
Tuesday
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DEPARTMENT OF AGRICULTURE

Office of the Secretary

7 CFR Part 6

Dairy Tariff-Rate Import Quota Licensing

AGENCY: Office of the Secretary, USDA.

ACTION: Interim rule.

SUMMARY: This rule amends Import Regulation 1, Revision 7 which governs the administration of the import licensing system for certain dairy products which will be subject to in-quota tariff rates established in the Harmonized Tariff Schedule of the United States resulting from the entry into force of certain provisions in the Uruguay Round Agreement on July 1, 1995, and with respect to the licensing for certain dairy product shipments denied entry during January 1–3, 1995.

DATES: This interim rule will be effective upon May 2, 1995. Comments should be submitted on or before June 16, 1995, to be assured of consideration.

ADDRESSES: Comments should be sent to Richard Warsack, Dairy Import Quota Manager, Import Policies and Programs Division, Room 5531–S, Foreign Agricultural Service, U.S. Department of Agriculture, 14th and Independence Avenue, S.W., Agricultural Box 1025, Washington, D.C. 20250–1025. All comments received will be available for public inspection in room 5541–S at the above address.

FOR FURTHER INFORMATION CONTACT:

Diana Wanamaker, Group Leader, Import Programs Group, Import Policies and Programs Division, Room 5531–S, Foreign Agricultural Service, U.S. Department of Agriculture, 14th and Independence Avenue, S.W., Washington, D.C. 20250, or telephone (202) 720–2916.

SUPPLEMENTARY INFORMATION:

Executive Order 12866

This supplement to the interim rule is issued in conformance with Executive Order 12866. It has been determined to be significant for the purposes of E.O. 12866 and, therefore, has been reviewed by the Office of Management and Budget (OMB).

Regulatory Flexibility Act

It has been determined that the Regulatory Flexibility Act is not applicable to this interim rule relating to foreign affairs since the Office of the Secretary is not required by 5 U.S.C. 553 or any other provision of law to publish a notice of proposed rulemaking with respect to the subject matter of this rule.

Executive Order 12372

This program is not subject to the provisions of Executive Order 12372, which requires intergovernmental consultation with State and local officials. See notice related to 7 CFR part 3015, subpart V, published at 48 FR 29115 (June 24, 1983).

Environmental Evaluation

It has been determined by an environmental evaluation that this action will not have a significant impact on the quality of the human environment. Therefore, neither an Environmental Assessment nor an Environmental Impact Statement is needed.

Paperwork Reduction Act

This interim rule amends the existing information collection as approved by the Office of Management and Budget (OMB) pursuant to the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*), under OMB control number 0551–0001, expiring June 30, 1997.

Due to the time constraints of implementing this interim rule, the agency has requested emergency clearance of this addendum from OMB. Comments on the information collection may be sent to the Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10202, NEOB, Washington, D.C. 20503. Attention: Desk Officer for USDA.

Executive Order 12778

This interim rule has been reviewed under Executive Order 12778. The provisions of this supplement to the

interim rule would have preemptive effect with respect to any state or local laws, regulations, or policies which conflict with such provisions or which otherwise impede their full implementation. The interim rule would not have retroactive effect.

Background

This interim rule amends Import Regulation 1, Revision 7 which governs the administration of the import licensing system for certain dairy products which are subject to in-quota tariff rates proclaimed in the Harmonized Tariff Schedule of the United States (HTS). Imports of certain cheese and non-cheese dairy products are subject to tariff-rate quotas proclaimed in the HTS as a result of the entry into force of the Uruguay Round Agreement.

These amendments to the Import Regulation are being published as an interim rule because the Uruguay Round commitments taking effect on July 1, 1995, were not finalized pursuant to bilateral agreements until recently and it is necessary to provide an application period as soon as possible in order to issue licenses prior to the effective date. With respect to certain dairy product shipments denied entry during January 1–3, 1995, these licenses must also be issued as soon as possible to fulfill our Uruguay Round commitments. Therefore, good cause is shown to publish this rule as interim without prior public participation.

This interim rule is issued under the authority of section 103 and 404 of the Uruguay Round Agreements Act and the notes to Chapter 4 and General Note 15 of the HTS. It completes the Uruguay Round implementation process for the 1995 quota year by establishing the import licensing system for the quantities of cheese and non-cheese dairy products subject to in-quota tariff rates in the HTS effective July 1, 1995.

