as the technology basis for PSES in the oils subcategory (which contains most of the small businesses affected by the final rule), in part, based on the incremental economic impact to small businesses. For EPA's option selection rationale, see Section VIII. Most of the other regulatory alternatives incorporated exemptions for groups of facilities. EPA rejected those options for multiple reasons, including implementation difficulty and concerns about environmental impacts. For a detailed discussion of EPA's rationale for rejection of these options, see Sections IV.A-IV.E.

3. Compliance Guide

As required by section 212 of SBREFA, EPA is also preparing a small entity compliance guide to help small businesses comply with this rule. To request a copy, use any of the contacts shown in **FOR FURTHER INFORMATION CONTACT** section of this preamble, above. EPA expects that the guide will be available in January 2001.

C. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), P.L. 104-4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments and the private sector. Under section 202 of the UMRA, EPA generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with "Federal mandates" that may result in expenditures to State, local, and tribal governments, in the aggregate, or to the private sector, of \$100 million or more in any one year. Before promulgating an EPA rule for which a written statement is needed, section 205 of the UMRA generally requires EPA to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, most cost-effective, or least burdensome alternative that achieves the objectives of the rule. The provisions of section 205 do not apply when they are inconsistent with applicable law. Moreover, section 205 allows EPA to adopt an alternative other than the least costly, most cost-effective, or least burdensome alternative if the Administrator publishes the final rule with an explanation of why that alternative was adopted. Before EPA establishes any regulatory requirements that may significantly or uniquely affect small governments, including tribal governments, it must have developed, under section 203 of the UMRA, a small government agency plan. The plan must provide for notifying potentially affected small governments, enabling officials of affected small governments to have meaningful and timely input in the development of EPA regulatory proposals with significant Federal intergovernmental mandates, and informing, educating, and advising small governments on compliance with the regulatory requirements.

EPA has determined that this rule does not contain a Federal mandate that may result in expenditures of \$100 million or more for State, local and tribal governments, in the aggregate, or the private sector in any one year. EPA has estimated total annualized costs of

the final rule as \$35.1 million (\$1997). Thus, today's rule is not subject to the requirements of sections 202 and 205 of UMRA.

EPA has determined that this rule contains no regulatory requirements that might significantly or uniquely affect small governments. No small governments are subject to this rule. The final rule, at most, imposes only minimal administrative requirements on small local governments that are administering approved pretreatment programs. The final rule does not uniquely affect small governments because small and large governments are affected in the same way. Thus, today's rule is not subject to the requirements of section 203 of the UMRA.

D. Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1980 (PRA), 44 U.S.C. 3501 *et seq.*, EPA must submit an information collection request covering information collection requirements in proposed rules to the Office of Management and Budget (OMB) for review and approval. There are no new information collection reporting requirements for facilities that comply with the limits for the metals-bearing, oily waste, and/or organics waste subcategories separately. The information collection reporting requirements and the burden estimates for these subcategories are contained in the "National Pollutant Discharge Elimination System (NPDES)/Compliance Assessment/Certification Information" ICR (No. 1427.05; OMB Approval No. 2040-0110) and in the "National Pretreatment Program (40 CFR Part 403)" ICR (No. 0002.081; OMB Approval No. 2040-0009).

EPA established a fourth multiple wastestream subcategory to simplify implementation and reduce burden for facilities treating wastes covered by more than one subcategory. EPA notes that no facility is required to use this subcategory and its requirements unless the facility chooses to. The new information reporting requirements under this subcategory, described at § 437.41, include submission of an initial certification statement and annual certification statements thereafter, and maintenance of on-site compliance paperwork. These requirements are the same as those previously approved by OMB for facilities in the pesticide formulating, packaging, and repackaging category that choose to comply with the pollution prevention alternative. OMB is in the process of approving the extension of these requirements to

multiple wastestream facilities in the CWT category, as part of the revisions to the ICRs listed above.

An Agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations are listed in 40 CFR part 9 and 48 CFR Chapter 15. The OMB control numbers for the information collection requirements in this rule will be listed in an amendment(s) to 40 CFR part 9 in a subsequent **Federal Register** document(s) after OMB approves the ICRs.

E. National Technology Transfer and Advancement Act

As noted in the proposed rule, section 12(d) of the National Technology Transfer and Advancement Act (NTTAA), Pub L. 104-113, section 12(d) (15 U.S.C. 272 note), directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures, business practices) that are developed or adopted by voluntary consensus standards bodies. The NTTAA directs EPA to provide Congress, through the Office of Management and Budget (OMB), explanations when the Agency decides not to use available and applicable voluntary consensus standards.

This rulemaking involves technical standards. EPA performed a search of the technical literature to identify any applicable analytical test methods from industry, academia, voluntary consensus standard bodies and other parties that could be used to measure the analytes in today's rulemaking. EPA's search revealed that there are consensus test procedures for many of the analytes in today's rule already specified in the tables at 40 CFR 136.3. Even prior to enactment of the NTTAA, EPA has traditionally included any applicable consensus test methods in its regulations. Consistent with the requirements of the CWA, those applicable consensus test methods are incorporated by reference in the tables at 40 CFR Part 136.3. The consensus test methods in these tables include American Society for Testing Materials (ASTM) and "Standard Methods."

Today's rule requires dischargers to monitor for up to 17 metals, 16 organics, BOD₅, total cyanide, Oil and Grease (HEM), and TSS. Examples of pollutants with consensus methods already in

place include the metals, total cyanide, BOD₅, TSS, and some organic pollutants such as fluoranthene and 2,4,6-trichlorophenol.

In addition, EPA noted in the 1999 proposed rule that EPA was developing additional data for certain additional pollutants not included in the Tables at 40 CFR 136.3. EPA asked commenters to identify any potentially applicable voluntary consensus standards for those pollutants. No commenters identified any such standards. Therefore, EPA has amended existing EPA test procedures included in 40 CFR 136.3 to cover the additional pollutants in today's rule.

F. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

The Executive Order "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997) applies to any rule that: (1) Is determined to be "economically significant" as defined under Executive Order 12866, and (2) concerns an environmental health risk or safety risk that the Agency has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency.

This rule is not subject to E.O. 13045 because it is not an economically significant rule as defined under Executive Order 12866. Further, EPA does not believe this rule concerns an environmental or safety risk that EPA has reason to believe may have a disproportionate effect on children. This rule sets technology based limits according to the requirements of the Clean Water Act. However, EPA did evaluate children's health effects (specifically, impaired IQ) in its analysis of environmental benefits of this rule (see Section XI.B). EPA estimates that this rule will reduce the number of children that might otherwise experience reduced IQ.

G. The Edible Oil Regulatory Reform Act

The Edible Oil Regulatory Reform Act, Public Law 104-55, requires most Federal agencies to differentiate between, and establish separate classes for (1) animal fats and oils and greases, fish and marine mammal oils, and oils of vegetable origin, and (2) other greases and oils, including petroleum, when issuing or enforcing any regulation or establishing any interpretation or guideline relating to the transportation,

storage, discharge, release, emission, or disposal of a fat, oil, or grease.

The Agency believes that vegetable oils and animal fats pose similar types of threats to the environment as petroleum oils when spilled to the environment (62 FR 54508 Oct. 20, 1997).

The deleterious environmental effects of spills of petroleum and non-petroleum oils, including animal fats and vegetable oils, are produced through physical contact and destruction of food sources (via smothering or coating) as well as toxic contamination (62 FR 54511). However, the permitted discharge of CWT wastewater containing residual and dilute quantities of petroleum and non-petroleum oils is significantly different from an uncontrolled spill of pure petroleum or non-petroleum oil products.

CWT facilities that would be subject to the rule do not typically accept wastes with appreciable amounts of animal fats and oils, *etc.* The exception are grease trap wastes. Today's rule will not apply to that portion of wastewater treated at CWT facilities that represents grease trap wastes.

H. Executive Order 13084: Consultation and Coordination With Indian Tribal Governments

Under Executive Order 13084, EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments, or EPA consults with those governments. If EPA complies by consulting, Executive Order 13084 requires EPA to provide to the Office of Management and Budget, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected officials and other representatives of Indian tribal governments "to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities."

Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. EPA has not

identified any facilities covered by today's rule that are owned and/or operated by Indian tribal governments. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

I. Executive Order 13132 (Federalism)

Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999), requires EPA to develop an accountable process to ensure "meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications." "Policies that have federalism implications" is defined in the Executive Order to include regulations that have "substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government."

This final rule does not have federalism implications. It will not have substantial direct effects on the States, on the relationship between the national government and the States or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132. The rule establishes effluent limitations and pretreatment standards imposing requirements that apply to CWT facilities when they discharge wastewater or introduce wastewater to a POTW. EPA has determined that there are no CWT facilities owned and operated by State or local governments that are subject to today's rule so the rule will not impose any treatment technology costs on State or local governments. Further, the rule will only affect State and local governments incidentally in their capacity as implementers of CWA permitting programs. Therefore, the final rule, at most, imposes only minimal administrative costs on States that have authorized NPDES programs and on local governments that are administering approved pretreatment programs. (These States and localities must incorporate the new limitations and standards in new and reissued NPDES permits or local pretreatment orders or permits). Thus, Executive Order 13132 does not apply to this rule.

Even though section 6 of Executive Order 13132 does not apply to this rule, EPA did consult with representatives of State and local governments in developing this rule. The concerns raised during those consultations and EPA's response to their concerns are reflected in the Response to Comments

section and elsewhere in the administrative record.

J. Submission to Congress and the General Accounting Office

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2). This rule will be effective January 22, 2001.

Appendix 1 to the Preamble— Definitions, Acronyms, and Abbreviations

ADMINISTRATOR—The Administrator of the U.S. Environmental Protection Agency.

AGENCY—The U.S. Environmental Protection Agency.

AVERAGE MONTHLY DISCHARGE LIMITATION—The highest allowable average of "daily discharges" over a calendar month, calculated as the sum of all "daily discharges" measured during the calendar month divided by the number of "daily discharges" measured during the month.

BAT—The best available technology economically achievable, applicable to effluent limitations to be achieved by March 31, 1984, for industrial discharges to surface waters, as defined by Sec. 304(b)(2)(B) of the CWA.

BCT—The best conventional pollutant control technology, applicable to discharges of conventional pollutants from existing industrial point sources, as defined by Sec. 304(b)(4) of the CWA.

BPT—The best practicable control technology currently available, applicable to effluent limitations to be achieved by July 1, 1977, for industrial discharges to surface waters, as defined by Sec. 304(b)(1) of the CWA.

CENTRALIZED WASTE TREATMENT FACILITY—Any facility that treats (for disposal, recycling, or recovery of materials) or recycles any hazardous or non-hazardous industrial waste, hazardous or non-hazardous industrial wastewater, and/or used material from off-site. "CWT facility" includes both a facility that treats waste received from off-site exclusively, and a facility that treats wastes generated on-site as well as waste received from off-site. For example, an organic chemical manufacturing plant may, in certain circumstances, be a CWT facility if it treats industrial wastes received from offsite as well as industrial waste generated at the

organic chemical manufacturing plant. CWT facilities include re-refiners and may be owned by the federal government.

CENTRALIZED WASTE TREATMENT WASTEWATER—Any wastewater generated as a result of CWT activities. CWT wastewater sources may include, but are not limited to: liquid waste receipts, solubilization water, used oil emulsion-breaking wastewater, tanker truck/drum/roll-off box washes, equipment washes, air pollution control scrubber blow-down, laboratory-derived wastewater, on-site landfill wastewaters, and contaminated storm water.

CLEAN WATER ACT (CWA)—The Federal Water Pollution Control Act Amendments of 1972 (33 U.S.C. Section 1251 *et seq.*), as amended.

CLEAN WATER ACT (CWA) SECTION 308 QUESTIONNAIRE—A questionnaire sent to facilities under the authority of Section 308 of the CWA, which requests information to be used in the development of national effluent guidelines and standards.

COMMERCIAL FACILITY—A CWT facility that accepts off-site generated wastes, wastewaters, or used material from other facilities not under the same ownership as this facility. Commercial operations are usually made available for a fee or other remuneration.

CONTAMINATED STORM WATER—Storm water which comes in direct contact with off-site waste, the waste handling and treatment areas, or other centralized waste treatment wastewater.

CONVENTIONAL POLLUTANTS—Constituents of wastewater as determined by Sec. 304(a)(4) of the CWA, including, but not limited to, pollutants classified as biochemical oxygen demand, total suspended solids, oil and grease, fecal coliform, and pH.

CWT—Centralized Waste Treatment

DAILY DISCHARGE—The discharge of a pollutant measured during any calendar day or any 24-hour period that reasonably represents a calendar day.

DETAILED MONITORING

QUESTIONNAIRE (DMQ)—Questionnaires sent to collect daily monitoring data from 20 selected CWT facilities based on responses to the Section 308 Questionnaire.

DIRECT DISCHARGER—A facility that discharges or may discharge treated or untreated wastewaters into waters of the United States.

EXISTING SOURCE—Any facility from which there is or may be a discharge of pollutants, the construction of which is commenced before the publication of the proposed regulations prescribing a standard of performance under Sec. 306 of the CWA.

FACILITY—All contiguous property owned, operated, leased, or under the control of the same person or entity

FUEL BLENDING—The process of combining waste, wastewater, or used material for the purpose of regenerating a fuel for reuse.

HAZARDOUS WASTE—Any waste, including wastewater, defined as hazardous under RCRA.

HIGH TEMPERATURE METALS RECOVERY (HTMR)—A metals recovery process in which solid forms of metal

containing materials are processed with a heat-based pyrometallurgical technology to produce metal products.

INDIRECT DISCHARGER—A facility that discharges or may discharge wastewaters into a publicly-owned treatment works.

INTERCOMPANY—Facilities that treat and/or recycle/recover waste, wastewater, and/or used material generated by off-site facilities not under the same corporate ownership. These facilities are also referred to as “commercial” CWT facilities.

INTRACOMPANY TRANSFER—Facilities that treat and/or recycle/recover waste, wastewater, and/or used material generated by off-site facilities under the same corporate ownership. These facilities are also referred to as “non-commercial” CWT facilities.

LTA (Long-Term Average)—For purposes of the effluent guidelines, average pollutant levels achieved over a period of time by a facility, subcategory, or technology option. LTAs were used in developing the limitations and standards in today’s proposed regulation.

MARINE-GENERATED WASTE—Any waste, wastewater, and/or used material generated as part of the normal maintenance and operation of a ship, boat, or barge operating on inland, coastal, or open waters, or while berthed.

METAL-BEARING WASTES—Wastes and/or used materials from manufacturing or processing facilities or other commercial operations that contain significant quantities of metal pollutants, but not significant quantities of oil and grease (generally less than 100 mg/L), from manufacturing or processing facilities or other commercial operations. Examples of these wastes are as follows: spent electroplating baths and sludges, metal finishing rinse water and sludges, chromate wastes, air pollution control blow down water and sludges, spent anodizing solutions, incineration air pollution control wastewaters, waste liquid mercury, cyanide containing wastes greater than 136 mg/L, and waste acids and bases with or without metals.

MINIMUM LEVEL—the lowest level at which the entire analytical system must give a recognizable signal and an acceptable calibration point for the analyte.

MIXED COMMERCIAL/NON-COMMERCIAL FACILITY—Facilities that treat and/or recycle/recover waste, wastewater, and/or used material generated by off-site facilities both under the same corporate ownership and different corporate ownership.

MULTIPLE WASTESTREAM CWT FACILITY—A CWT facility that accepts waste in more than one CWT subcategory (metals, oils, or organics) and combines any portion of these different subcategory wastes at any point prior to the compliance discharge sampling location.

NATIONAL POLLUTANT DISCHARGE ELIMINATION SYSTEM (NPDES) PERMIT—A permit to discharge wastewater into waters of the United States issued under the National Pollutant Discharge Elimination system, authorized by Section 402 of the CWA.

NEW SOURCE—Any facility from which there is or may be a discharge of pollutants,

the construction of which is commenced after the promulgation of regulations prescribing a standard of performance under section 306 of the Act and 403.3(k).

NON-COMMERCIAL FACILITY—Facilities that accept waste from off-site for treatment and/or recovery from generating facilities under the same corporate ownership as the CWT facility.

NON-CONTAMINATED STORMWATER—Stormwater that does not come into direct contact with the waste, the waste handling and treatment areas, or other centralized waste treatment wastewater.

NON-CONVENTIONAL POLLUTANTS—Pollutants that are neither conventional pollutants nor priority pollutants listed at 40 CFR Section 401.

NON-DETECT VALUE—The analyte is below the level of detection that can be reliably measured by the analytical method. This is also known, in statistical terms, as left-censoring.

NON-WATER QUALITY

ENVIRONMENTAL IMPACT—Deleterious aspects of control and treatment technologies applicable to point source category wastes, including, but not limited to air pollution, noise, radiation, sludge and solid waste generation, and energy used.

NSPS—New Sources Performance Standards, applicable to industrial facilities whose construction is begun after the publication of the proposed regulations, as defined by Sec. 306 of the CWA.

OCPSF—Organic chemicals, plastics, and synthetic fibers manufacturing point source category. (40 CFR Part 414).

OFF SITE—Outside the boundaries of a facility.

OILY ABSORBENT RECYCLING—The process of recycling oil soaked or contaminated disposable rags, paper, or pads for the purpose of regenerating a fuel for reuse.