The following changes made by this interim rule are intended to fulfill the Uruguay Round obligations of the United States and to facilitate the administration of the tariff-rate import quota licensing system for 1995.

1. The Import Regulation is amended to: (1) Administer Uruguay Round tariff-rate quotas for those countries whose Uruguay Round schedules of concessions will take effect on July 1, 1995; (2) establish Appendix 3 supplementary licenses for such

countries and the respective in-quota tariff-rate quota quantities of cheese, and (3) provide for an application period for such licenses.

2. The Import Regulation is amended to permit the European Community (EC) to endorse in writing eligible applicants for the increments in quantities of cheese subject to the in-quota tariff rate as provided for in the Uruguay Round Agreement.

3. The Import Regulation is also amended to ensure that the orderly marketing of trade in the United States is not disrupted for articles for which entry was attempted into the United States after January 1, 1995, without prior knowledge that an unlicensed article would be made subject to licensing as of January 1, 1995. This interim rule provides a very limited exclusion from license-size limitations for certain shipments which were denied entry into the United States by the U.S. Customs Service during a brief period the Department considers licensing to have been unanticipated. This exclusion applies only to that part of the in-quota tariff-rate quantity which had been unlicensed prior to January 1, 1995 and will be prorated among licensees as necessary.

An Advance Notice of Proposed Rulemaking (ANPR) was published in the **Federal Register** on June 2, 1994, seeking comments on methods for allocating articles that would be subject to the in-quota tariff rate proclaimed in the HTS on January 1, 1995, and suggestions on other changes intended to update and make more enforceable the provisions of the Import Regulation. A proposed rule embodying fundamental changes to the Import Regulation as envisaged in the ANPR will be published in the near future.

An interim rule was published in the **Federal Register** on January 6, 1995, which amended the Import Regulation to the extent necessary to implement the Uruguay Round commitments which became effective on January 1, 1995. The interim rule established an import licensing system for in-quota tariff-rate quota quantities of cheese and certain other non-cheese dairy products subject to in-quota tariff rates in the HTS. These quantities included both the quantities which were previously subject to absolute quotas under section 22 of the Agricultural Adjustment Act of 1933, as amended, and additional quantities of cheese and certain non-cheese dairy articles negotiated under the Uruguay Round of multilateral trade negotiations for those countries which implemented their Uruguay Round commitments on January 1, 1995. The interim rule provided for a 30-day public comment

period ending on February 21, 1995. Written comments were received from seven different entities.

In addition to amending the Import Regulation to implement the changes to the HTS effective on July 1, 1995, this interim rule amends the Import Regulation in accordance with certain comments on the interim rule published on January 6, 1995, recommending changes deemed both administratively possible or necessary to implement during the remainder of the 1995 quota year. Other comments on the January 6 interim rule will be considered for inclusion in the proposed rule as envisaged in the ANPR.

The comment reflected herein requested entry for that quantity of butter substitutes being detained which was previously subject to an unlicensed global quota. The interim rule provides for a very limited and strict license size exclusion to enter certain butter substitutes. Another comment recommended clarifying the minimum license size of supplementary quota shares and certain article descriptions in Appendix 1 and Appendix 2 of the interim rule. This interim rule makes these technical corrections.

List of Subjects in 7 CFR Part 6

Agricultural commodities, Cheese, Dairy products, Imports, and Reporting and record keeping requirements.

Interim Rule

PART 6—[AMENDED]

Accordingly, 7 CFR Part 6, Subpart—Tariff-Rate Quotas is amended as follows:

1. Section 6.25 is revised by revising the first sentence of paragraph (c)(2) to read as follows:

§ 6.25 Eligibility.

* * * * *

(c) * * * (2) Notwithstanding paragraph (b)(4) of this section, certification required to establish supplementary eligibility for license for articles under Appendix 3 of this subpart must be postmarked no earlier than January 30, 1995 and no later than February 20, 1995 for those licenses issued for in-quota tariff-rate quota quantities which became effective on January 1, 1995, and no earlier than May 10, 1995 and no later than May 19, 1995 for those licenses that will be issued for in-quota tariff-rate quota quantities that will become effective on July 1, 1995. * * *

* * * * *

2. Section 6.26 is amended by revising the second sentence of paragraph (c)(3)(ii), revising paragraph (d)(2), and

revising paragraph (d)(3) (i) and (ii) to read as follows:

§ 6.26 Allocation of annual quota and issuance of licenses.

* * * * *

(c) * * *

(3) * * *

(ii) * * * If eligible applicants whose applications have been endorsed by the government of the supplying country as set forth in (c)(3)(i) of this section request an aggregate amount of a specific quota from a specific country (not the EC, except for those additional quantities of cheese made subject to the in-quota tariff rate in the Uruguay Round Agreement) smaller than is available for allocation, or if no endorsement is made, the Licensing Authority shall allocate remaining portions among applicants who have not been endorsed, following a procedure identical to that set forth in paragraph (c)(2) of this section for the EC, replacing, for this purpose, the words "the EC" wherever they appear with "a particular non-EC country".

* * * * *

(d) * * *

(2) The size of a supplementary quota share issued to an eligible applicant shall not exceed 57,000 kilograms, except that this maximum share provided for in (d)(ii) above shall not be applicable to that quantity of an in-quota tariff-rate quota which was not subject to licensing prior to January 1, 1995 when the import of such product was offered for entry and denied entry into the United States by U.S. Customs during January 1–3, 1995. Not later than June 1, 1995, an applicant must submit with its application, an invoice, bill of lading, and other relevant documentation to the Licensing Authority for his determination that there is sufficient documentary evidence that such import was offered for entry during January 1–3, 1995. If the Licensing Authority determines that a quantity greater than that available is requested by eligible applicants, the quantity available will be prorated among the licensees.

(3) * * *

(i) 19,000 kilograms where the total amount available for allocation is 550,000 kilograms or less;

(ii) 38,000 kilograms where the total amount available for allocation is greater than 550,000 kilograms.

3. In Appendix 1, the article description for Edam and Gouda in Group II(a) and the article description for Italian-type cheese in Group IV(a) are revised as follows:

Appendix 1—Articles Subject to the Historical and Nonhistorical Licensing Provisions of Import Regulation 1, Revision 7, and Respective Annual Import Quotas for Each Quota Year

* * * * *

Group II

(a) Edam and Gouda cheese, and cheese and substitutes for cheese containing, or processed from Edam and Gouda cheese (Note 20) * * *

* * * * *

Group IV

(a) Italian-type cheese made from cow's milk (Romano made from cow's milk, Reggiano, Parmesano, Provolone, Provolette,

Sbrinz, and Goya not in original loaves), and cheeses and substitutes for cheese containing, or processed from, such Italian-type cheeses, whether or not in original loaves (Note 21) * * *

* * * * *

4. In Appendix 2, the article description for Italian-type cheese in Group IV (a) is revised as follows:

Appendix 2—Articles Subject to the Historical and Nonhistorical Licensing Provisions of Import Regulation 1, Revision 7, and Respective Annual Import Quotas for Each Quota Year

* * * * *

Group IV

(a) Italian-type cheese made from cow's milk (Romano made from cow's milk, Reggiano, Parmesano, Provolone, Provolette, Sbrinz, and Goya not in original loaves), and cheeses and substitutes for cheese containing, or processed from, such Italian-type cheeses, whether or not in original loaves (Note 21) * * *

* * * * *

5. Appendix 3 is revised to read as follows:

Appendix 3—Articles Subject to the Supplementary Licensing Provisions of Import Regulation 1, Revision 7, and Respective Annual Import Quotas for Each Quota Year