OILY WASTES—Wastes and/or used materials that contain oil and grease (generally at or in excess of 100 mg/L) from manufacturing or processing facilities or other commercial operations. Examples of these wastes are as follows: used oils, oil-water emulsions or mixtures, lubricants, coolants, contaminated groundwater clean-up from petroleum sources, used petroleum products, oil spill clean-up, bilge water, rinse/wash waters from petroleum sources, interceptor wastes, off-specification fuels, underground storage tank remediation waste, and tank clean out from petroleum or oily sources.

ON SITE—Within the boundaries of a facility. A facility may encompass land areas that are bisected by public thoroughfares but are under the control of a common owner.

ORGANIC WASTES—Wastes and/or used materials that contain organic pollutants, but not a significant quantity of oil and grease (generally less than 100 mg/L) from manufacturing or processing facilities or other commercial operations. Examples of these wastes are as follows: landfill leachate, contaminated groundwater clean-up from non-petroleum sources, solvent-bearing wastes, off-specification organic product, still bottoms, waste byproduct glycols, wastewater from paint washes, wastewater

from adhesives and/or epoxies formulation, wastewater from chemical product operations, and tank clean-out from organic, non-petroleum sources.

OUTFALL—The mouth of conduit drains and other conduits from which a facility effluent discharges into receiving waters.

OUT-OF-SCOPE—Out-of-scope facilities are facilities that only perform centralized waste treatment activities that EPA has not determined to be subject to provisions of this guideline or facilities that do not accept off-site waste for treatment.

PIPELINE—Pipeline means an open or closed conduit used for the conveyance of material. A conduit includes a channel, pipe, tube, trench, ditch, or fixed delivery system.

PASS THROUGH—A pollutant is determined to “pass through” a POTW when the national average percentage removed by efficiently operated POTWs is less than the average percentage removed by the industry’s direct dischargers that are using well-defined, well-operated BAT technology.

POINT SOURCE—Any discernable, confined, and discrete conveyances from which pollutants are or may be discharged.

POLLUTANTS OF CONCERN (POCs)—Pollutants commonly found in centralized waste treatment wastewaters. For the purposes of this guideline, a POC is a pollutant that is detected at or above a treatable level in influent wastewater samples from centralized waste treatment facilities. Additionally, a CWT POC must be present in at least ten percent of the influent wastewater samples.

PRIORITY POLLUTANT—One hundred twenty-six compounds that are a subset of the 65 toxic pollutants and classes of pollutants outlined in Section 307 of the CWA. The priority pollutants are specified in the NRDC settlement agreement (Natural Resources Defense Council et al. v. Train, 8 E.R.C. 2120 [D.D.C. 1976], modified 12 E.R.C. 1833 [D.D.C. 1979]).

PRODUCT STEWARDSHIP—For purposes of this final rule, product stewardship means a manufacturer’s treatment or recovery of its own unused products, shipping and storage containers with product residues, off-specification products, and does not include spent or used materials from use of its products.

PSSES—Pretreatment standards for existing sources of indirect discharges, under Sec. 307(b) of the CWA.

PSNS—Pretreatment standards for new sources of indirect discharges, under Sec. 307(b) of the CWA.

PUBLICLY OWNED TREATMENT WORKS (POTW)—Any device or system, owned by a state or municipality, used in the treatment (including recycling and reclamation) of municipal sewage or industrial wastes of a liquid nature that is owned by a state or municipality. This includes sewers, pipes, or other conveyances only if they convey wastewater to a POTW providing treatment (40 CFR 122.2).

RCRA—The Resource Conservation and Recovery Act of 1976 (RCRA) (42 U.S.C. Section 6901 *et seq.*), which regulates the generation, treatment, storage, disposal, or recycling of solid and hazardous wastes.

RE-REFINING—Distillation, hydrotreating, and/or other treatment employing acid,

caustic, solvent, clay and/or chemicals of used oil in order to produce high quality base stock for lubricants or other petroleum products.

RECOVERY—The recycling or processing of a waste, wastewater, or used material such that the material, or a portion thereof, may be reused or converted to a raw material, intermediate, or product.

SIC—Standard Industrial Classification (SIC)—A numerical categorization system used by the U.S. Department of Commerce to catalogue economic activity. SIC codes refer to the products, or group of products, produced or distributed, or to services rendered by an operating establishment. SIC codes are used to group establishments by the economic activities in which they are engaged. SIC codes often denote a facility’s primary, secondary, tertiary, etc. economic activities.

SMALL BUSINESS—Businesses with annual sales revenues less than \$6 million. This is the Small Business Administration definition of small business for SIC code 4953, Refuse Systems (13 CFR Ch.1, § 121.601) which is being used to characterize the CWT industry.

SOLIDIFICATION—The addition of sorbents to convert liquid or semi-liquid waste to a solid by means of adsorption, absorption or both. The process is usually accompanied by stabilization.

SOLVENT RECOVERY—Fuel blending operations and the recycling of spent solvents through separation of solvent mixtures in distillation columns. Solvent recovery may require an additional, pretreatment step prior to distillation.

STABILIZATION—A waste process that decreases the mobility of waste constituents by means of a chemical reaction. For the purpose of this rule, chemical precipitation is not a technique for stabilization.

SUBCHAPTER N—Refers to Subchapter N of Chapter I of Title 40 of the Federal Regulations. This includes, but is not limited to, the industrial effluent limitation guidelines and standards included in 40 CFR Parts 405 through 471.

TREATMENT—Any method, technique, or process designed to change the physical, chemical or biological character or composition of any metal-bearing, oily, or organic waste so as to neutralize such wastes, to render such wastes amenable to discharge or to recover energy or recover metal, oil, or organic content from the wastes.

USED OIL FILTER RECYCLING—The process of crushing and draining of used oil filters of entrained oil and/or shredding and separation of used oil filters.

VARIABILITY FACTOR—Used in calculating a limitation (or standard) to allow for reasonable variation in pollutant concentrations when processed through extensive and well-designed treatment systems. Variability factors assure that normal fluctuations in a facility’s treatment are accounted for in the limitations. By accounting for these reasonable excursions above the long-term average, EPA’s use of variability factors results in limitations that are generally well above the actual long-term averages.

WASTE—Includes aqueous, non-aqueous, and solid waste, wastewater, and/or used material.

WASTE RECEIPT—Wastes, wastewater, or used material received for treatment and/or recovery. Waste receipts can be liquids or solids.

ZERO OR ALTERNATIVE DISCHARGE—No discharge of pollutants to waters of the United States or to a POTW. Also included in this definition is disposal of pollutants by way of evaporation, deep-well injection, off-site transfer, and land application.

List of Subjects

40 CFR Part 136

Environmental protection, Reporting and recordkeeping requirements, Water pollution control.

40 CFR Part 437

Environmental protection, Waste treatment and disposal, Water pollution control.

Dated: August 28, 2000.

Carol M. Browner,
Administrator.

For the reasons set out in the preamble, title 40, chapter 1 of the Code of Federal Regulations is amended as follows:

PART 136—TEST PROCEDURES FOR THE ANALYSIS OF POLLUTANTS

1. The authority citation for Part 136 continues to read as follows:

Authority: Secs. 301, 304(h), 307, and 501(a) Pub. L. 95–217, 91 Stat. 1566, *et seq.* (33 U.S.C. 1251, *et seq.*).

Appendix A—[Amended]

2. Appendix A to Part 136 is amended by revising Attachment 1 of Method 625 to read as follows:

Appendix A To Part 136—Methods for Organic Chemical Analysis of Municipal and Industrial Wastewater

* * * * *

Method 625—Base/Neutrals and Acids

* * * * *

Attachment 1 to Method 625

Introduction

To support measurement of several semivolatile pollutants, EPA has developed this attachment to EPA Method 625.¹ The modifications listed in this attachment are approved only for monitoring wastestreams from the Centralized Waste Treatment Point Source Category (40 CFR Part 437) and the Landfills Point Source Category (40 CFR Part 445). EPA Method 625 (the Method) involves sample extraction with methylene chloride followed by analysis of the extract using either packed or capillary column gas

¹ EPA Method 625: Base/Neutrals and Acids, 40 CFR Part 136, Appendix A.

chromatography/mass spectrometry (GC/MS). This attachment addresses the addition of the semivolatile pollutants listed in Tables 1 and 2, to all applicable standard, stock, and spiking solutions utilized for the determination of semivolatile organic compounds by EPA Method 625.

1.0 EPA METHOD 625 MODIFICATION SUMMARY

The additional semivolatile organic compounds listed in Tables 1 and 2 are added to all applicable calibration, spiking, and other solutions utilized in the determination of base/neutral and acid compounds by EPA Method 625. The instrument is to be calibrated with these compounds, using a capillary column, and all procedures and quality control tests stated in the Method must be performed.

2.0 SECTION MODIFICATIONS

Note: All section and figure numbers in this Attachment reference section and figure numbers in EPA Method 625 unless noted otherwise. Sections not listed here remain unchanged.

Section 6.7 The stock standard solutions described in this section are modified such that the analytes in Tables 1 and 2 of this attachment are required in

addition to those specified in the Method.

Section 7.2 The calibration standards described in this section are modified to include the analytes in Tables 1 and 2 of this attachment.

Section 8.2 The precision and accuracy requirements are modified to include the analytes listed in Tables 1 and 2 of this attachment. Additional performance criteria are supplied in Table 5 of this attachment.

Section 8.3 The matrix spike is modified to include the analytes listed in Tables 1 and 2 of this attachment.

Section 8.4 The QC check standard is modified to include the analytes listed in Tables 1 and 2 of this attachment. Additional performance criteria are supplied in Table 5 of this attachment.

Section 16.0 Additional method performance information is supplied with this attachment.

TABLE 1.—BASE/NEUTRAL EXTRACTABLES

Parameter	CAS No.
acetophenone ¹	98–86–2
alpha-terpineol ³	98–55–5

TABLE 1.—BASE/NEUTRAL EXTRACTABLES—Continued

Parameter	CAS No.
aniline ²	62–53–3
carbazole ¹	86–74–8
o-cresol ¹	95–48–7
n-decane ¹	124–18–5
2,3-dichloroaniline ¹	608–27–5
n-octadecane ¹	593–45–3
pyridine ²	110–86–1

CAS = Chemical Abstracts Registry.

¹ Analysis of this pollutant is approved only for the Centralized Waste Treatment industry.

² Analysis of this pollutant is approved only for the Centralized Waste Treatment and Landfills industries.

³ Analysis of this pollutant is approved only for the Landfills industry.

TABLE 2.—ACID EXTRACTABLES

Parameter	CAS No.
p-cresol ¹	106–44–5

CAS = Chemical Abstracts Registry.

¹ Analysis of this pollutant is approved only for the Centralized Waste Treatment and Landfills industries.

TABLE 3.—CHROMATOGRAPHIC CONDITIONS,¹ METHOD DETECTION LIMITS (MDLs), AND CHARACTERISTIC M/Z'S FOR BASE/NEUTRAL EXTRACTABLES

Analyte	Retention time (min) ²	MDL (µg/L)	Characteristic m/z's		
			Electron impact		
			Primary	Secondary	Secondary
pyridine ³	4.93	4.6	79	52	51
N-Nitro sodimethylamine	4.95		42	74	44
aniline ³	10.82	3.3	93	66	65
Bis(2-chloroethyl)ether	10.94		93	63	95
n-decane ⁴	11.11	5.0	57		
1,3-Dichlorobenzene	11.47		146	148	113
1,4-Dichlorobenzene	11.62		146	148	113
1,2-Dichlorobenzene	12.17		146	148	113
o-creso ¹	12.48	4.7	108	107	79
Bis(2-chloro- isopropyl)ether	12.51		45	77	79
acetophenone ⁴	12.88	3.4	105	77	51
N-Nitrosodi-n-propylamine	12.97		130	42	101
Hexachloroethane	13.08		117	201	199
Nitrobenzene	13.40		77	123	65
Isophorone	14.11		82	95	138
Bis (2-chloro ethoxy)methane	14.82		93	95	123
1,2,4-Trichlorobenzene	15.37		180	182	145
alpha-terpineol	15.55	5.0	59		
Naphthalene	15.56		128	129	127
Hexachlorobutadiene	16.12		225	223	227
Hexachlorocyclopentadiene	18.47		237	235	272
2,3-dichloroaniline ⁴	18.82	2.5	161	163	90
2-Chloronaphthalene	19.35		162	164	127
Dimethyl phthalate	20.48		163	194	164
Acenaphthylene	20.69		152	151	153
2,6-Dinitrotoluene	20.73		165	89	121
Acenaphthene	21.30		154	153	152
2,4-Dinitrotoluene	22.00		165	63	182
Diethylphthalate	22.74		149	177	150
4-Chlorophenyl phenyl ether	22.90		204	206	141
Fluorene	22.92		166	165	167
N-Nitro sodiphenylamine	23.35		169	168	167
4-Bromophenyl phenyl ether	24.44		248	250	141
Hexachlorobenzene	24.93		284	142	249
n-octadecane ⁴	25.39	2.0	57		

TABLE 3.—CHROMATOGRAPHIC CONDITIONS,¹ METHOD DETECTION LIMITS (MDLs), AND CHARACTERISTIC M/Z'S FOR BASE/NEUTRAL EXTRACTABLES—Continued

Analyte	Retention time (min) ²	MDL (µg/L)	Characteristic m/z's		
			Electron impact		
			Primary	Secondary	Secondary
Phenanthrene	25.98		178	179	176
Anthracene	26.12		178	179	176
Carbazole ⁴	26.66	4.0	167		
Dibutyl phthalate	27.84		149	150	104
Fluoranthene	29.82		202	101	100
Benzidine	30.26		184	92	185
Pyrene	30.56		202	101	100
Butyl benzyl phthalate	32.63		149	91	206
3,3'-Dichlorobenzidine	34.28		252	254	126
Benzo(a)anthracene	34.33		228	229	226
Bis(2-ethyl hexyl)phthalate	34.36		149	167	279
Chrysene	34.44		228	226	229
Di-n-octyl-phthalate	36.17		149		
Benzo(b)fluoranthene	37.90		252	253	125
Benzo(k)fluoranthene	37.97		252	253	125
Benzo(a)pyrene	39.17		252	253	125
Dibenzo(a,h) anthracene	44.91		278	139	279
Indeno(1,2,3-c,d)pyrene	45.01		276	138	277
Benzo(ghi)perylene	46.56		276	138	277

¹ The data presented in this table were obtained under the following conditions:

Column—30 ±5 meters × 0.25 ±0.02 mm i.d., 94% methyl, 5% phenyl, 1% vinyl, bonded phase fused silica capillary column (DB-5).

Temperature program—Five minutes at 30 °C; 30–280 °C at 8 °C per minute; isothermal at 280 °C until benzo(ghi)perylene elutes.

Gas velocity—30±5 cm/sec at 30 °C.

² Retention times are from Method 1625, Revision C, using a capillary column, and are intended to be consistent for all analytes in Tables 4 and 5 of this attachment.

³ Analysis of this pollutant is approved only for the Centralized Waste Treatment and Landfills industries.

⁴ Analysis of this pollutant is approved only for the Centralized Waste Treatment industry.

TABLE 4.—CHROMATOGRAPHIC CONDITIONS,¹ METHOD DETECTION LIMITS (MDLs), AND CHARACTERISTIC M/Z'S FOR ACID EXTRACTABLES

Analyte	Retention time ² (min)	MDL (µg/L)	Characteristic m/z's		
			Electron impact		
			Primary	Secondary	Secondary
Phenol	10.76		94	65	66
2-Chlorophenol	11.08		128	64	130
p-cresol ³	12.92	7.8	108	107	77
2-Nitrophenol	14.38		139	65	109
2,4-Dimethylphenol	14.54		122	107	121
2,4-Dichlorophenol	15.12		162	164	98
4-Chloro-3-methylphenol	16.83		142	107	144
2,4,6-Trichlorophenol	18.80		196	198	200
2,4-Dinitrophenol	21.51		184	63	154
4-Nitrophenol	21.77		65	139	109
2-Methyl-4,6-dinitrophenol	22.83		198	182	77
Pentachlorophenol	25.52		266	264	268

¹ The data presented in this table were obtained under the following conditions:

Column—30 +/- 5 meters × 0.25 +/- .02 mm i.d., 94% methyl, 5% phenyl, 1% vinyl silicone bonded phase fused silica capillary column (DB-5).

Temperature program—Five minutes at 30 °C; 30–280 °C at 8 °C per minute; isothermal at 280 °C until benzo(ghi)perylene elutes.

Gas velocity—30+/- 5 cm/sec at 30 °C

² Retention times are from EPA Method 1625, Revision C, using a capillary column, and are intended to be consistent for all analytes in Tables 3 and 4 of this attachment.

³ Analysis of this pollutant is approved only for the Centralized Waste Treatment and Landfills industries.

TABLE 5.—QC ACCEPTANCE CRITERIA

Analyte	Test conclusion (µg/L)	Limits for s (µg/L)	Range for X (µg/L)	Range for P, P _s (%)
acetophenone ¹	100	51	23–254	61–144
alpha-terpineol	100	47	46–163	58–156
aniline ²	100	71	15–278	46–134

TABLE 5.—QC ACCEPTANCE CRITERIA—Continued

Analyte	Test conclusion (µg/L)	Limits for s (µg/L)	Range for X (µg/L)	Range for P, P _s (%)
carbazole ¹	100	17	79–111	73–131
o-cresol ¹	100	23	30–146	55–126
p-cresol ²	100	22	11–617	76–107
n-decane ¹	100	70	D–651	D–ns
2,3-dichloroaniline ¹	100	13	40–160	68–134
n-octadecane ¹	100	10	52–147	65–123
pyridine ²	100	ns	7–392	33–158

s = Standard deviation for four recovery measurements, in µg/L (Section 8.2)

X = Average recovery for four recovery measurements in µg/L (Section 8.2)

P, P_s = Percent recovery measured (Section 8.3, Section 8.4)

D = Detected; result must be greater than zero.

ns = no specification; limit is outside the range that can be measured reliably.