Article by HTS note number	Annual supplementary quota (kilograms)
Butter (Note 6)	3,656,311
Dried Skim Milk (Note 7)	441,359
Dried Whole Milk (Note 8)	368,125
Butter Substitutes Containing over 45% by weight of butterfat and butteroil (Note 14)	3,480,500
Cheese and substitutes for cheese (except cheese not containing cow's milk and soft ripened cow's milk cheese, cheese (except cottage cheese) containing 0.5 percent or less by weight of butterfat, and articles within the scope of other tariff-rate quotas provided for in this subchapter) (Note 16)	2,978,834
Australia	291,667
Austria	45,500
Costa Rica	1,000,000
Czech Republic	200,000
EC	150,000
Poland*	300,000
Slovak Republic	600,000
Switzerland	41,667
Uruguay	250,000
Any Country	100,000
Blue-mold cheese (except Stilton produced in the United Kingdom) and cheese and substitutes for cheese containing, or processed from, blue-mold cheese (Note 17)	88,333
Chile	13,333
Czech Republic	50,000
EC	25,000
Cheddar cheese, and cheese and substitutes for cheese containing, or processed from, Cheddar cheese (Note 18)	1,328,333
Australia	208,333
EC	83,333
Chile	36,667
Czech Republic	50,000
New Zealand	850,000
Any Country	100,000
American-type cheese, including Colby, washed curd, and granular cheese (but not including cheddar) and cheese and substitutes for cheese containing or processed from such American-type cheese (Note 19)	8,333
EC	8,333
Edam and Gouda cheese, and cheese and substitutes for cheese containing, or processed from, Edam and Gouda Cheese (Note 20)	293,333
Argentina	110,000
Austria	33,333
EC	50,000
Czech Republic	100,000
Italian-Type cheeses, made from cow's milk (Romano made from cow's milk, Reggiano, Parmesan, Provolone, Provoletti, Sbrinz, and Goya not in original loaves) and cheese and substitutes for cheese containing, or processed from, such Italian-Type cheeses, whether or not in original loaves (Note 21)	4,281,666
Argentina	1,890,000
EC	58,333
Uruguay	750,000
Hungary	400,000
Poland*	1,100,000
Romania	83,333
Swiss and Emmenthaler cheese other than with eye formation Gruyere-process, and cheese and substitutes for cheese containing, or processed from such cheese (Note 22)	31,666
Austria	6,666
EC	25,000
Swiss and Emmenthaler cheese with eye formation (Note 25)	1,043,332

Article by HTS note number	Annual supplementary quota (kilograms)
Austria	18,333
EC	58,333
Sweden	150,000
Switzerland	16,666
Czech Republic	400,000
Hungary	400,000

*Issuance of licenses and quota quantities are conditioned on completion of a bilateral memorandum of understanding between the Governments of the United States and Poland.

Signed at Washington, D.C., on April 21, 1995.

Richard E. Rominger,

Acting Secretary of Agriculture.

[FR Doc. 95-10712 Filed 4-27-95; 12:36 pm]

BILLING CODE 3410-02-P

Animal and Plant Health Inspection Service

9 CFR Part 94

[Docket No. 94-107-2]

Switzerland; Change in Disease Status

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: We are declaring Switzerland free of rinderpest, foot-and-mouth disease, and Exotic Newcastle disease (VVND). As part of this action, we are adding Switzerland to the lists of countries that, although declared free of rinderpest, foot-and-mouth disease, and VVND, are subject to restrictions on meat and other animal products offered for importation into the United States. This rule removes the prohibition on the importation of ruminants and fresh, chilled, and frozen meat of ruminants into the United States from Switzerland, although those importations will be subject to certain restrictions. This rule also relieves certain prohibitions and restrictions on the importation, from Switzerland, of milk and milk products of ruminants and of certain poultry and poultry products.

EFFECTIVE DATE: May 17, 1995.

FOR FURTHER INFORMATION CONTACT: Dr. Kathleen Akin, Senior Staff Veterinarian, Import/Export Products, National Center for Import and Export, VS, APHIS, Suite 3B05, 4700 River Road Unit 40, Riverdale, MD 20737-1231, (301) 734-7830.

SUPPLEMENTARY INFORMATION:

Background

The regulations in 9 CFR part 94 (referred to below as the regulations)

govern the importation into the United States of specified animals and animal products in order to prevent the introduction into the United States of various animal diseases, including rinderpest, foot-and-mouth disease (FMD), and Exotic Newcastle disease (VVND). FMD and rinderpest are dangerous and destructive communicable diseases of ruminants and swine. VVND is a contagious, infectious, and communicable disease of poultry.

On February 2, 1995, we published in the **Federal Register** (60 FR 6454-6456, Docket No. 94-107-1) a proposal to amend the regulations by adding Switzerland to the list in § 94.1(a)(2) of countries declared free of both rinderpest and FMD and to the list in § 94.6(a)(2) of countries declared free of VVND. In that document, we also proposed to add Switzerland to the list in § 94.11(a) of countries that, although declared free of rinderpest and FMD, are subject to special restrictions on the importation of their meat and other animal products into the United States.

We solicited comments concerning our proposal for 60 days ending April 3, 1995. We did not receive any comments. The facts presented in the proposed rule still provide the basis for this final rule.

Therefore, based on the rationale set forth in the proposed rule, we are adopting the provisions of the proposal as a final rule without change.

Effective Date

This is a substantive rule that relieves restrictions and, pursuant to the provisions of 5 U.S.C. 553, may be made effective less than 30 days after publication in the **Federal Register**.

This rule removes the prohibition on the importation of ruminants and fresh, chilled, and frozen meat of ruminants into the United States from Switzerland and relieves restrictions on the importation from Switzerland of milk and milk products of ruminants and certain poultry and poultry products. We have determined that approximately 2 weeks are needed to ensure that Animal and Plant Health Inspection

Service personnel at ports of entry receive official notice of this change in the regulations. Therefore, the Administrator of the Animal and Plant Health Inspection Service has determined that this rule should be made effective 15 days after publication in the **Federal Register**.

Executive Order 12866 and Regulatory Flexibility Act

This rule has been reviewed under Executive Order 12866. For this action, the Office of Management and Budget has waived its review process required by Executive Order 12866.

This final rule amends the regulations in part 94 by adding Switzerland to the list of countries declared free of rinderpest and FMD and to the list of countries declared free of VVND. This action will remove the prohibition on the importation of ruminants and fresh, chilled, and frozen meat of ruminants into the United States from Switzerland, although those importations will be subject to certain restrictions. This revision will also relieve restrictions on the importation from Switzerland of milk and milk products of ruminants and certain poultry and poultry products. This action will not relieve certain restrictions on the importation of live swine and fresh, chilled, and frozen meat of swine from Switzerland because Switzerland is still considered to be affected with hog cholera. Similarly, this action will not relieve certain restrictions on the importation from Switzerland, of ruminant meat and edible products from ruminants because bovine spongiform encephalopathy (BSE) exists in Switzerland.

Based on available information, the Department does not anticipate a major increase in exports of ruminants and fresh, chilled, or frozen meat of ruminants or poultry from Switzerland into the United States as a result of this final rule.

The primary effects due of this change in the regulations will be limited to bovine meat and prepared products, since swine and swine products are excluded because of restrictions due to

hog cholera, live cattle and breeding material are excluded due to BSE, and there is no sheep, lamb, or goat production in Switzerland (USDA, National Agricultural Statistics Service (NASS), "Agricultural Statistics," 1993). Commencement of such production is not expected due to the regulation change. The impact of increased beef imports resulting from the regulation changes will likely be minimal because the cattle industry in Switzerland is relatively small and high cost compared to the United States domestic market. Cattle inventories in Switzerland were estimated to be about 1.78 million head in 1993, while U.S. inventories were over 101 million head in 1993 (USDA, Foreign Agricultural Service, Switzerland's Annual Livestock Report, August 8, 1994, and USDA, NASS, "Agricultural Statistics," 1993).

Due to current restrictions, the United States does not import any uncooked meat or meat products from Switzerland. Total meat production in the United States in 1992 was just under 18.587 million metric tons, while Swiss meat production in 1992 reached approximately 429,000 metric tons, about 2.3 percent of the United States total (USDA, National Agricultural Statistics Service, "Agricultural Statistics," 1993). Therefore, even if Switzerland exported a significant portion of its meat production exclusively to the United States, which is unlikely, the effect of those exports on United States domestic prices or supplies would be negligible.

As with the ruminants and meat products discussed above, the Department does not anticipate a major increase in exports of milk and milk products from Switzerland into the United States as a result of this final rule. The importation into the United States of all dairy products, except for casein and other caseinates, is restricted by quotas. Although the importation of casein into the United States is not regulated by quotas, world prices of casein are competitively set. The United States does not produce casein, but does import more than half of the casein produced in the world. The regulations currently allow casein and other caseinates to be imported into the United States from countries where rinderpest or FMD exists if the importer has applied for and obtained written permission from the Administrator of the Animal and Plant Health Inspection Service. The United States did not import any casein from Switzerland in 1993 (USDA, Economic Research Service (ERS), "Foreign Agricultural Trade of the United States: Calendar Year 1993 Supplement," 1993).