¹ Analysis of this pollutant is approved only for the Centralized Waste Treatment industry.

² Analysis of this pollutant is approved only for the Centralized Waste Treatment and Landfills industries.

3. Appendix A to Part 136 is amended by revising Attachment 1 of Method 1625 to read as follows:

* * * * *

Method 1625—Revision B—Semivolatile Organic Compounds by Isotope Dilution GC/MS

* * * * *

Attachment 1 to Method 1625

Introduction

To support measurement of several semivolatile pollutants, EPA has developed this attachment to EPA Method 1625B.¹ The modifications listed in this attachment are approved only for monitoring wastestreams from the Centralized Waste Treatment Point Source Category (40 CFR Part 437) and the Landfills Point Source Category (40 CFR Part 445). EPA Method 1625B (the Method) employs sample extraction with methylene chloride followed by analysis of the extract using capillary column gas chromatography-mass spectrometry (GC/MS). This attachment addresses the addition of the semivolatile pollutants listed in Tables 1 and 2 to all applicable standard, stock, and spiking solutions utilized for the determination of semivolatile organic compounds by EPA Method 1625B.

1.0 EPA METHOD 1625 REVISION B MODIFICATION SUMMARY

The additional semivolatile organic compounds listed in Tables 1 and 2 are added to all applicable calibration, spiking, and other solutions utilized in the determination of semivolatile compounds by EPA Method 1625. The instrument is to be calibrated with these compounds, and all

procedures and quality control tests described in the Method must be performed.

2.0 SECTION MODIFICATIONS

Note: All section and figure numbers in this Attachment reference section and figure numbers in EPA Method 1625 Revision B unless noted otherwise. Sections not listed here remain unchanged.

Section 6.7 The stock standard solutions described in this section are modified such that the analytes in Tables 1 and 2 of this attachment are required in addition to those specified in the Method.

Section 6.8 The labeled compound spiking solution in this section is modified to include the labeled compounds listed in Tables 5 and 6 of this attachment.

Section 6.9 The secondary standard is modified to include the additional analytes listed in Tables 1 and 2 of this attachment.

Section 6.12 The solutions for obtaining authentic mass spectra are to include all additional analytes listed in Tables 1 and 2 of this attachment.

Section 6.13 The calibration solutions are modified to include the analytes listed in Tables 1 and 2 and the labeled compounds listed in Tables 5 and 6 of this attachment.

Section 6.14 The precision and recovery standard is modified to include the analytes listed in Tables 1 and 2 and the labeled compounds listed in Tables 5 and 6 of this attachment.

Section 6.15 The solutions containing the additional analytes listed in Tables 1 and 2 of this attachment are to be analyzed for stability.

Section 7.2.1 This section is modified to include the analytes listed in Tables 1 and 2 and the labeled compounds listed in Tables 5 and 6 of this attachment.

Section 7.4.5 This section is modified to include the analytes listed in Tables 1 and 2 and the labeled compounds listed in Tables 5 and 6 in the calibration.

Section 8.2 The initial precision and recovery (IPR) requirements are modified to include the analytes listed in Tables 1 and 2 and the labeled compounds listed in Tables 5 and 6 of this attachment. Additional IPR performance criteria are supplied in Table 7 of this attachment.

Section 8.3 The labeled compounds listed in Tables 3 and 4 of this attachment are to be included in the method performance tests. Additional method performance criteria are supplied in Table 7 of this attachment.

Section 8.5.2 The acceptance criteria for blanks includes the analytes listed in Tables 1 and 2 of this attachment.

Section 10.1.2 The labeled compound solution must include the labeled compounds listed in Tables 5 and 6 of this attachment.

Section 10.1.3 The precision and recovery standard must include the analytes listed in Tables 1 and 2 and the labeled compounds listed in Tables 5 and 6 of this attachment.

Section 12.5 Additional QC requirements for calibration verification are supplied in Table 7 of this attachment.

Section 12.7 Additional QC requirements for ongoing precision and recovery are supplied in Table 7 of this attachment.

TABLE 1.—BASE/NEUTRAL EXTRACTABLE COMPOUNDS

Compound	Pollutant	
	CAS Registry	EPA—EGD
acetophenone ¹	98–86–2	758

¹ EPA Method 1625 Revision B, Semivolatile Organic Compounds by Isotope Dilution GC/MS, 40 CFR Part 136, Appendix A.

TABLE 1.—BASE/NEUTRAL EXTRACTABLE COMPOUNDS—Continued

Compound	Pollutant	
	CAS Registry	EPA-EGD
aniline ²	62-53-3	757
-2,3-dichloroaniline ¹	608-27-5	578
-o-cresol ¹	95-48-7	771
pyridine ²	110-86-1	1330

CAS = Chemical Abstracts Registry.

EGD = Effluent Guidelines Division.

¹ Analysis of this pollutant is approved only for the Centralized Waste Treatment industry.² Analysis of this pollutant is approved only for the Centralized Waste Treatment and Landfills industries.

TABLE 2.—ACID EXTRACTABLE COMPOUNDS

Compound	Pollutant	
	CAS Registry	EPA-EGD
p-cresol ¹	106-44-5	1744

CAS = Chemical Abstracts Registry.

EGD = Effluent Guidelines Division.

¹ Analysis of this pollutant is approved only for the Centralized Waste Treatment and Landfills industries.TABLE 3.—GAS CHROMATOGRAPHY ¹ OF BASE/NEUTRAL EXTRACTABLE COMPOUNDS

EGD No.	Compound	Retention time ²			Minimum level ³ (µg/L)
		Mean (sec)	EGD Ref	Relative	
758	acetophenone ⁴	818	658	1.003-1.005	10
757	aniline ⁵	694	657	0.994-1.023	10
578	2,3-dichloroaniline ⁴	1160	164	1.003-1.007	10
771	o-cresol ⁴	814	671	1.005-1.009	10
1330	pyridine ⁵	378	1230	1.005-1.011	10

EGD = Effluent Guidelines Division.

¹ The data presented in this table were obtained under the chromatographic conditions given in the footnote to Table 3 of EPA Method 1625B.² Retention times are approximate and are intended to be consistent with the retention times for the analytes in EPA Method 1625B.³ See the definition in footnote 2 to Table 3 of EPA Method 1625B.⁴ Analysis of this pollutant is approved only for the Centralized Waste Treatment industry.⁵ Analysis of this pollutant is approved only for the Centralized Waste Treatment and Landfills industries.TABLE 4.—GAS CHROMATOGRAPHY ¹ OF ACID EXTRACTABLE COMPOUNDS

EGD No.	Compound	Retention time ²			Minimum level (µ/L) ³
		Mean (sec)	EGD Ref	Relative	
1744	p-cresol ⁴	834	1644	1.004-1.008	20

EGD = Effluent Guidelines Division.

¹ The data presented in this table were obtained under the chromatographic conditions given in the footnote to Table 4 of EPA Method 1625B.² Retention times are approximate and are intended to be consistent with the retention times for the analytes in EPA Method 1625B.³ See the definition in footnote 2 to Table 4 of EPA Method 1625B.⁴ Analysis of this pollutant is approved only for the Centralized Waste Treatment and Landfills industries.

TABLE 5.—BASE/NEUTRAL EXTRACTABLE COMPOUND CHARACTERISTIC M/Z'S

Compound	Labeled Analog	Primary m/z ¹
acetophenone ²	d ₅	105/110
aniline ³	d ₇	93/100
o-cresol ²	d ₇	108/116
2,3-dichloroaniline ²	n/a	161
pyridine ³	d ₅	79/84

m/z = mass to charge ratio.

¹ Native/labeled.² Analysis of this pollutant is approved only for the Centralized Waste Treatment industry.³ Analysis of this pollutant is approved only for the Centralized Waste Treatment and Landfills industries.

TABLE 6.—ACID EXTRACTABLE COMPOUND CHARACTERISTIC M/Z'S

Compound	Labeled Analog	Primary m/z ¹
p-cresol ²	d ₇	108/116

m/z = mass to charge ratio.

¹ Native/labeled.

² Analysis of this pollutant is approved only for the Centralized Waste Treatment and Landfills industries.

TABLE 7.—ACCEPTANCE CRITERIA FOR PERFORMANCE TESTS

EGD No.	Compound	Acceptance criteria			Calibration verification sec. 12.5 µg/mL)	On-going accuracy sec. 12.7 R (µg/L)
		Initial precision and accuracy section 8.2 (µg/L)		Labeled compound recovery sec. 8.3 and 14.2 P (percent)		
		s (µg/L)	X			
758	acetophenone ¹	34	44–167		85–115	45–162
658	acetophenone-d ₅ ¹	51	23–254	45–162	85–115	22–264
757	aniline ²	32	30–171		85–115	33–154
657	aniline-d ₇ ²	71	15–278	33–154	85–115	12–344
771	o-cresol ¹	40	31–226		85–115	35–196
671	o-cresol-d ₇ ¹	23	30–146	35–196	85–115	31–142
1744	p-cresol ²	59	54–140		85–115	37–203
1644	p-cresol-d ₇ ²	22	11–618	37–203	85–115	16–415
578	2,3-dichloroaniline ¹	13	40–160		85–115	44–144
1330	pyridine ²	28	10–421		83–117	18–238
1230	pyridine-d ₅ ²	ns	7–392	19–238	85–115	4–621

s = Standard deviation of four recovery measurements.

X = Average recovery for four recovery measurements.

EGD = Effluent Guidelines Division.

ns = no specification; limit is outside the range that can be measured reliably.

¹ Analysis of this pollutant is approved only for the Centralized Waste Treatment industry.

² Analysis of this pollutant is approved only for the Centralized Waste Treatment and Landfills industries.

4. Part 437 is added to read as follows:

PART 437—THE CENTRALIZED WASTE TREATMENT POINT SOURCE CATEGORY

Sec.

437.1 General applicability.

437.2 General definitions.

437.3 General pretreatment standards.

437.4 Monitoring requirements.

Subpart A—Metals Treatment and Recovery

437.10 Applicability.

437.11 Effluent limitations attainable by the application of the best practicable control technology currently available (BPT).

437.12 Effluent limitations attainable by the application of the best conventional pollutant control technology (BCT).

437.13 Effluent limitations attainable by the application of the best available technology economically achievable (BAT).

437.14 New source performance standards (NSPS).

437.15 Pretreatment standards for existing sources (PSES).

437.16 Pretreatment standards for new sources (PSNS).

Subpart B—Oils Treatment and Recovery

437.20 Applicability.

437.21 Effluent limitations attainable by the application of the best practicable

control technology currently available (BPT).

437.22 Effluent limitations attainable by the application of the best conventional pollutant control technology (BCT).

437.23 Effluent limitations attainable by the application of the best available technology economically achievable (BAT).

437.24 New source performance standards (NSPS).

437.25 Pretreatment standards for existing sources (PSES).

437.26 Pretreatment standards for new sources (PSNS).

Subpart C—Organics Treatment and Recovery

437.30 Applicability.

437.31 Effluent limitations attainable by the application of the best practicable control technology currently available (BPT).

437.32 Effluent limitations attainable by the application of the best conventional pollutant control technology (BCT).

437.33 Effluent limitations attainable by the application of the best available technology economically achievable (BAT).

437.34 New source performance standards (NSPS).

437.35 Pretreatment standards for existing sources (PSES).

437.36 Pretreatment standards for new sources (PSNS).

Subpart D—Multiple Wastestreams

437.40 Applicability.

437.41 Special Definitions.

437.42 Effluent limitations attainable by the application of the best practicable control technology currently available (BPT).

437.43 Effluent limitations attainable by the application of the best conventional pollutant control technology (BCT).

437.44 Effluent limitations attainable by the application of the best available technology economically achievable (BAT).

437.45 New source performance standards (NSPS).

437.46 Pretreatment standards for existing sources (PSES).

437.47 Pretreatment standards for new sources (PSNS).

Authority: Secs 301, 304, 306, 307, 308, 402, and 501 of the Clean Water Act, as amended; 33 U.S.C. 1311, 1314, 1316, 1317, 1318, 1342, and 1361.

§ 437.1 General applicability.

(a) Except as provided in paragraphs (b), (c), or (d) of this section, this part applies to that portion of wastewater discharges from a centralized waste treatment (CWT) facility that results from any of the following activities:

(1) Treatment and recovery of hazardous or non-hazardous industrial

metal-bearing wastes, oily wastes and organic-bearing wastes received from off-site; and

(2) The treatment of CWT wastewater.

(b) This part does not apply to the following discharges of wastewater from a CWT facility:

(1) Wastewater from the treatment of wastes that are generated on-site when the wastes generated on-site are otherwise subject to another part of subchapter N.

(2) Wastewater from the treatment of wastes that are generated off-site if the discharger: a) demonstrates that the off-site wastes are generated at a facility that is subject to the same provisions in 40 CFR subchapter N as non-CWT wastes generated at the CWT facility or b) demonstrates that the off-site wastes are of similar nature and the treatment of such wastes are compatible with the treatment of non-CWT wastes generated and treated at the CWT.

(3) Wastewater from the treatment of wastes received from off-site via conduit (e.g., pipelines, channels, ditches, trenches, etc.) from the facility that generates the wastes unless the resulting wastewaters are commingled with other wastewaters subject to this provision. A facility that acts as a waste collection or consolidation center is not a facility that generates wastes.

(4) Wastewater from product stewardship activities, the treatment of sanitary wastes and wastes of domestic origin including chemical toilet wastes, septage, and restaurant wastes or thermal drying of POTW biosolids. Product stewardship activities for purposes of this provision are limited to the following activities at a manufacturing facility: acceptance for treatment or recovery of its unused products, shipping and storage containers with product residues and off-spec products.

(5) Wastewater from solids recovery operations so long as the wastes recovered are from non-industrial sources, and recovery of the wastes does not generate a wastewater or leach appreciable metal or organic chemicals or petroleum-based oil and grease into the water. Examples of solids recovery operations to which this subpart would not apply include, but are not limited to, the recycling of aluminum cans, glass and plastic bottles.

(6) Wastewater from scrap metal processing or auto salvage operations.

(7) Wastewater from transfer stations or municipal recycling centers.

(8) Wastewater from the treatment of, or recovery of material from, animal or vegetable fats/oils from grease traps or interceptors generated by facilities engaged in food service activities.

(9) Wastewater from the treatment of, or recovery of material from, off-site wastes generated by facilities engaged only in food processing.

(10) Wastewater from facilities that are subject to 40 CFR part 442. Wastewater resulting from the treatment of off-site wastewater generated in cleaning transportation equipment (or on-site wastewater generated in cleaning equipment) along with other off-site wastes (subject to this part) not generated in cleaning transportation equipment is, however, subject to this part.

(11) Wastewater resulting from solvent recovery operations if the solvent recovery operations involve the separation of solvent mixtures by distillation.

(12) Wastewater from facilities that are engaged exclusively in centralized silver recovery from used photographic or x-ray materials activities. The discharge resulting from centralized silver recovery from used photographic or x-ray materials that is treated at a CWT facility along with other off-site wastestreams (subject to this part) is subject to this part.

(13) Wastewater from facilities that accept off-site wastes only for treatability studies, research and development, or chemical or physical analysis. The wastewater resulting from treatability studies, research and development, or chemical or physical analysis that is treated at a CWT facility along with other off-site wastestreams (subject to this part) is subject to this part.

(c) This part also does not apply to the following activities:

(1) "Dry" fuel blending operations, "dry" waste solidification/stabilization operations, "dry" used oil filter or oily absorbents recycling operations, or "dry" high temperature metals recovery operations. However, this part does apply to wastewater discharges from a CWT resulting from any of these operations that do produce wastewater.

(2) The discharge of marine generated wastes including wash water from equipment and tank cleaning, ballast water, bilge water, and other wastes generated (while operating on inland, coastal, or open waters or while berthed) as part of routine ship maintenance and operation as long as they are treated and discharged at the ship servicing facility where it is off-loaded. The discharges resulting from the treatment of marine generated wastes that are off-loaded and subsequently sent to a centralized waste treatment facility at a separate location are, however, subject to this part.

(3) Discharge of wastewater from land treatment units or land application operations.

(4) Discharge of wastewater from facilities that are engaged exclusively in landfilling activities and/or the treatment of landfill wastewaters (whether generated on or off-site). The discharge resulting from the treatment of landfill wastewater, whether generated on-site or off-site, treated at CWT facilities along with other off-site waste is, however, subject to this part.

(5) Discharge of wastewater from facilities that are engaged exclusively in incineration activities. The discharge resulting from the treatment of off-site wastewater generated in the incineration of industrial waste that is treated at a CWT facility along with other off-site wastestreams (subject to this part) is subject to this part.

(d) Notwithstanding paragraph (a) of this section, the provisions of this part are not applicable to any metals treatment and recovery wastewater discharges which are subject to the secondary metals provisions of 40 CFR part 421, the Nonferrous Metals Manufacturing Point Source Category. These secondary metals subcategories are Subpart C (Secondary Aluminum Smelting Subcategory), Subpart F (Secondary Copper Subcategory), Subpart L (Secondary Silver Subcategory), Subpart M (Secondary Lead Subcategory), Subpart P (Primary and Secondary Germanium and Gallium Subcategory), Subpart Q (Secondary Indium Subcategory), Subpart R (Secondary Mercury Subcategory), Subpart T (Secondary Molybdenum and Vanadium Subcategory), Subpart V (Secondary Nickel Subcategory), Subpart X (Secondary Precious Metals Subcategory), Subpart Z (Secondary Tantalum Subcategory), Subpart AA (Secondary Tin Subcategory), Subpart AB (Primary and Secondary Titanium Subcategory), Subpart AC (Secondary Tungsten and Cobalt Subcategory), and Subpart AD (secondary Uranium Subcategory).

§ 437.2 General definitions.

As used in this part:

(a) The general definitions and abbreviations in 40 CFR part 401 apply to this part.

(b) *Alternative effluent limitations or pretreatment standards* mean effluent limitations determined on a case-by-case basis under section 402(a)(1) of the CWA or pretreatment standards developed as local limits by the control authority under 40 CFR § 403.6(c) that apply to the discharge of wastewater subject to this provision. The permit writer (or control authority) will

calculate these limitations or standards using a "building block" approach or the "combined wastestream formula." Under this approach, the permit writer (or control authority) will develop flow-weighted effluent limitations or standards for the treated combined wastestream by applying the limitations or standards in 40 CFR subchapter N that would otherwise apply to a particular wastestream received from off-site if the wastestream were treated and discharged from the facility at which it was generated.

(c) *Centralized waste treatment (CWT) facility* means any facility that treats (for disposal, recycling or recovery of material) any hazardous or non-hazardous industrial wastes, hazardous or non-hazardous industrial wastewater, and/or used material received from off-site. "CWT facility" includes both a facility that treats waste received exclusively from off-site and a facility that treats wastes generated on-site as well as waste received from off-site. For example, an organic chemical manufacturing plant may, in certain circumstances, be a CWT facility if it treats industrial wastes received from offsite as well as industrial waste generated at the organic chemical manufacturing plant. CWT facilities may also include re-refiners and may be owned by the federal government.

(d) *Centralized waste treatment wastewater* means any wastewater generated as a result of CWT activities. CWT wastewater sources may include, but are not limited to: liquid waste receipts, solubilization water, used oil emulsion-breaking wastewater, tanker truck/drum/roll-off box washes, equipment washes, air pollution control scrubber blow-down, laboratory-derived wastewater, on-site landfill wastewaters, and contaminated storm water.

(e) *Contaminated storm water* means storm water which comes in direct contact with CWT wastes, the waste handling and treatment areas, or other centralized waste treatment wastewater as defined in paragraph (d) of this section.

(f) *Discharger* means a facility that discharges wastewater directly to waters of the United States or introduces wastewater to a publicly-owned treatment works.

(g) *Dry* means not producing a wastewater.

(h) *Equivalent treatment* means a wastewater treatment system that achieves comparable pollutant removals to the applicable treatment technology selected as the basis for the limitations and pretreatment standards. Comparable removals may be demonstrated through

literature, treatability tests, or self-monitoring data.

(i) *Fuel blending* means the process of combining waste, wastewater, or used material for the purpose of regenerating a fuel for reuse. However, fuel blending may be loosely applied to any process where recovered hydrocarbons are combined as a fuel product where some pretreatment operations generate wastewater.

(j) *High temperature metals recovery* means a metals recovery process in which solid forms of metal-containing materials are processed with a heat-based pyrometallurgical technology to produce a metal product.

(k) *Marine generated waste* means any waste, wastewater, and/or used material generated as part of the normal maintenance and operation of a ship, boat, or barge operating on inland, coastal, or open waters, or while berthed.

(l) *Metal-bearing wastes* means wastes and/or used materials from manufacturing or processing facilities or other commercial operations that contain significant quantities of metal pollutants, but not significant quantities of oil and grease (generally less than 100 mg/L). Examples of these wastes are spent electroplating baths and sludges, metal-finishing rinse water and sludges, chromate wastes, blow-down water and sludges from air pollution control, spent anodizing solutions, incineration air pollution control wastewaters, waste liquid mercury, cyanide containing wastes greater than 136 mg/L, and waste acids and bases with or without metals.

(m) *Multiple wastestream CWT facility* means a CWT facility which accepts waste in more than one CWT subcategory (metals, oils, or organics) and combines any portion of these different subcategory wastes at any point prior to the compliance discharge sampling location.

(n) *Off-site* means outside the boundaries of a facility.

(o) *Oily absorbent recycling* means the process of recycling oil-soaked or contaminated disposable rags, paper, or pads for the purpose of regenerating a fuel for reuse.

(p) *Oily wastes* means wastes and/or used materials that contain oil and grease (generally at or in excess of 100 mg/L) from manufacturing or processing facilities or other commercial operations. Examples of these wastes are used oils, oil-water emulsions or mixtures, lubricants, coolants, contaminated groundwater clean-up from petroleum sources, used petroleum products, oil spill clean-up, bilge water, rinse/wash waters from petroleum sources, interceptor wastes, off-

specification fuels, underground storage tank remediation waste, and tank clean out from petroleum or oily sources.

(q) *On-site* means within the boundaries of a facility. A facility may encompass land areas that are bisected by public thoroughfares but are under the control of a common owner.

(r) *Organic wastes* means wastes and/or used materials that contain organic pollutants, but not a significant quantity of oil and grease (generally less than 100 mg/L) from manufacturing or processing facilities or other commercial operations. Examples of these wastes are landfill leachate, contaminated groundwater clean-up from non-petroleum sources, solvent-bearing wastes, off-specification organic product, still bottoms, byproduct glycols, wastewater from paint washes, wastewater from adhesives and/or epoxies, wastewater from chemical product operations, and tank clean-out from organic, non-petroleum sources.

(s) The following regulated parameters are listed with approved methods of analysis in Table 1B at 40 CFR 136.3, and are defined as follows:

- (1) *Antimony* means total antimony.
- (2) *Arsenic* means total arsenic.
- (3) *Barium* means total barium.
- (4) *BOD₅* means 5-day biochemical oxygen demand.
- (5) *Cadmium* means total cadmium.
- (6) *Chromium* means total chromium.
- (7) *Cobalt* means total cobalt.
- (8) *Copper* means total copper.
- (9) *Cyanide* means total cyanide.
- (10) *Lead* means total lead.
- (11) *Mercury* means total mercury.
- (12) *Molybdenum* means total molybdenum.
- (13) *Nickel* means total nickel.
- (14) *O&G* means total recoverable oil and grease (n-hexane extractable material).
- (15) *Selenium* means total selenium.
- (16) *Silver* means total silver.
- (17) *Tin* means total tin.
- (18) *Titanium* means total titanium.
- (19) *TSS* means total suspended solids.
- (20) *Vanadium* means total vanadium.
- (21) *Zinc* means total zinc.

(t) The following regulated parameters are listed with approved methods of analysis in Table 1C at 40 CFR 136.3:

- (1) Bis(2-ethylhexyl) phthalate.
- (2) Butylbenzyl phthalate.
- (3) Fluoranthene.
- (4) Phenol.
- (5) 2,4,6-trichlorophenol.

(u) The following regulated parameters are listed with approved methods of analysis (Methods 625 and 1625) at 40 CFR 136.3, Appendix A:

- (1) Acetone.
- (2) Acetophenone.

- (3) Aniline.
- (4) 2-Butanone.
- (5) Carbazole.
- (6) o-Cresol.
- (7) p-Cresol.
- (8) n-Decane.
- (9) 2,3-dichloroaniline.
- (10) n-Octadecane.
- (11) Pyridine.

(v) *Pipeline* means an open or closed conduit used for the conveyance of material. A pipeline includes a channel, pipe, tube, trench, or ditch, or fixed delivery system.

(w) *Product stewardship* means a manufacturer's treatment or recovery of its own unused products, shipping and storage containers with product residues, off-specification products, and does not include spent or used materials from use of its products.

(x) *Re-refining* means the processing of used oil using distillation, hydrotreating, and/or other treatment employing acid, caustic, solvent, clay and/or chemicals in order to produce high quality base stock for lubricants or other petroleum products.

(y) *Recovery* means the recycling or processing of a waste, wastewater or used material such that the material, or a portion thereof, may be reused or converted to a raw material, intermediate, or product. Recovery does not include the re-use of treated or untreated wastewater in place of potable or pure water in industrial processes such as the use of secondary POTW effluents as non-contact cooling water, storm water in place of process water, or the re-use of spent chemicals in place of virgin treatment chemicals.

(z) *Solidification* means the addition of sorbents to convert liquid or semi-liquid waste to a solid by means of adsorption, absorption or both. The process is usually accompanied by stabilization.

(aa) *Solvent recovery* includes fuel blending operations and the recycling of spent solvents through separation of solvent mixtures in distillation columns. Solvent recovery may require an additional, pretreatment step prior to distillation.

(bb) *Stabilization* means a waste process that decreases the mobility of waste constituents by means of a chemical reaction. For the purpose of this rule, chemical precipitation is not a technique for stabilization.

(cc) *Treatment* means any method, technique, or process designed to change the physical, chemical or biological character or composition of any metal-bearing, oily, or organic wastes to neutralize such wastes; to render such wastes amenable to discharge; or to recover energy or

recover metal, oil, or organic content from the wastes. Treatment does not include (a) the re-use of treated or untreated wastewater in place of potable or pure water in industrial processes such as the use of secondary POTW effluents as non-contact cooling water or storm water in place of process water or (b) the re-use of treated or untreated spent chemicals (such as pickle liquor) as treatment chemicals.

(dd) *Non-contaminated storm water* means storm water which does not come in direct contact with CWT wastes, the waste handling and treatment areas, or other CWT wastewater that is defined in paragraph (d) of this section.

(ee) *Used oil filter recycling* means crushing and draining of used oil filters of entrained oil and/or shredding and separation of used oil filters.

(ff) *Waste* includes aqueous, non-aqueous, and solid waste, wastewater, and/or used material.

§ 437.3 General pretreatment standards.

Any source subject to this part that introduces process wastewater pollutants into a publicly owned treatment works (POTW) must comply with 40 CFR part 403.

§ 437.4 Monitoring requirements.

(a) Permit compliance monitoring is required for each regulated parameter.

(b) Any CWT facility that discharges wastewater resulting from the treatment of metal-bearing waste, oily waste, or organic-bearing waste must monitor as follows:

(1) Facilities subject to more than one subpart of this part must monitor for compliance for each subpart after treatment and before mixing of the waste with wastes of any other subpart. Alternatively, a multiple wastestream subcategory facility may certify that it provides equivalent treatment as defined in § 437.2(h) for the applicable waste and monitor for compliance with the applicable set of multiple wastestream subcategory limitations after mixing.

(2) Facilities subject to one or more subpart of this part must monitor for compliance with the applicable subpart after treatment and before mixing of the waste with wastes of any other subpart, uncontaminated storm water, or wastewater subject to another effluent limitation or standard in Subchapter N. If, however, the facility can demonstrate to the receiving POTW or permitting authority the capability of achieving the effluent limitation or standard for each subpart after treatment and before mixing with other wastestreams, the facility may monitor for compliance

after mixing. In the case of a facility which elects to comply with the applicable set of multiple wastestream subcategory limitations or standards, it is only subject to one subpart.

(3) When a CWT facility treats any waste receipt that contains cyanide at a concentration higher than 136 mg/L, the CWT facility must monitor for cyanide after cyanide treatment and before dilution with other wastestreams. If, however, the facility can demonstrate to the receiving POTW or permitting authority the capability of achieving the cyanide limitation or standard after cyanide treatment and before mixing with other wastestreams, the facility may monitor for compliance after mixing.

Subpart A—Metals Treatment and Recovery

§ 437.10 Applicability.

(a) Except as provided in § 437.1(b), (c), or (d) or in paragraph (b) of this section, this subpart applies to that portion of the discharge of wastewater from a CWT facility that results from the treatment of, or recovery of metals from, both metal-bearing wastes received from off-site and other CWT wastewater associated with the treatment of, or recovery of metal-bearing wastes.

(b) In order to ensure appropriate treatment rather than dilution of dissimilar wastes, an NPDES permit writer or control authority may require a new source or an existing facility subject to this subpart to achieve alternative effluent limitations and standards as defined in § 437.2(b) in the following circumstances:

(1) The facility receives, on a continuing basis, flows of process wastewater from five or fewer facilities subject to 40 CFR Subchapter N limitations and standards; and

(2) The process wastewater flows received for treatment at the facility have relatively consistent pollutant profiles.

§ 437.11 Effluent limitations attainable by the application of the best practicable control technology currently available (BPT).

(a) Except as provided in 40 CFR 125.30 through 125.32 or 437.10(b), any existing point source subject to this subpart must achieve the following effluent limitations representing the application of BPT:

BPT LIMITATIONS

Regulated parameter	Maximum daily ¹	Maximum monthly avg. ¹

Conventional Parameters

O&G	205	50.2
pH	(²)	(²)
TSS	60.0	31.0

Metal Parameters

Antimony	0.249	0.206
Arsenic	0.162	0.104
Cadmium	0.474	0.0962
Chromium	15.5	3.07
Cobalt	0.192	0.124
Copper	4.14	1.06
Lead	1.32	0.283
Mercury	0.00234	0.000739
Nickel	3.95	1.45
Selenium	1.64	0.408
Silver	0.120	0.0351
Tin	0.409	0.120
Titanium	0.0947	0.0618
Vanadium	0.218	0.0662
Zinc	2.87	0.641

¹ mg/L (ppm).² Within the range 6 to 9.

(b) The following in-plant limitations apply to metal-bearing wastewater containing cyanide:

IN-PLANT LIMITATIONS

Regulated parameter	Maximum daily ¹	Maximum monthly avg. ¹
Cyanide	500	178

¹ mg/L (ppm).

§ 437.12 Effluent limitations attainable by the application of the best conventional pollutant control technology (BCT).

Except as provided in 40 CFR 125.30 through 125.32 or 437.10(b), any existing point source subject to this subpart must achieve the following effluent limitations representing the application of BCT: Limitations for oil and grease, pH, and TSS are the same as the corresponding limitation specified in § 437.11(a).

§ 437.13 Effluent limitations attainable by the application of the best available technology economically achievable (BAT).

(a) Except as provided in 40 CFR 125.30 through 125.32 or 437.10(b), any existing point source subject to this subpart must achieve the following effluent limitations representing the application of BAT: Limitations for antimony, arsenic, cadmium, chromium, cobalt, copper, lead, mercury, nickel, selenium, silver, tin, titanium, vanadium, and zinc are the same as the corresponding limitation specified in § 437.11(a).

(b) In-plant standards for cyanide are the same as the limitations specified in § 437.11(b).

§ 437.14 New source performance standards (NSPS).

(a) Except as provided in § 437.10(b), any new source subject to this subpart must achieve the following performance standards:

PERFORMANCE STANDARDS

Regulated parameter	Maximum daily ¹	Maximum monthly avg. ¹

Contentional Parameters

O&G	205	50.2
pH	(²)	(²)
TSS	29.6	11.3

Metal Parameters

Antimony	0.111	0.0312
Arsenic	0.0993	0.0199
Cadmium	0.782	0.163
Chromium	0.167	0.0522
Cobalt	0.182	0.0703
Copper	0.659	0.216
Lead	1.32	0.283
Mercury	0.000641	0.000246
Nickel	0.794	0.309
Selenium	0.176	0.0698
Silver	0.0318	0.0122
Tin	0.0955	0.0367
Titanium	0.0159	0.00612
Vanadium	0.0628	0.0518
Zinc	0.657	0.252

¹ mg/L (ppm).² Within the range 6 to 9.

(b) In-plant standards for cyanide are the same as the limitations specified in § 437.11(b).

§ 437.15 Pretreatment standards for existing sources (PSES).

(a) Except as provided in 40 CFR 403.7, 403.13 or 437.10(b), and no later than December 22, 2003, any existing source subject to this subpart must achieve the following pretreatment standards: Standards for antimony, arsenic, cadmium, chromium, cobalt, copper, lead, mercury, nickel, selenium, silver, tin, titanium, vanadium, and zinc are the same as the corresponding limitation specified in § 437.11(a).

(b) In-plant standards for cyanide are the same as the limitations specified in § 437.11(b).

§ 437.16 Pretreatment standards for new sources (PSNS).

(a) Except as provided in 40 CFR 403.7 or 437.10(b), any new source subject to this subpart must achieve the following pretreatment standards: Standards for antimony, arsenic, cadmium, chromium, cobalt, copper, lead, mercury, nickel, selenium, silver,

tin, titanium, vanadium, and zinc are the same as the corresponding limitation specified in § 437.11(a).

(b) In-plant standards for cyanide are the same as the limitations specified in § 437.11(b).

Subpart B—Oils Treatment and Recovery

§ 437.20 Applicability.

(a) Except as provided in § 437.1(b), (c), or (d) or in paragraph (b) of this section, this subpart applies to that portion of the discharge of wastewater from a CWT facility that results from the treatment or recovery of oil from both oily wastes received from off-site and other CWT wastewater associated with the treatment of, or recovery of oily wastes.

(b) In order to ensure appropriate treatment rather than dilution of dissimilar wastes, an NPDES permit writer or control authority may require a new source or an existing source subject to this subpart to achieve alternative effluent limitations and standards, as defined in § 437.2(b), in the following circumstances:

(1) The facility receives, on a continuing basis, flows of process wastewater from five or fewer facilities subject to 40 CFR Subchapter N limitations and standards; and

(2) The process wastewater flows received for treatment at the facility have relatively consistent pollutant profiles.

§ 437.21 Effluent limitations attainable by the application of the best practicable control technology currently available (BPT).