Declaring Switzerland free of rinderpest and FMD, thus removing the requirement for written permission from the Administrator, is not expected to have any effect on the amount of casein imported into the United States from Switzerland because the current restrictions do not substantially impede imports.

Imports of poultry and poultry products into the United States from Switzerland in 1992 and 1993 fell into two categories: live poultry, and feathers and down. Total live poultry imports into the United States were valued at \$14.4 million and \$14.5 million in 1992 and 1993, respectively. United States live poultry imports from Switzerland were valued at \$67 thousand and \$74 thousand in 1992 and 1993, respectively, about 0.5 percent of the total imports. Total United States imports of feathers and down were valued at \$84 million and \$60.1 million in 1992 and 1993, respectively. United States imports of feathers and down from Switzerland were valued at \$1.2 million and \$0.41 million in 1992 and 1993, respectively, less than 1.5 percent of the total imports (USDA, ERS, "Foreign Agricultural Trade of the United States: Calendar Year 1993 Supplement," 1993). Also, Switzerland is dependent on imports for over 50 percent of domestic poultry consumption. Consequently, the changes in current regulations concerning VVND are not expected to result in increased exports to the United States.

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

Executive Order 12778

This rule has been reviewed under Executive Order 12778, Civil Justice Reform. This rule: (1) Preempts all State and local laws and regulations that are inconsistent with this rule; (2) has no retroactive effect; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule.

Paperwork Reduction Act

This rule contains no information collection or recordkeeping requirements under the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*).

List of Subjects in 9 CFR Part 94

Animal diseases, Imports, Livestock, Meat and meat products, Milk, Poultry

and poultry products, Reporting and recordkeeping requirements.

Accordingly, 9 CFR part 94 is amended as follows:

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

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

Authority: 7 U.S.C. 147a, 150ee, 161, 162, and 450; 19 U.S.C. 1306; 21 U.S.C. 111, 114a, 134a, 134b, 134c, 134f, 136, and 136a; 31 U.S.C. 9701; 42 U.S.C. 4331, and 4332; 7 CFR 2.17, 2.51, and 371.2(d).

§ 94.1 [Amended]

2. In § 94.1, paragraph (a)(2) is amended by adding "Switzerland," immediately after "Sweden,".

§ 94.6 [Amended]

3. In § 94.6, paragraph (a)(2) is amended by removing "and Sweden" and adding "Sweden, and Switzerland" in its place.

§ 94.11 [Amended]

4. In § 94.11, paragraph (a), the first sentence is amended by removing "and Sweden," and adding "Sweden, and Switzerland," in its place.

Done in Washington, DC, this 26th day of May 1995.

Terry L. Medley,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 95-10745 Filed 5-1-95; 8:45 am]

BILLING CODE 3410-34-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 94-NM-44-AD; Amendment 39-9214; AD 74-08-09 R1]

Airworthiness Directives; Transport Category Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

SUMMARY: This amendment revises an existing airworthiness directive (AD) that is applicable to all transport category airplanes. The existing AD currently requires installation of placards prohibiting smoking in the lavatory and disposal of cigarettes in the

lavatory waste receptacles; establishment of a procedure to announce to airplane occupants that smoking is prohibited in the lavatories; installation of ashtrays at certain locations; and repetitive inspections to ensure that lavatory waste receptacle doors operate correctly. That action was prompted by fires occurring in lavatories, which were caused by, among other things, the improper disposal of smoking materials in lavatory waste receptacles. The actions specified by the AD are intended to prevent such fires. This amendment provides for an alternative action regarding the current requirement to install specific placards at certain locations.

EFFECTIVE DATE: June 1, 1995.

ADDRESSES: Information pertaining to this rulemaking action may be examined at the Federal Aviation Administration (FAA), Transport Airplane Directorate, Rules Docket, 1601 Lind Avenue, SW., Renton, Washington.

FOR FURTHER INFORMATION CONTACT: Monica Nemecek, Aerospace Engineer, Airframe Branch, ANM-120S, Seattle Aircraft Certification Office, FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington 98055-4056; telephone (206) 227-2773; fax (206) 227-1181.

SUPPLEMENTARY INFORMATION: A proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) by revising AD 74-08-09, amendment 39-1917, which is applicable to all transport category airplanes having one or more lavatories equipped with paper or linen waste receptacles, was published in the **Federal Register** on November 1, 1994 (59 FR 54535). The action proposed to provide for an alternative action regarding the current requirement to install specific placards at certain locations.