Except as provided in 40 CFR 125.30 through 125.32 or 437.20(b), any existing point source subject to this subpart must achieve the following effluent limitations representing the application of BPT:

BPT LIMITATIONS

Regulated parameter	Maximum daily ¹	Maximum monthly avg. ¹

Conventional Parameters

O&G	127	38.0
pH	(²)	(²)
TSS	74.1	30.6

Metal Parameters

Antimony	0.237	0.141
Arsenic	2.95	1.33
Barium	0.427	0.281
Cadmium	0.0172	0.0102
Chromium	0.746	0.323
Cobalt	56.4	18.8
Copper	0.500	0.242
Lead	0.350	0.160

BPT LIMITATIONS—Continued

Regulated parameter	Maximum daily ¹	Maximum monthly avg. ¹
Mercury	0.0172	0.00647
Molybdenum	3.50	2.09
Tin	0.335	0.165
Titanium	0.0510	0.0299
Zinc	8.26	4.50

Organic Parameters

Bis(2-ethylhexyl) phthalate ...	0.215	0.101
Butylbenzyl phthalate ...	0.188	0.0887
Carbazole	0.598	0.276
n-Decane	0.948	0.437
Fluoranthene	0.0537	0.0268
n-Octadecane	0.589	0.302

¹ mg/L (ppm).² Within the range 6 to 9.**§ 437.22 Effluent limitations attainable by the application of the best conventional pollutant control technology (BCT).**

Except as provided in 40 CFR 125.30 through 125.32 or 437.20(b), any existing point source subject to this subpart must achieve the following effluent limitations attainable by the application of BCT: Limitations for O&G, pH, and TSS are the same as the corresponding limitation specified in § 437.21.

§ 437.23 Effluent limitations attainable by the application of the best available technology economically achievable (BAT).

Except as provided in 40 CFR 125.30 through 125.32 or 437.20(b), any existing point source subject to this subpart must achieve the following effluent limitations by the application of BAT: Limitations for antimony, arsenic, barium, cadmium, chromium, cobalt, copper, lead, mercury, molybdenum, tin, titanium, zinc, butylbenzyl phthalate, carbazole, n-decane, bis(2-ethylhexyl) phthalate, fluoranthene, and n-octadecane are the same as the corresponding limitation specified in § 437.21.

§ 437.24 New source performance standards (NSPS).

Except as provided in § 437.20(b), any new source subject to this subpart must achieve the following performance standards: Standards for oil and grease, pH, TSS, antimony, arsenic, barium, cadmium, chromium, cobalt, copper, lead, mercury, molybdenum, tin, titanium, zinc, butylbenzyl phthalate, carbazole, n-decane, bis(2-ethylhexyl) phthalate, fluoranthene, and n-octadecane are the same as the corresponding limitation specified in § 437.21.

§ 437.25 Pretreatment standards for existing sources (PSES).

Except as provided in 40 CFR 403.7, 403.13 or § 437.20(b), and no later than December 22, 2003, any existing source subject to this subpart must achieve the following pretreatment standards:

PRETREATMENT STANDARDS (PSES)

Regulated parameter	Maximum daily ¹	Maximum monthly avg. ¹
Metal Parameters		
Antimony	0.237	0.141
Barium	0.427	0.281
Chromium	0.947	0.487
Cobalt	56.4	18.8
Copper	0.405	0.301
Lead	0.222	0.172
Molybdenum	3.50	2.09
Tin	0.249	0.146
Zinc	6.95	4.46
Organic Parameters		
Bis(2-ethylhexyl) phthalate ...	0.267	0.158
Carbazole	0.392	0.233
n-Decane	5.79	3.31
Fluoranthene	0.787	0.393
n-Octadecane	1.22	0.925

¹ mg/L (ppm).**§ 437.26 Pretreatment standards for new sources (PSNS).**

Except as provided in 40 CFR 403.7 or § 437.20(b), any new source subject to this subpart must achieve the following pretreatment standards: Standards for antimony, barium, chromium, cobalt, copper, lead, molybdenum, tin, zinc, carbazole, n-decane, bis(2-ethylhexyl) phthalate, fluoranthene, and n-octadecane are the same as the corresponding limitation specified in § 437.21.

Subpart C—Organics Treatment and Recovery**§ 437.30 Applicability.**

(a) Except as provided in § 437.1(b), (c), or (d) or in paragraph (b) of this section, this subpart applies to that portion of the discharge of wastewater from a CWT facility that results from the treatment of, or recovery of organic material from, both organic wastes received from off-site and other CWT wastewater associated with the treatment of, or recovery of organic wastes.

(b) In order to ensure appropriate treatment rather than dilution of dissimilar wastes, an NPDES permit writer or control authority may require a new source or an existing facility subject to § 437.30 to achieve alternative effluent limitations and standards as

defined in § 437.2 (h) in the following circumstances:

(1) The facility receives, on a continuing basis, flows of process wastewater from five or fewer facilities subject to 40 CFR Subchapter N limitations and standards; and

(2) The process wastewater flows received for treatment at the facility have relatively consistent pollutant profiles.

§ 437.31 Effluent limitations attainable by the application of the best practicable control technology currently available (BPT).

Except as provided in 40 CFR 125.30 through 125.32 or § 437.30(b), any existing point source subject to this subpart must achieve the following effluent limitations representing the application of BPT:

BPT LIMITATIONS

Regulated parameter	Maximum daily ¹	Maximum monthly avg. ¹
Conventional Parameters		
BOD ₅	163	53.0
pH	(²)	(²)
TSS	216	61.3
Metal Parameters		
Antimony	0.928	0.679
Copper	0.865	0.757
Molybdenum	1.01	0.965
Zinc	0.497	0.420
Organic Parameters		
Acetone	30.2	7.97
Acetophenone	0.114	0.0562
Aniline	0.0333	0.0164
2-Butanone	4.81	1.85
o-Cresol	1.92	0.561
p-Cresol	0.698	0.205
2,3-Dichloroaniline	0.0731	0.0361
Phenol	3.65	1.08
Pyridine	0.370	0.182
2,4,6-Trichlorophenol	0.155	0.106

¹ mg/L (ppm).² Within the range 6 to 9.**§ 437.32 Effluent limitations attainable by the application of the best conventional pollutant control technology (BCT).**

Except as provided in 40 CFR 125.30 through 125.32 or § 437.30(b), any existing point source subject to this subpart must achieve the following effluent limitations representing the application of BCT: Limitations for BOD₅, pH, and TSS are the same as the corresponding limitation specified in § 437.31.

§ 437.33 Effluent limitations attainable by the application of the best available technology economically achievable (BAT).

Except as provided in 40 CFR 125.30 through 125.32 or § 437.30(b), any existing point source subject to this subpart must achieve limitations representing the application of BAT: Limitations for antimony, copper, molybdenum, zinc, acetone, acetophenone, aniline, 2-butanone, o-cresol, p-cresol, 2,3-dichloroaniline, phenol, pyridine, and 2,4,6-trichlorophenol are the same as the corresponding limitation specified in § 437.31.

§ 437.34 New source performance standards (NSPS).

Except as provided in § 437.30(b), any new source subject to this subpart must achieve the following new source performance standards: Standards for BOD₅, pH, TSS, antimony, copper, molybdenum, zinc, acetone, acetophenone, aniline, 2-butanone, o-cresol, p-cresol, 2,3-dichloroaniline, phenol, pyridine, and 2,4,6-trichlorophenol are the same as the corresponding limitation specified in § 437.31.

§ 437.35 Pretreatment standards for existing sources (PSES).

Except as provided in 40 CFR 403.7, 403.13 or § 437.30(b), and no later than December 22, 2003, any existing source subject to this subpart must achieve the following pretreatment standards: Standards for molybdenum, 2,3-dichloroaniline, o-cresol, p-cresol, 2,4,6-trichlorophenol are the same as the corresponding limitation specified in § 437.31.

§ 437.36 Pretreatment standards for new sources (PSNS).

Except as provided in 40 CFR 403.7 or § 437.30(b), any new source subject to this subpart must achieve the following pretreatment standards: Standards for molybdenum, 2,3-dichloroaniline, o-cresol, p-cresol, 2,4,6-trichlorophenol are the same as the corresponding limitation specified in § 437.31.

Subpart D—Multiple Wastestreams

§ 437.40 Applicability.

(a) Except as provided in § 437.1(b), (c), or (d) or in paragraph (b) of this section, facilities that treat wastes subject to more than one of the previous Subparts must comply with either provisions of this subpart or the applicable provisions of Subpart A, B, or C. The provisions of this subpart are applicable to that portion of wastewater discharges from a centralized waste treatment facility that results from

mixing any combination of treated or untreated waste otherwise subject to Subpart A, Subpart B, or Subpart C of this part only if a facility requests the permit writer or control authority to develop Subpart D limitations (or standards) and establishes that it provides equivalent treatment as defined in § 437.2(h).

(b) In order to ensure appropriate treatment rather than dilution of dissimilar wastes, an NPDES permit writer or control authority may require a new or existing facility subject to paragraph (a) of this section to achieve alternative effluent limitations or standards as defined in § 437.2 (b) in the following circumstances:

(1) The facility receives, on a continuing basis, flows of process wastewater from five or fewer facilities subject to 40 CFR Subchapter N limitations and standards; and

(2) The process wastewater flows received for treatment at the facility have relatively consistent pollutant profiles.

§ 437.41 Special definitions.

(a) Initial Certification Statement for this subpart means a written submission to the appropriate permitting authority (either the local control authority (the POTW) or NPDES permit writer) that is signed by the responsible corporate officer as defined in 40 CFR 403.12(l) or 40 CFR 122.22. The statement must:

(1) List and describe the subcategories of wastes accepted for treatment at the facility;

(2) List and describe the treatment systems in-place at the facility and conditions under which the treatment systems are operated for the subcategories of wastes accepted for treatment at the facility;

(3) Include information and supporting data establishing that these treatment systems will achieve equivalent treatment.

(b) Periodic Certification Statement for this subpart means a written submission to the appropriate permitting authority (the local control authority (the POTW) or NPDES permit writer) which certifies that the facility is operating its treatment systems to provide equivalent treatment as set forth in the initial certification. In the event that the facility has modified its treatment systems, the facility should submit a description of the modified systems and information and supporting data to establish that the modified system will achieve equivalent treatment. The periodic certification statement must be signed by the responsible corporate officer as defined in 40 CFR 403.12(l) or 40 CFR 122.22.

(c) On-site Compliance Paperwork for this subpart means data or information retained in the offices of the facility which supports the initial and periodic certification statements. This Paperwork must:

(1) List and describe the subcategory wastes being accepted for treatment at the facility;

(2) List and describe the treatment systems in-place at the facility, modifications to the treatment systems and the conditions under which the systems are operated for the subcategories of wastes accepted for treatment at the facility;

(3) Provide information and supporting data establishing that these treatment systems will achieve equivalent treatment;

(4) Describe the procedures it follows to ensure that its treatment systems are well-operated and maintained; and

(5) Explain why the procedures it has adopted will ensure its treatment systems are well-operated and maintained.

§ 437.42 Effluent limitations attainable by the application of the best practicable control technology currently available (BPT).

(a) Except as provided in 40 CFR 125.30 through 125.32 or § 437.40(b), any existing facility subject to this subpart which combines treated or untreated wastes from subparts A, B, or C of this part may be subject to Multiple Wastestream Subcategory effluent limitations representing the application of BPT set forth in paragraphs (b), (c), (d), or (e) of this section if the discharger agrees to the following conditions in its NPDES permit:

(1) The discharger will meet the applicable Multiple Wastestream Subcategory limitations set forth in (b), (c), (d) or (e);

(2) The discharger will notify its NPDES permit writer at the time of renewal or modification of its permit, of its desire to be subject to the Multiple Waste Subcategory by submitting to the NPDES permit writer an initial certification statement as described in § 437.41(a);

(3) The discharger will submit to its NPDES permitting authority a periodic certification statement as described in § 437.41(b) once a year; and

(4) The discharger will maintain at the office of the facility and make available for inspection the on-site compliance paperwork as described in § 437.41(c).

(b) Combined waste receipts from subparts A, B, and C of this part. (1) As provided in § 437.42(a), any existing point source subject to this paragraph must achieve the following effluent

limitations representing the application of BPT:

BPT LIMITATIONS

Regulated parameter	Maximum daily ¹	Maximum monthly avg. ¹
Conventional Parameters		
BOD ₅	163	53.0
O&G	127	38.0
pH	(²)	(²)
TSS	74.1	30.6

Metal Parameters

Antimony	0.237	0.141
Arsenic	0.162	0.104
Barium	0.427	0.281
Cadmium	0.0172	0.0102
Chromium	0.746	0.323
Cobalt	0.192	0.124
Copper	0.500	0.242
Lead	0.350	0.160
Mercury	0.00234	0.000739
Molybdenum	1.01	0.965
Nickel	3.95	1.45
Selenium	1.64	0.408
Silver	0.120	0.0351
Tin	0.409	0.120
Titanium	0.0510	0.0299
Vanadium	0.218	0.0662
Zinc	0.497	0.420

Organic Parameters

Acetone	30.2	7.97
Acetophenone	0.114	0.0562
Aniline	0.0333	0.0164
Bis(2-ethylhexyl) phthalate ...	0.215	0.101
2-Butanone ...	4.81	1.85
Butylbenzyl phthalate ...	0.188	0.0887
Carbazole	0.598	0.276
<i>o</i> -Cresol	1.92	0.561
<i>p</i> -Cresol	0.698	0.205
<i>n</i> -Decane	0.948	0.437
2,3-Dichloroaniline	0.0731	0.0361
Fluoranthene	0.0537	0.0268
<i>n</i> -Octadecane	0.589	0.302
Phenol	3.65	1.08
Pyridine	0.370	0.182
2,4,6-Trichlorophenol	0.155	0.106

¹ mg/L (ppm).

² OSC Within the range 6 to 9.

(2) The following in-plant limitations apply to metal-bearing wastewater containing cyanide:

IN-PLANT LIMITATIONS

Regulated parameter	Maximum daily ¹	Maximum monthly avg. ¹
Cyanide	500	178

¹ mg/L (ppm).

(c) Combined waste receipts from subparts A and B of this part. (1) As provided in § 437.42(a), any existing point source subject to this paragraph must achieve the following effluent limitations representing the application of BPT:

BPT LIMITATIONS

Regulated parameter	Maximum daily ¹	Maximum monthly avg. ¹
Conventional Parameters		
O&G	127	38.0
pH	(²)	(²)
TSS	74.1	30.6

Metal Parameters

Antimony	0.237	0.141
Arsenic	0.162	0.104
Barium	0.427	0.281
Cadmium	0.0172	0.0102
Chromium	0.746	0.323
Cobalt	0.192	0.124
Copper	0.500	0.242
Lead	0.350	0.160
Mercury	0.00234	0.000739
Molybdenum	3.50	2.09
Nickel	3.95	1.45
Selenium	1.64	0.408
Silver	0.120	0.0351
Tin	0.409	0.120
Titanium	0.0510	0.0299
Vanadium	0.218	0.0662
Zinc	2.87	0.641

Organic Parameters

Bis(2-ethylhexyl) phthalate ...	0.215	0.101
Butylbenzyl phthalate ...	0.188	0.0887
Carbazole	0.598	0.276
<i>n</i> -Decane	0.948	0.437
Fluoranthene	0.0537	0.0268
<i>n</i> -Octadecane	0.589	0.302

¹ mg/L (ppm).

² Within the range 6 to 9.

(2) The following in-plant limitations apply to metal-bearing wastewater containing cyanide:

IN-PLANT LIMITATIONS

Regulated parameter	Maximum daily ¹	Maximum monthly avg. ¹
Cyanide	500	178

¹ mg/L (ppm).

(d) Combined waste receipts from subparts A and C of this part. (1) As provided in § 437.42(a), any existing point source subject to this paragraph must achieve the following effluent limitations representing the application of BPT:

BPT LIMITATIONS

Regulated parameter	Maximum daily ¹	Maximum monthly avg. ¹
Conventional Parameters		
BOD ₅	163	3.0
O&G	205	50.2
pH	(²)	(²)
TSS	60.0	31.0

Metal Parameters

Antimony	0.249	0.206
Arsenic	0.162	0.104
Cadmium	0.474	0.0962
Chromium	15.5	3.07
Cobalt	0.192	0.124
Copper	0.865	0.757
Lead	1.32	0.283
Mercury	0.00234	0.000739
Molybdenum	1.01	0.965
Nickel	3.95	1.45
Selenium	1.64	0.408
Silver	0.120	0.0351
Tin	0.409	0.120
Titanium	0.0947	0.0618
Vanadium	0.218	0.0662
Zinc	0.497	0.420

Organic Parameters

Acetone	30.2	7.97
Acetophenone	0.114	0.0562
Aniline	0.0333	0.0164
2-Butanone ...	4.81	1.85
<i>o</i> -Cresol	1.92	0.561
<i>p</i> -Cresol	0.698	0.205
2,3-Dichloroaniline	0.0731	0.0361
Phenol	3.65	1.08
Pyridine	0.370	0.182
2,4,6-Trichlorophenol	0.155	0.106

¹ mg/L (ppm).

² Within the range 6 to 9.

(2) The following in-plant limitations apply to metal-bearing wastewater containing cyanide:

IN-PLANT LIMITATIONS

Regulated parameter	Maximum daily ¹	Maximum monthly avg. ¹
Cyanide	500	178

¹ mg/L (ppm).

(e) Combined waste receipts from subparts B and C of this part. As provided in § 437.42(a), any existing point source subject to this paragraph must achieve the following effluent limitations representing the application of BPT:

BPT LIMITATIONS

Regulated parameter	Maximum daily ¹	Maximum monthly avg. ¹
Conventional Parameters		
BOD ₅	163	53.0
O&G	127	38.0
pH	(²)	(²)
TSS	74.1	30.6
Metal Parameters		
Antimony	0.237	0.141
Arsenic	2.95	1.33
Barium	0.427	0.281
Cadmium	0.0172	0.0102
Chromium	0.746	0.323
Cobalt	56.4	18.8
Copper	0.500	0.242
Lead	0.350	0.160
Mercury	0.0172	0.00647
Molybdenum	1.01	0.965
Tin	0.335	0.165
Titanium	0.0510	0.0299
Zinc	0.497	0.420
Organic Parameters		
Acetone	30.2	7.97
Acetophenone	0.114	0.0562
Aniline	0.0333	0.0164
Bis(2-ethylhexyl) phthalate ...	0.215	0.101
2-Butanone ..	4.81	1.85
Butylbenzyl phthalate ...	0.188	0.0887
Carbazole	0.598	0.276
<i>o</i> -Cresol	1.92	0.561
<i>p</i> -Cresol	0.698	0.205
<i>n</i> -Decane	0.948	0.437
2,3-Dichloroaniline	0.0731	0.0361
Fluoranthene	0.0537	0.0268
<i>n</i> -Octadecane	0.589	0.302
Phenol	3.65	1.08
Pyridine	0.370	0.182
2,4,6-Trichlorophenol	0.155	0.106

¹ mg/L (ppm).² Within the range 6 to 9.**§ 437.43 Effluent limitations attainable by the application of the best conventional pollutant control technology (BCT).**

(a) Except as provided in 40 CFR 125.30 through 125.32 or 437.40(b), any existing facility subject to this subpart which combines treated or untreated wastes from subparts A, B, or C of this part may be subject to Multiple Wastestream Subcategory effluent limitations representing the application of BCT set forth in paragraphs (b), (c), (d), or (e) of this section if the discharger agrees to the following conditions in its NPDES permit:

(1) The discharger will meet the applicable Multiple Wastestream

Subcategory limitations set forth in paragraphs (b), (c), (d) or (e) of this section;

(2) The discharger will notify its NPDES permit writer at the time of renewal or modification of its permit, of its desire to be subject to the Multiple Waste Subcategory by submitting to the NPDES permit writer an initial certification statement as described in § 437.41(a);

(3) The discharger will submit to its NPDES permitting authority a periodic certification statement as described in § 437.41(b) once a year; and

(4) The discharger will maintain at the office of the facility and make available for inspection the on-site compliance paperwork as described in § 437.41(c).

(b) Combined waste receipts from subparts A, B and C of this part:

Limitations for BOD₅, O&G, pH, and TSS are the same as the corresponding limitation specified in § 437.42(b).

(c) Combined waste receipts from subparts A and B of this part: Limitations for O&G, pH, and TSS are the same as the corresponding limitation specified in § 437.42(c).

(d) Combined waste receipts from subparts A and C of this part:

Limitations for BOD₅, O&G, pH, and TSS are the same as the corresponding limitation specified in § 437.42(d).

(e) Combined waste receipts from subparts B and C of this part: Limitations for BOD₅, O&G, pH, and TSS are the same as the corresponding limitation specified in § 437.42(e).

§ 437.44 Effluent limitations attainable by the application of the best available technology economically achievable (BAT).

(a) Except as provided in 40 CFR 125.30 through 125.32 or 437.40(b), any existing facility subject to this subpart which combines treated or untreated wastes from subparts A, B, or C of this part may be subject to Multiple Wastestream Subcategory effluent limitations representing the application of BAT set forth in paragraphs (b), (c), (d), or (e) of this section if the discharger agrees to the following conditions in its NPDES permit:

(1) The discharger will meet the applicable Multiple Wastestream Subcategory limitations set forth in paragraphs (b), (c), (d) or (e) of this section;

(2) The discharger will notify its NPDES permit writer at the time of renewal or modification of its permit, of its desire to be subject to the Multiple Waste Subcategory by submitting to the NPDES permit writer an initial certification statement as described in § 437.41(a);

(3) The discharger will submit to its NPDES permitting authority a periodic

certification statement as described in § 437.41(b) once a year; and

(4) The discharger will maintain at the office of the facility and make available for inspection the on-site compliance paperwork as described in § 437.41(c).

(b) Combined waste receipts from subparts A, B and C of this part. (1) Limitations for the following parameters are the same as the corresponding limitation specified in § 437.42(b)(1):

Organic parameters	Metal parameters
Acetone	Antimony.
Acetophenone	Arsenic.
Aniline	Barium.
bis (2-ethylhexyl) phthalate.	Cadmium.
2-Butanone	Chromium.
Butylbenzyl phthalate	Cobalt.
Carbazole	Copper.
<i>o</i> -Cresol	Lead.
<i>p</i> -Cresol	Mercury.
<i>n</i> -Decane	Molybdenum.
2,3-dichloroaniline	Nickel.
Fluoranthene	Selenium.
<i>n</i> -Octadecane	Silver.
Phenol	Tin.
Pyridine	Titanium.
2,4,6-trichlorophenol	Vanadium.
	Zinc.

(2) The in-plant limitations that apply to metal-bearing wastewater containing cyanide are the same as the corresponding limitations specified in § 437.42(b)(2).

(c) Combined waste receipts from subparts A and B of this part. (1) Limitations for the following parameters are the same as the corresponding limitation specified in § 437.42(c)(1):

Organic parameters	Metal parameters
Bis (2-ethylhexyl) phthalate.	Antimony.
Butylbenzyl phthalate	Arsenic.
Carbazole	Barium.
<i>n</i> -Decane	Cadmium.
Fluoranthene	Chromium.
<i>n</i> -Octadecane	Cobalt.
	Copper.
	Lead.
	Mercury.
	Molybdenum.
	Nickel.
	Selenium.
	Silver.
	Tin.
	Titanium.
	Vanadium.
	Zinc.

(2) The in-plant limitations that apply to metal-bearing wastewater containing cyanide are the same as the corresponding limitations specified in § 437.42(c)(2).

(d) Combined waste receipts from subparts A and C of this part. (1) Limitations for the following parameters

are the same as the corresponding limitation specified in § 437.42(d)(1):

Organic parameters	Metal parameters
Acetone	Antimony.
Acetophenone	Arsenic.
Aniline	Cadmium.
2-Butanone	Chromium.
<i>o</i> -Cresol	Cobalt.
<i>p</i> -Cresol	Copper.
Phenol	Lead.
Pyridine	Mercury.
2,4,6-trichlorophenol	Molybdenum.
	Nickel.
	Selenium.
	Silver.
	Tin.
	Titanium.
	Vanadium.
	Zinc.

(2) The in-plant limitations that apply to metal-bearing wastewater containing cyanide are the same as the corresponding limitations specified in § 437.42(e)(2).

(e) Combined waste receipts from subparts B and C of this part. Limitations for the following parameters are the same as the corresponding limitation specified in § 437.42(e):

Organic parameters	Metal parameters
Acetone	Antimony.
Acetophenone	Arsenic.
Aniline	Barium.
Bis(2-ethylhexyl) phthalate.	Cadmium.
2-Butanone	Chromium.
Butylbenzyl phthalate	Cobalt.
Carbazole	Copper.
<i>o</i> -Cresol	Lead.
<i>p</i> -Cresol	Mercury.
<i>n</i> -Decane	Molybdenum.
2,3-dichloroaniline	Tin.
Fluoranthene	Titanium.
<i>n</i> -Octadecane	Zinc.
Phenol	
Pyridine	
2,4,6-trichlorophenol	

§ 437.45 New source performance standards (NSPS).

(a) Except as provided in § 437.40(b), any new source subject to this subpart which combines treated or untreated wastes from subparts A, B, or C of this part may be subject to Multiple Wastestream Subcategory effluent limitations representing the application of NSPS set forth in paragraphs (b), (c), (d), or (e) of this section if the discharger agrees to the following conditions in its NPDES permit:

(1) The discharger will meet the applicable Multiple Wastestream Subcategory limitations set forth in paragraphs (b), (c), (d) or (e) of this section;

(2) The discharger will notify its NPDES permit writer at the time of submitting its application for permit, of its desire to be subject to the Multiple Waste Subcategory by submitting to the NPDES permit writer an initial certification statement as described in § 437.41(a);

(3) The discharger will submit to its NPDES permitting authority a periodic certification statement as described in § 437.41(b) once a year; and

(4) The discharger will maintain at the office of the facility and make available for inspection the on-site compliance paperwork as described in § 437.41(c).

(b) Combined waste receipts from subparts A, B and C of this part. (1) As provided in § 437.45(a), any new source subject to this paragraph must achieve the following performance standards:

PERFORMANCE STANDARDS

Regulated parameter	Maximum daily ¹	Maximum monthly avg. ¹
Conventional Parameters		
BOD ₅	163	53.0
O&G	127	38.0
pH	(²)	(²)
TSS	29.6	11.3

Metal Parameters

Antimony	0.111	0.0312
Arsenic	0.0993	0.0199
Barium	0.427	0.281
Cadmium	0.0172	0.0102
Chromium	0.167	0.0522
Cobalt	0.182	0.0703
Copper	0.659	0.216
Lead	0.350	0.160
Mercury	0.000641	0.000246
Molybdenum	1.01	0.965
Nickel	0.794	0.309
Selenium	0.176	0.0698
Silver	0.0318	0.0122
Tin	0.0955	0.0367
Titanium	0.0159	0.00612
Vanadium	0.0628	0.0518
Zinc	0.657	0.252

Organic Parameters

Acetone	30.2	7.97
Acetophenone	0.114	0.0562
Aniline	0.0333	0.0164
Bis(2-ethylhexyl) phthalate ...	0.215	0.101
2-Butanone ...	4.81	1.85
Butylbenzyl phthalate ...	0.188	0.0887
Carbazole	0.598	0.276
<i>o</i> -Cresol	1.92	0.561
<i>p</i> -Cresol	0.698	0.205
<i>n</i> -Decane	0.948	0.437
2,3-Dichloroaniline	0.0731	0.0361
Fluoranthene	0.0537	0.0268
<i>n</i> -Octadecane	0.589	0.302

PERFORMANCE STANDARDS—Continued

Regulated parameter	Maximum daily ¹	Maximum monthly avg. ¹
Phenol	3.65	1.08
Pyridine	0.370	0.182
2,4,6-Trichlorophenol	0.155	0.106

¹ mg/L (ppm).

² Within the range 6 to 9.

(2) The following in-plant limitations apply to metal-bearing wastewater containing cyanide:

IN-PLANT LIMITATIONS

Regulated parameter	Maximum daily ¹	Maximum monthly avg. ¹
Cyanide	500	178

¹ mg/L (ppm).

(c) Combined waste receipts from subparts A and B of this part. (1) As provided in § 437.45(a), any new source subject to this paragraph must achieve the following standards:

PERFORMANCE STANDARDS

Regulated parameter	Maximum daily ¹	Maximum monthly avg. ¹
Conventional Parameters		
O&G	127	38.0
pH	(²)	(²)
TSS	29.6	11.3

Metal Parameters

Antimony	0.111	0.0312
Arsenic	0.0993	0.0199
Barium	0.427	0.281
Cadmium	0.0172	0.0102
Chromium	0.167	0.0522
Cobalt	0.182	0.0703
Copper	0.659	0.216
Lead	0.350	0.160
Mercury	0.000641	0.000246
Molybdenum	3.50	2.09
Nickel	0.794	0.309
Selenium	0.176	0.0698
Silver	0.0318	0.0122
Tin	0.0955	0.0367
Titanium	0.0159	0.00612
Vanadium	0.0628	0.0518
Zinc	0.657	0.252

Organic Parameters

Bis(2-ethylhexyl) phthalate ...	0.215	0.101
Butylbenzyl phthalate ...	0.188	0.0887
Carbazole	0.598	0.276
<i>n</i> -Decane	0.948	0.437
Fluoranthene	0.0537	0.0268

PERFORMANCE STANDARDS—
Continued

Regulated parameter	Maximum daily ¹	Maximum monthly avg. ¹
n-Octadecane	0.589	0.302

¹ mg/L (ppm).² Within the range 6 to 9.

(2) The following in-plant limitations apply to metal-bearing wastewater containing cyanide:

IN-PLANT LIMITATIONS

Regulated parameter	Maximum daily ¹	Maximum monthly avg. ¹
Cyanide	500	178

¹ 1 mg/L (ppm).

(d) Combined waste receipts from subparts A and C of this part. (1) As provided in § 437.45(a), any new source subject to this paragraph must achieve the following performance standards:

PERFORMANCE STANDARDS

Regulated parameter	Maximum daily ¹	Maximum monthly avg. ¹

Conventional Parameters

BOD ₅	163	53.0
O&G	205	50.2
pH	(²)	(²)
TSS	29.6	11.3

Metal Parameters

Antimony ...	0.111	0.0312
Arsenic	0.0993	0.0199
Cadmium ..	0.782	0.163
Chromium ..	0.167	0.0522
Cobalt	0.182	0.0703
Copper	0.659	0.216
Lead	1.32	0.283
Mercury	0.000641	0.000246
Molybdenum ...	1.01	0.965
Nickel	0.794	0.309
Selenium ...	0.176	0.0698
Silver	0.0318	0.0122
Tin	0.0955	0.0367
Titanium	0.0159	0.00612
Vanadium ..	0.0628	0.0518
Zinc	0.657	0.252

Organic Parameters

Acetone	30.2	7.97
Acetophenone	0.114	0.0562
Aniline	0.0333	0.0164
2-Butanone ..	4.81	1.85
<i>o</i> -Cresol ...	1.92	0.561
<i>p</i> -Cresol ...	0.698	0.205
2,3-Dichloroaniline ...	0.0731	0.0361
Phenol	3.65	1.08
Pyridine	0.370	0.182

PERFORMANCE STANDARDS—
Continued

Regulated parameter	Maximum daily ¹	Maximum monthly avg. ¹
2,4,6-Trichlorophenol ...	0.155	0.106

¹ mg/L (ppm).² Within the range 6 to 9.

(2) The following in-plant limitations apply to metal-bearing wastewater containing cyanide:

IN-PLANT LIMITATIONS

Regulated parameter	Maximum daily ¹	Maximum monthly avg. ¹
Cyanide	500	178

¹ mg/L (ppm).

(e) Combined waste receipts from subparts B and C of this part. As provided in § 437.45(a), any new source subject to this paragraph must achieve the following performance standards:

PERFORMANCE STANDARDS

Regulated parameter	Maximum daily ¹	Maximum monthly avg. ¹

Conventional Parameters

BOD ₅	163	53.0
O&G	127	38.0
pH	(²)	(²)
TSS	74.1	30.6

Metal Parameters

Antimony	0.237	0.141
Arsenic	2.95	1.33
Barium	0.427	0.281
Cadmium	0.0172	0.0102
Chromium	0.746	0.323
Cobalt	56.4	18.8
Copper	0.500	0.242
Lead	0.350	0.160
Mercury	0.0172	0.00647
Molybdenum ..	1.01	0.965
Tin	0.335	0.165
Titanium	0.0510	0.0299
Zinc	0.497	0.420

Organic Parameters

Acetone	30.2	7.97
Acetophenone ..	0.114	0.0562
Aniline	0.0333	0.0164
Bis(2-ethylhexyl) phthalate ...	0.215	0.101
2-Butanone ...	4.81	1.85
Butylbenzyl phthalate ...	0.188	0.0887
Carbazole	0.598	0.276
<i>o</i> -Cresol	1.92	0.561
<i>p</i> -Cresol	0.698	0.205
n-Decane	0.948	0.437

PERFORMANCE STANDARDS—
Continued

Regulated parameter	Maximum daily ¹	Maximum monthly avg. ¹
2,3-Dichloroaniline	0.0731	0.0361
Fluoranthene ..	0.0537	0.0268
n-Octadecane ..	0.589	0.302
Phenol	3.65	1.08
Pyridine	0.370	0.182
2,4,6-Trichlorophenol	0.155	0.106

¹ mg/L (ppm).² Within the range 6 to 9.

§ 437.46 Pretreatment standards for existing sources (PSES)

(a) Except as provided in 40 CFR 403.7, 403.13 or 437.40(b), any new source subject to this subpart which combines treated or untreated wastes from subparts A, B, or C of this part may be subject to Multiple Wastestream Subcategory pretreatment standards representing the application of PSES set forth in paragraphs (b), (c), (d), or (e) of this section if the discharger agrees to the following conditions in its permit:

(1) The discharger will meet the applicable Multiple Wastestream Subcategory standards set forth in paragraphs (b), (c), (d) or (e) of this section;

(2) The discharger will notify its local control authority of its desire to be subject to the Multiple Waste Subcategory by submitting to the local control authority an initial certification statement as described in § 437.41(a);

(3) The discharger will submit to its local control authority a periodic certification statement as described in § 437.41(b) once a year; and

(4) The discharger will maintain at the office of the facility and make available for inspection the on-site compliance paperwork as described in § 437.41(c).

(b) Combined waste receipts from subparts A, B and C of this part. (1) As provided in § 437.46(a), and no later than [Insert date—three years after publication], any existing source subject to this paragraph must achieve the following pretreatment standards:

PRETREATMENT STANDARDS (PSES)

Regulated parameter	Maximum daily ¹	Maximum monthly avg. ¹

Metal Parameters

Antimony	0.237	0.141
Arsenic	0.162	0.104
Barium	0.427	0.281
Cadmium	0.474	0.0962

PRETREATMENT STANDARDS (PSES)—
Continued

Regulated parameter	Maximum daily ¹	Maximum monthly avg. ¹
Chromium	0.947	0.487
Cobalt	0.192	0.124
Copper	0.405	0.301
Lead	0.222	0.172
Mercury	0.00234	0.000739
Molybdenum	1.01	0.965
Nickel	3.95	1.45
Selenium	1.64	0.408
Silver	0.120	0.0351
Tin	0.409	0.120
Titanium	0.0947	0.0618
Vanadium	0.218	0.0662
Zinc	2.87	0.641

Organic Parameters

Bis(2-ethylhexyl) phthalate ...	0.267	0.158
Carbazole	0.392	0.233
<i>o</i> -Cresol	1.92	0.561
<i>p</i> -Cresol	0.698	0.205
<i>n</i> -Decane	5.79	3.31
2,3-Dichloroaniline	0.0731	0.0361
Fluoranthene	0.787	0.393
<i>n</i> -Octadecane	1.22	0.925
2,4,6-Trichlorophenol	0.155	0.106

¹ mg/L (ppm).

(2) The following in-plant limitations apply to metal-bearing wastewater containing cyanide:

IN-PLANT LIMITATIONS

Regulated parameter	Maximum daily ¹	Maximum monthly avg. ¹
Cyanide	500	178

¹ mg/L (ppm).

(c) Combined waste receipts from subparts A and B of this part. (1) As provided in § 437.46(a), and no later than December 22, 2003, any existing source subject to this paragraph must achieve the following pretreatment standards:

PRETREATMENT STANDARDS (PSES)

Regulated parameter	Maximum daily ¹	Maximum monthly avg. ¹
Metal Parameters		
Antimony	0.237	0.141
Arsenic	0.162	0.104
Barium	0.427	0.281
Cadmium	0.474	0.0962
Chromium	0.947	0.487
Cobalt	0.192	0.124
Copper	0.405	0.301

PRETREATMENT STANDARDS (PSES)—
Continued

Regulated parameter	Maximum daily ¹	Maximum monthly avg. ¹
Lead	0.222	0.172
Mercury	0.00234	0.000739
Molybdenum	3.50	2.09
Nickel	3.95	1.45
Selenium	1.64	0.408
Silver	0.120	0.0351
Tin	0.409	0.120
Titanium	0.0947	0.0618
Vanadium	0.218	0.0662
Zinc	2.87	0.641

Organic Parameters

Bis(2-ethylhexyl) phthalate ...	0.267	0.158
Carbazole	0.392	0.233
<i>n</i> -Decane	5.79	3.31
Fluoranthene	0.787	0.393
<i>n</i> -Octadecane	1.22	0.925

¹ mg/L (ppm).

(2) The following in-plant limitations apply to metal-bearing wastewater containing cyanide:

IN-PLANT LIMITATIONS

Regulated parameter	Maximum daily ¹	Maximum monthly avg. ¹
Cyanide	500	178

¹ mg/L (ppm).

(d) Combined waste receipts from subparts A and C of this part. (1) As provided in § 437.46(a), and no later than December 22, 2003, any existing source subject to this paragraph must achieve the following pretreatment standards:

PRETREATMENT STANDARDS (PSES)

Regulated parameter	Maximum daily ¹	Maximum monthly avg. ¹

Metal Parameters

Antimony	0.249	0.206
Arsenic	0.162	0.104
Cadmium	0.474	0.0962
Chromium	15.5	3.07
Cobalt	0.192	0.124
Copper	4.14	1.06
Lead	1.32	0.283
Mercury	0.00234	0.000739
Molybdenum	1.01	0.965
Nickel	3.95	1.45
Selenium	1.64	0.408
Silver	0.120	0.0351
Tin	0.409	0.120
Titanium	0.0947	0.0618
Vanadium	0.218	0.0662
Zinc	2.87	0.641

PRETREATMENT STANDARDS (PSES)—
Continued

Regulated parameter	Maximum daily ¹	Maximum monthly avg. ¹
Organic Parameters		
<i>o</i> -Cresol	1.92	0.561
<i>p</i> -Cresol	0.698	0.205
2,3-Dichloroaniline	0.0731	0.0361
2,4,6-Trichlorophenol	0.155	0.106

¹ mg/L (ppm).

(2) The following in-plant limitations apply to metal-bearing wastewater containing cyanide:

IN-PLANT LIMITATIONS

Regulated parameter	Maximum daily ¹	Maximum monthly avg. ¹
Cyanide	500	178

¹ mg/L (ppm).

(e) Combined waste receipts from subparts B and C of this part. As provided in § 437.46(a), and no later than December 22, 2003, any existing source subject to this paragraph must achieve the following pretreatment standards:

PRETREATMENT STANDARDS (PSES)

Regulated parameter	Maximum daily ¹	Maximum monthly avg. ¹

Metal Parameters

Antimony	0.237	0.141
Barium	0.427	0.281
Chromium	0.947	0.487
Cobalt	56.4	18.8
Copper	0.405	0.301
Lead	0.222	0.172
Molybdenum	1.01	0.965
Tin	0.249	0.146
Zinc	6.95	4.46

Organic Parameters

Bis (2-ethylhexyl) phthalate ...	0.267	0.158
Carbazole	0.392	0.233
<i>o</i> -Cresol	1.92	0.561
<i>p</i> -Cresol	0.698	0.205
<i>n</i> -Decane	5.79	3.31
2,3-Dichloroaniline	0.0731	0.0361
Fluoranthene	0.787	0.393
<i>n</i> -Octadecane	1.22	0.925
2,4,6-Trichlorophenol	0.155	0.106

¹ mg/L (ppm).

§ 437.47 Pretreatment standards for new sources (PSNS).

(a) Except as provided in 40 CFR 403.7 or 437.40(b), any new source subject to this subpart which combines treated or untreated wastes from subparts A, B, or C of this part may be subject to Multiple Wastestream Subcategory pretreatment standards representing the application of PSNS set forth in paragraphs (b), (c), (d), or (e) of this section if the discharger agrees to the following conditions in its permit:

(1) The discharger will meet the applicable Multiple Wastestream Subcategory standards set forth in paragraphs (b), (c), (d) or (e) of this section;

(2) The discharger will notify its local control authority at the time of submitting its application for an individual control mechanism or pretreatment agreement of its desire to be subject to Multiple Waste Subcategory by submitting to the local control authority an initial certification statement as described in § 437.41(a);

(3) The discharger will submit to its local control authority a periodic certification statements as described in § 437.41(b) once a year; and

(4) The discharger will maintain at the office of the facility and make available for inspection the on-site compliance paperwork as described in § 437.41(c).

(b) Combined waste receipts from subparts A, B and C of this part. (1) As provided in § 437.47(a), any new source subject to this paragraph must achieve the following pretreatment standards:

PRETREATMENT STANDARDS (PSNS)

Regulated parameter	Maximum daily ¹	Maximum monthly avg. ¹

Metal Parameters

Antimony	0.237	0.141
Arsenic	0.162	0.104
Barium	0.427	0.281
Cadmium	0.474	0.0962
Chromium	0.746	0.323
Cobalt	0.192	0.124
Copper	0.500	0.242
Lead	0.350	0.160
Mercury	0.00234	0.000739
Molybdenum	1.01	0.965
Nickel	3.95	1.45
Selenium	1.64	0.408
Silver	0.120	0.0351
Tin	0.409	0.120
Titanium	0.0947	0.0618
Vanadium	0.218	0.0662
Zinc	2.87	0.641

Organic Parameters

Bis(2-ethylhexyl) phthalate ...	0.215	0.101
Carbazole	0.598	0.276

<i>o</i> -Cresol	1.92	0.561
<i>p</i> -Cresol	0.698	0.205
<i>n</i> -Decane	0.948	0.437
2,3-Dichloroaniline	0.0731	0.0361
Fluoranthene	0.0537	0.0268
<i>n</i> -Octadecane	0.589	0.302
2,4,6-Trichlorophenol	0.155	0.106

¹ mg/L (ppm).

(2) The following in-plant limitations apply to metal-bearing wastewater containing cyanide:

IN-PLANT LIMITATIONS

Regulated parameter	Maximum daily ¹	Maximum monthly avg. ¹
Cyanide	500	178

¹ mg/L (ppm).

(c) Combined waste receipts from subparts A and B of this part. (1) As provided in § 437.47(a), any new source subject to this paragraph must achieve the following pretreatment standards:

PRETREATMENT STANDARDS (PSNS)

Regulated parameter	Maximum daily ¹	Maximum monthly avg. ¹

Metal Parameters

Antimony	0.237	0.141
Arsenic	0.162	0.104
Barium	0.427	0.281
Cadmium	0.474	0.0962
Chromium	0.746	0.323
Cobalt	0.192	0.124
Copper	0.500	0.242
Lead	0.350	0.160
Mercury	0.00234	0.000739
Molybdenum	3.50	2.09
Nickel	3.95	1.45
Selenium	1.64	0.408
Silver	0.120	0.0351
Tin	0.409	0.120
Titanium	0.0947	0.0618
Vanadium	0.218	0.0662
Zinc	2.87	0.641

Organic Parameters

Bis(2-ethylhexyl) phthalate ...	0.215	0.101
Carbazole	0.598	0.276
<i>n</i> -Decane	0.948	0.437
Fluoranthene	0.0537	0.0268
<i>n</i> -Octadecane	0.589	0.302

¹ mg/L (ppm).

(2) The following in-plant limitations apply to metal-bearing wastewater containing cyanide:

IN-PLANT LIMITATIONS

Regulated parameter	Maximum daily ¹	Maximum monthly avg. ¹
Cyanide	500	178

¹ mg/L (ppm).

(d) Combined waste receipts from subparts A and C of this part. (1) As provided in § 437.47(a), any new source subject to this paragraph must achieve the following pretreatment standards:

PRETREATMENT STANDARDS (PSNS)

Regulated parameter	Maximum daily ¹	Maximum monthly avg. ¹

Metal Parameters

Antimony	0.249	0.206
Arsenic	0.162	0.104
Cadmium	0.474	0.0962
Chromium	15.5	3.07
Cobalt	0.192	0.124
Copper	4.14	1.06
Lead	1.32	0.283
Mercury	0.00234	0.000739
Molybdenum	1.01	0.965
Nickel	3.95	1.45
Selenium	1.64	0.408
Silver	0.120	0.0351
Tin	0.409	0.120
Titanium	0.0947	0.0618
Vanadium	0.218	0.0662
Zinc	2.87	0.641

Organic Parameters

<i>o</i> -Cresol	1.92	0.561
<i>p</i> -Cresol	0.698	0.205
2,3-Dichloroaniline	0.0731	0.0361
2,4,6-Trichlorophenol	0.155	0.106

¹ mg/L (ppm).

(2) The following in-plant limitations apply to metal-bearing wastewater containing cyanide:

IN-PLANT LIMITATIONS

Regulated parameter	Maximum daily ¹	Maximum monthly avg. ¹
Cyanide	500	178

¹ mg/L (ppm).

(e) Combined waste receipts from subparts B and C of this part. As provided in § 437.47(a), any new source subject to this paragraph must achieve the following pretreatment standards:

PRETREATMENT STANDARDS (PSNS)

Regulated parameter	Maximum daily ¹	Maximum monthly avg. ¹
Metal Parameters		
Antimony	0.237	0.141
Barium	0.427	0.281
Chromium	0.746	0.323
Cobalt	56.4	18.8
Copper	0.500	0.242
Lead	0.350	0.160
Molybdenum	1.01	0.965
Tin	0.335	0.165
Zinc	8.26	4.50

PRETREATMENT STANDARDS (PSNS)—
Continued

Regulated parameter	Maximum daily ¹	Maximum monthly avg. ¹
Organic Parameters		
Bis(2-ethylhexyl) phthalate ...	0.215	0.101
Carbazole	0.598	0.276
<i>o</i> -Cresol	1.92	0.561
<i>p</i> -Cresol	0.698	0.205
<i>n</i> -Decane	0.948	0.437
2,3-Dichloroaniline	0.0731	0.0361

PRETREATMENT STANDARDS (PSNS)—
Continued

Regulated parameter	Maximum daily ¹	Maximum monthly avg. ¹
Fluoranthene	0.0537	0.0268
<i>n</i> -Octadecane	0.589	0.302
2,4,6-Trichlorophenol	0.155	0.106

¹ mg/L (ppm).

[FR Doc. 00-24565 Filed 12-21-00; 8:45 am]

BILLING CODE 6560-50-U



Federal Register

**Friday,
December 22, 2000**

Part X

Department of Transportation

Federal Aviation Administration

14 CFR Part 91

**Emergency Locator Transmitters; Final
Rule**

DEPARTMENT OF TRANSPORTATION**Federal Aviation Administration****14 CFR Part 91**

[Docket No. FAA-2000-8552 Amendment No. 91-265]

RIN No. 2120-AH16

Emergency Locator Transmitters**AGENCY:** Federal Aviation Administration (FAA), DOT,**ACTION:** Final rule.

SUMMARY: This final rule is being issued to comply with Congressionally-mandated changes to FAA requirements for emergency locator transmitters. This legislation removed the current exception of turbojet-powered aircraft from the emergency locator transmitter requirement, and added a new exception for aircraft with a maximum payload capacity of more than 18,000 pounds when used in air transportation. The intended effect of this rule change is to facilitate search and rescue efforts by increasing the likelihood of locating turbojet-powered aircraft after accidents.

DATES: This regulation is effective December 22, 2000. However, compliance with the new ELT requirements in § 91.207 is delayed until January 1, 2004.

FOR FURTHER INFORMATION CONTACT: Dean Chamberlain, AFS-820, Flight Standards Service, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591. Telephone: (202) 267-7956.

SUPPLEMENTARY INFORMATION:**Availability of Final Rules**

You can get an electronic copy using the Internet by taking the following steps:

(1) Go to the search function of the Department of Transportation's electronic Docket Management System (DMS) Web page (<http://dms.dot.gov/search>).

(2) On the search page type in the last four digits of the Docket number shown at the beginning of this amendment. Click on "search."

(3) On the next page, which contains the Docket summary information for the Docket you selected, click on the final rule.

You can also get an electronic copy using the Internet through FAA's web page at <http://www.faa.gov/avr/armhome.htm> or the **Federal Register's** web page at http://www.access.gpo.gov/su_docs/aces/aces140.html.

You can also get a copy by submitting a request to the Federal Aviation

Administration, Office of Rulemaking, ARM-1, 800 Independence Avenue SW., Washington, DC 20591, or by calling (202) 267-9680. Make sure to identify the amendment number or docket number of this final rule.

Small Business Regulatory Enforcement Fairness Act

The Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996, requires the FAA to comply with small entity requests for information or advice about compliance with statutes and regulations within its jurisdiction. Therefore, any small entity that has a question regarding this document may contact their local FAA official, or the person listed under **FOR FURTHER INFORMATION CONTACT**. You can find out more about SBREFA on the Internet at our site <http://www.faa.gov/avr/arm/sbreffa.htm>. For more information on SBREFA, e-mail us at 9-AWA-SBREFA@faa.gov.

Background

In 1971, responding to a Congressional mandate for rulemaking (Pub. L. 91-96), the FAA adopted amendments to parts 25, 29, 91, 121, and 135 of title 14 of the Code of Federal Regulations (CFR) to require the installation and use of Emergency Locator Transmitters (ELTs), automatic or survival, as required, that met the requirements of Technical Standard Order (TSO)-C91.

The amendments required that certain U.S.-registered civil airplanes be equipped with automatic ELTs. An automatic ELT is a crash-activated electronic signaling device used to facilitate search and rescue efforts in locating downed aircraft. The ELTs crash sensor is commonly called a G-switch (an actuation device that operates on acceleration forces measured in G's; one G denotes the acceleration of the earth's gravity). In most installations, the ELT is attached to the aircraft structure as far aft as practicable in the fuselage in such a manner that damage to the device will be minimized in the event of impact.

Certain aircraft, such as turbojet-powered aircraft and aircraft engaged in scheduled air carrier operations, were excepted from this requirement because they were considered to be more readily located after an accident and because they operate within the air traffic control system and their operators have filed instrument flight plans.

The rule was applicable to those airplanes that were considered to be most difficult to locate after an accident, such as general aviation type airplanes. An ELT was considered particularly

helpful in locating an airplane that is operated by a pilot who does not file a flight plan or operate within the air traffic control system on an instrument flight plan.

Since the adoption of those amendments requiring installation of ELTs, there had been unsatisfactory field experience with the automatic ELTs manufactured under TSO-C91, specifically, a significant failure-to-activate rate, and false alarms. (NTSB Safety Recommendations A-78-5 through A-78-12, issued in 1978 addressed some of these ELT problems.) As a result, the FAA requested RTCA, Inc. (formerly the Radio Technical Commission for Aeronautics) to develop a revised technical standard that would address these problems. The RTCA project produced a minimum operational performance standard that was referenced in TSO-C91a, issued in April 1985. Installation of ELTs that met this improved standard, however, was voluntary.

Following the issuance of the new TSO, in 1987 the NTSB issued safety recommendation A-87-104, that recommended that existing ELTs be replaced with ELTs that comply with TSO-C91a by 1989. That safety recommendation also urged that ELTs be subject to specific maintenance requirements.

In October 1990, the National Aeronautics and Space Administration (NASA) and the FAA completed a report entitled, "Current Emergency Locator Transmitter (ELT) Deficiencies and Potential Improvements Utilizing TSO-C91a ELTs." This report consolidated and analyzed most of the known data on ELT problems and quantified the safety problem. General aviation accident and fatality data from the NTSB formed the cornerstone of the report. The most significant conclusions derived from the report showed: 23 to 58 lives were lost per year due to rescue operations made more difficult because of ELT failures. Fifteen percent of ELT failures were attributed to poor or no ELT maintenance; and, after excluding lives lost attributed to maintenance-related ELT failures, 64 percent or 13 to 31 of the lives lost each year could have been saved with a complete transition to TSO-C91a ELTs.

Based on the known unsatisfactory performance of the TSO-C91 ELTs during the 1970's and 1980's, the FAA issued Notice No. 90-11 (55 FR 12316 April 2, 1990). This notice proposed that ELTs approved under TSO-C91a (or later issued TSOs for ELTs) be required for all future installations. The NPRM further proposed that the manufacture of the TSO-C91 ELTs be

simultaneously terminated with issuance of a final rule. The term "future installations" applied to newly manufactured airplanes, and to the replacement of existing ELTs as they became unusable or unserviceable. Additionally, the FAA solicited comments on the need for a fleet-wide ELT replacement program and specific maintenance requirements.

On June 21, 1994, the FAA issued a final rule requiring that newly installed ELTs on U.S.-registered aircraft be of an improved design that met the requirements of TSO-C91a or later TSOs issued for ELTs (54 FR 32057). The final rule also addressed certain safety recommendations made by the NTSB and the search and rescue (SAR) community. The FAA also adopted improved standards for survival ELTs. The rule was expected to have a dramatic effect on reducing activation failures and would increase the likelihood of locating airplanes after accidents. In addition, publication of the final rule coincided with notice of the FAA's withdrawal of manufacturing authority for ELTs produced under TSO-C91.

This final rule was amended with a correction, published on July 6, 1994, which stated that ELTs meeting the requirements of TSO-C91 could no longer be used for new installations after June 21, 1995. (54 FR 34578)

Recent Congressional Action

As stated earlier, turbojet-powered aircraft had been excepted from the part 91 ELT requirement because such aircraft are normally flown under Instrument Flight Rules and are normally in radio contact throughout their flight with air traffic control (ATC); as a result, their location is generally known by ATC throughout their flight.

However, Congress took action to remove this exception and require ELT equipment on turbojet-powered aircraft as a result of a missing "business jet" type of turbojet-powered aircraft that crashed on approach to Lebanon Municipal Airport in New Hampshire in 1996. This aircraft, a Learjet 35A, which had been operating under instrument meteorological conditions but did not have an ELT, was not found until 1999 (by a forester) approximately 17 nautical miles from the airport.

On April 5, 2000, Congress passed H.R. 1000, the Wendell H. Ford Aviation Investment and Reform Act for the 21st Century (AIR-21) (Pub. L. 106-181). Section 501 of this legislation set forth the following requirements: (1) It removed the current exception of turbojet-powered aircraft from the ELT requirement; (2) It limited the scope of

the rule change by creating a new exception category for aircraft with a maximum payload capacity of more than 18,000 pounds when used in air transportation; (3) It required that the affected turbojet-powered aircraft be equipped with ELTs that transmit on the 121.5/243 megahertz frequency or the 406 megahertz frequency or with other equipment approved by the Secretary; and (4) It specified a compliance date for the new changes, of January 1, 2002, unless the Administrator grants operators up to 2 years after January 1, 2002, to equip affected turbojet-powered aircraft with ELT equipment.

The removal of the exception for turbojet-powered aircraft in § 91.207(f)(1) affects not only private business jets, such as the one lost after the 1996 accident in New Hampshire, but also any turbojet-powered aircraft that does not qualify for one of the other exceptions. Since current § 91.207(f)(2) excepts scheduled operations by air carriers, the remaining operations that are affected are unscheduled operations conducted under parts 119, 121, and 135 with turbojet-powered aircraft, as well as turbojet-powered aircraft operated under part 91 or part 125. However, such operations conducted in large turbojet powered aircraft in air transportation are normally flown under IFR and are in radio contact with a flight-following or dispatch system or with ATC throughout the flight. For this reason Congress limited the scope of its action by adding an exception for aircraft with a maximum payload capacity of more than 18,000 pounds when used in air transportation. "Air transportation" is the carriage of persons or property as a common carrier for compensation or hire, *i.e.*, operations conducted by air carriers. For purposes of this regulation, the definition of "maximum payload capacity" in § 119.3 will be used.

The provision in AIR-21 allowing the use of ELTs operating on either the 121.5/243 megahertz frequency or the 406 megahertz frequency is consistent with the types of ELTs that are currently approved by the FAA for installation on aircraft. However, the FAA strongly urges operators who are installing an ELT for the first time, in order to comply with this new requirement, to install an ELT that operates on the 406 megahertz frequency, even though this is the more costly option. There are two reasons to do this:

1. In the final rule published on June 21, 1994 (59 FR 32050), the FAA recommended the use of the 406 MHz ELT, stating that the higher frequency ELT provides an enhancement and more life-saving benefits, especially for

operations conducted over water and in remote areas. Commenters to the NPRM on which the 1994 final rule was based argued that the 406 MHz ELT has significant technical improvements over the 121.5/243 MHz ELT and that it is compatible with the Search and Rescue Satellite-Aided Tracking System (COSPAS-SARSAT). Commenters further argued that COSPAS/SARSAT has proven to be an effective tool in detecting and locating both maritime and aeronautical distress incidents, that the satellite system had been credited with saving more than 1,700 lives, and that, in many of these cases, the satellite system was the only means of detecting the distress signal.

In addition, not only does the 406 MHz ELT transmit a stronger signal that can be detected almost instantaneously by geostationary satellites, the 406 MHz ELT signal can be coded with the owner's identification or aircraft coding. This coding permits Search and Rescue Coordination Centers to contact the registered owner or operator and verify if the aircraft is flying or safely tied down or in a hangar. This permits a rapid SAR response or allows the owner or operator to deactivate a 406 MHz ELT that is inadvertently transmitting. This valuable feature permits a very rapid SAR response in the event of a real accident, and it saves valuable SAR resources in the event of an inadvertent 406 MHz ELT activation. In addition to its many other benefits, newer 406 MHz ELTs are being designed with the capability to transmit an aircraft's last known position. This capability further reduces the 406 MHz's already small search area.

The current 121.5 MHz ELT is lower-powered, does not transmit any owner or aircraft coding, and its signal does not produce as small a search area as a 406 MHz ELT. In addition, United States SAR organizations do not respond as quickly to a 121.5 MHz ELT alert as they do to a 406 MHz alert. The reason is the large number of 121.5 MHz ELT false alerts. Because of the large number of 121.5 MHz ELT false alerts, the common practice is to wait for either a confirmation of an alert by additional satellite passes or through confirmation of an overdue aircraft or similar notification.

2. In the year 2009, the international COSPAS-SARSAT satellite system will no longer provide satellite-based monitoring of the 121.5/243 MHz frequency. After the date of the satellite termination, in 2009, 121.5 MHz signals transmitted from ELTs operating on the lower frequency will only be detected by ground-based receivers such as local

airport facilities or air traffic control facilities or by overflying aircraft.

Because of the many safety benefits of installing ELTss operating on the 406 MHz frequency, and the pending termination of the satellite-based monitoring of the 121.5/243 MHz frequency, the Administrator has decided to extend the compliance period for this new ELT requirement to January 1, 2004, as allowed under AIR-21, to permit those owners or operators who want to install the more effective 406 MHz ELT time to do so. This extra time will ensure that manufacturers can provide an adequate supply of the higher frequency 406 MHz ELTs, which in turn may lower the cost for operators required to purchase and install an ELT under this final rule.

Waiver Under the Administrative Procedure Act

Under the Administrative Procedure Act (APA) (5 U.S.C. 553(b)), an agency may waive the normal notice and comment requirements if it finds, for good cause, that they are impracticable, unnecessary, or contrary to the public interest. Since AIR-21 mandated the changes to the ELT requirements and directed the FAA to issue a final rule by January 1, 2001, the FAA has determined that it has good cause to waive prior notice and comment and to make this final rule effective in less than 30 days after publication.

Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (44 U.S.C. 3507 (d)) requires that the FAA consider the impact of paperwork and other information collection burdens imposed on the public. The FAA has determined that there are no new information collection requirements associated with this rule.

Regulatory Evaluation Summary

Changes to Federal regulations must undergo several economic analyses. First, Executive Order 12866 directs that each Federal agency must propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs. Second, the Regulatory Flexibility Act of 1980 requires agencies to analyze the economic effect of regulatory changes on small entities. Third, OMB directs agencies to assess the effect of regulatory changes on international trade. Fourth, the Unfunded Mandates Reform Act of 1995 requires agencies to prepare a written assessment of the costs, benefits and other effects of proposed or final rules that include a Federal mandate likely to result in the expenditure by State, local or tribal

governments, in the aggregate, or by the private sector, of \$100 million or more annually (adjusted for inflation).

Since this rule carries forth the direction and scope of the law, the cost and the benefit are attributed to the law and not to this implementing rule. Thus, in conducting these analyses, the FAA has determined that this rule is not "a significant regulatory action" under section 3(f) of Executive order 12866 and, therefore, is not subject to review by the Office of Management and Budget. The rule is not considered significant under the regulatory policies and procedures of the Department of Transportation (44 FR 11034, February 26, 1979). For the reason given above, this rule will not have a significant impact on a substantial number of small entities, will not constitute a barrier to international trade, and does not impose an unfunded mandate on state, local, or tribal governments, or on the private sector.

The cost and the benefit of this rule are attributed to Section 501 of this legislation which set forth the following requirements: (1) It removed the current exemption of turbojet-powered aircraft from the ELT requirement; and (2) It required that these turbo-powered aircraft be equipped with ELT's that transmit on the 121.5/243 megahertz frequency or the 406 megahertz frequency or with other equipment approved by the Secretary. This rule does not exceed the direction and scope of the law as just described.

Final Regulatory Flexibility Determination

The Regulatory Flexibility Act of 1980 (RFA) establishes "as a principle of regulatory issuance that agencies must endeavor, consistent with the objective of the rule and of applicable statutes, to fit regulatory and informational requirements to the scale of the business, organizations, and governmental jurisdictions subject to regulation." To achieve that principle, the Act requires agencies to solicit and consider flexible regulatory proposals and to explain the rationale for their actions. The Act covers a wide-range of small entities, including small businesses, not-for-profit organizations and small governmental jurisdictions.

Agencies must perform a review to determine whether a proposed or final rule will have a significant economic impact on a substantial number of small entities. If the determination is that it will, the agency must prepare a regulatory flexibility analysis as described in the Act.

However, if an agency determines that a final rule is not expected to have a

significant economic impact on a substantial number of small entities, section 605(b) of the 1980 act provides that the head of the agency may so certify and an regulatory flexibility analysis is not required. The certification must include a statement providing the factual basis for this determination, and the reasoning should be clear.

This rule carries forth the direction and scope of section 501 of the Wendall H. Ford Aviation Investment and Reform Act. The cost and the benefit are attributed to the law and not to this implementing rule. Consequently, the FAA certifies that this rule will not have a significant economic impact on a substantial number of small entities.

International Trade Impact Statement

The Trade Agreement Act of 1979 prohibits Federal agencies from engaging in any standards or related activities that create unnecessary obstacles to the foreign commerce of the United States. Legitimate domestic objectives, such as safety, are not considered unnecessary obstacles. The statute also requires consideration of international standards and where appropriate, that they be the basis for U.S. standards. In addition, consistent with the Administration's belief in the general superiority and desirability of free trade, it is the policy of the Administration to remove or diminish to the extent feasible, barriers to international trade, including both barriers affecting the export of American goods and services to foreign countries and barriers affecting the import of foreign goods and services into the United States.

In accordance with the above statute and policy, the FAA has assessed the potential effect of this final rule and has determined that it will impose the same costs on domestic and international entities and thus has a neutral trade impact.

Federalism Implications

The regulations 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 13132, the FAA has determined that this rule will not have sufficient federalism implications to warrant the preparation of a federalism assessment.

Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (the Act), codified

as 2 U.S.C. 1501–1571, requires each Federal agency, to the extent permitted by law, to prepare a written assessment of the effects of any Federal mandate in a proposed or final agency rule that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million or more (adjusted annually for inflation) in any one year. Section 204(a) of the Act, 2 U.S.C. 1534(a), requires the Federal agency to develop an effective process to permit timely input by elected officers (or their designees) of State, local, and tribal governments on a proposed “significant intergovernmental mandate.” A “significant intergovernmental mandate” under the Act is any provision in a Federal agency regulation that would impose an enforceable duty upon State, local, and tribal governments, in the aggregate, of \$100 million (adjusted annually for inflation) in any one year. Section 203 of the Act, 2 U.S.C. 1533, which supplements section 204(a), provides that before establishing any regulatory requirements that might significantly or uniquely affect small governments, the agency must have developed a plan that, among other things, provides for notice to potentially affected small governments, if any, and for a meaningful and timely opportunity to provide input in the development of regulatory proposals.

The FAA has determined that this rule does not contain a Federal intergovernmental or private sector mandate that exceeds \$100 million in any one year.

Environmental Analysis

FAA Order 1050.1D defines FAA actions that may be categorically excluded from preparation of a National Environmental Policy Act (NEPA) environmental assessment or environmental impact statement. In accordance with FAA Order 1050.1D, appendix 4, paragraph 4(j), regulations, standards, and exceptions (excluding those that, if implemented, may cause a significant impact on the human environment) qualify for a categorical exclusion. The FAA has determined that this rule qualifies for a categorical exclusion because no significant impacts to the environment are expected to result from its implementation.

List of Subjects in 14 CFR Part 91

Air traffic control, Aircraft, Aviation safety, Safety.

The Amendment

For the reasons set forth above, the Federal Aviation Administration amends 14 CFR part 91 as follows:

PART 91—GENERAL OPERATING AND FLIGHT RULES

1. The authority citation for part 91 continues to read as follows:

Authority 49 U.S.C. 106(g), 40103, 40113, 40120, 44101, 44111, 44701, 44709, 44711, 44712, 44715, 44716, 44717, 44722, 46306, 46315, 46316, 46502, 46504, 46506–46507, 47122, 47508, 47528–47531.

2. Amend § 91.207 as follows:

- a. By revising paragraphs (f) introductory text, and (f)(1);
- b. Removing “; and” from the end of paragraph (f)(9) and adding a period;
- c. Removing at the end of paragraph (f)(10)(ii) and adding “; and”; and
- d. Adding paragraph (f)(11). The revisions and addition read as follows:

§ 91.207 Emergency locator transmitters.

* * * * *

(f) Paragraph (a) of this section does not apply to—

(1) Before January 1, 2004, turbo-powered aircraft;

* * * * *

(11) On and after January 1, 2004, aircraft with a maximum payload capacity of more than 18,000 pounds when used in air transportation.

Issued in Washington, DC on December 15, 2000.

Jane F. Garvey,
Administrator.

[FR Doc. 00–32511 Filed 12–21–00; 8:45 am]

BILLING CODE 4910–13–M

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Consumer Product Safety Act: Multi-purpose lighters; child resistance standard; published 12-22-99

GENERAL ACCOUNTING OFFICE

Federal Claims Collection Standards; CFR chapter removed; published 11-22-00

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Early release consideration; drug abuse treatment and intensive confinement center programs; published 12-22-00

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Cotton research and promotion order:

Levy assessments; automatic exemptions adjustment; comments due by 12-27-00; published 11-27-00

AGRICULTURE DEPARTMENT**Rural Business-Cooperative Service**

Guaranteed loanmaking:

Domestic lamb industry adjustment assistance program set aside; comments due by 12-29-00; published 10-30-00

AGRICULTURE DEPARTMENT**Rural Utilities Service**

Guaranteed loanmaking:

Domestic lamb industry adjustment assistance program set aside; comments due by 12-29-00; published 10-30-00

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LIST OF PUBLIC LAWS

This is a continuing list of public bills from the current session of Congress which have become Federal laws. It may be used in conjunction with "PLUS" (Public Laws Update Service) on 202-523-6641. This list is also available online at <http://www.nara.gov/fedreg>.

The text of laws is not published in the **Federal Register** but may be ordered in "slip law" (individual pamphlet) form from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402 (phone, 202-512-1808). The text will also be made available on the Internet from GPO Access at <http://www.access.gpo.gov/nara/index.html>. Some laws may not yet be available.

H.R. 3048/P.L. 106-544

Presidential Threat Protection Act of 2000 (Dec. 19, 2000; 114 Stat. 2715)

H.R. 4281/P.L. 106-545

ICCVAM Authorization Act of 2000 (Dec. 19, 2000; 114 Stat. 2721)

H.R. 4640/P.L. 106-546

DNA Analysis Backlog Elimination Act of 2000 (Dec. 19, 2000; 114 Stat. 2726)

H.R. 4827/P.L. 106-547

Enhanced Federal Security Act of 2000 (Dec. 19, 2000; 114 Stat. 2738)

S. 1972/P.L. 106-548

To direct the Secretary of Agriculture to convey to the town of Dolores, Colorado, the

current site of the Joe Rowell Park. (Dec. 19, 2000; 114 Stat. 2741)

S. 2594/P.L. 106-549

To authorize the Secretary of the Interior to contract with the Mancos Water Conservancy District to use the Mancos Project facilities for impounding, storage, diverting, and carriage of nonproject water for the purpose of irrigation, domestic, municipal, industrial, and any other beneficial purposes. (Dec. 19, 2000; 114 Stat. 2743)

S. 3137/P.L. 106-550

James Madison Commemoration Commission Act (Dec. 19, 2000; 114 Stat. 2745)

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