Disposition of Comments

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

One commenter supports the proposal.

The FAA responds to additional comments and requests for revision of the proposal as follows:

Request To Add Inspections of Smoke Detectors

One commenter requests that the proposal be revised to include an additional requirement for a periodic inspection and test of the lavatory smoke detector. The commenter

suggests that such inspections be required either every six months or at the same time as the inspections of the trash receptacle doors are required. This commenter considers that such inspections are necessary because smoke and fire, as a result of smoking materials deposited in lavatories, continue to be a hazard. The commenter points out that, in the span of time since the AD was originally issued in 1974, there have been numerous lavatory fires reported on transport category airplanes; many of these fires were not detected by the smoke detectors, but by passengers and crew. The commenter acknowledges that it is not clear whether the fire detector failed to function in these cases of fire; however, it is clear that the detector failed to perform as intended. Since the National Fire Protection Association recommends inspection and testing of residential smoke detectors because they are subject to failure, the commenter believes that a comparable test and inspection of detectors on airplanes is also warranted.

The FAA does not concur with the commenter's suggestion to revise the proposal. The FAA has issued numerous AD's, applicable to specific aircraft models, whenever an unsafe condition has been identified relative to potential fires in the lavatories. In fact, many AD's as well as many individual operator's maintenance programs already call for repetitive inspections of the smoke detectors located in the lavatories. Notwithstanding these current AD's and practices, the FAA will continue to monitor the situation within the transport fleet and may consider the commenter's comments for possible separate rulemaking action.

Request To Revise Applicability of AD

One commenter requests that the applicability of the proposal be revised to include only those aircraft types known to be affected by the existing AD's provisions, and to exclude all aircraft that were type certificated after August 6, 1974 (the effective date of AD 74-08-09), when the FAA has confirmed that the approved type design incorporates the provisions intended by AD 74-08-09. As justification for this request, the commenter points out the following:

1. The current applicability of the AD makes it applicable to all transport category airplanes ever built, including those that were type certificated after the effective date of AD 74-08-09. It also encompasses all aircraft certificated under Federal Aviation Regulations (FAR) part 25 (14 CFR part 25) whose type design has originated during the

past 20 years. The applicability of the AD appears to be a burdensome action placed on the aviation industry for only a minor FAA administrative convenience.

2. The current "open-ended" applicability of the AD places the manufacturer of airplanes type certificated after August 6, 1974, in a peculiar position: The FAA makes a finding during type certification that, in compliance with FAR 21.21(b)(2), "* * * no feature or characteristic makes it unsafe for the category in which certification is requested;" yet, at the same time, the FAA states that a newly type certificated/manufactured airplane is "unsafe" by the terms of AD 74-08-09.

The FAA does not consider that revising the applicability of this AD, as requested by the commenter, is necessary for the following reasons:

As for Item 1, above, the FAA acknowledges that almost all of the requirements of this AD are similar to other requirements of newly-certified airplanes. However, the FAA does not consider that accomplishment of the requirements of this AD constitutes any additional undue burden on operators. For the most part, operators will be required merely to enter a one-time sign-off in the airplane log to indicate compliance. (The only requirement of this AD that is not similar to any other is the requirement that calls for repetitive inspections of the waste receptacle doors. As is explained later in this preamble, service history data indicates that the 1,000-hour repetitive inspections are necessary and appropriate.) To the extent that the requirements of this AD are similar to those of other rules, their continued presence as part of this AD emphasizes their importance and makes it less likely that they will be overlooked.

Additionally, since the various requirements of this AD were adopted in certification and operating rules at different times and by different amendments to the FAR, it would make the AD unnecessarily complex to create exceptions for those airplanes and operators subject to other requirements.

As for Item 2, above, the FAA does not consider that any manufacturer would be placed in a "peculiar situation," as described by the commenter. During the certification process, the manufacturer will necessarily have to consider the requirements of this AD prior to certification of an airplane, and will eliminate the unsafe condition by complying with the AD; therefore, there will be no feature or characteristic that

makes the airplane unsafe as certificated.

Request To Include Terminating Actions for Requirements of AD

This commenter also requests that the proposal be revised to provide for "terminating actions" for operators whenever the required ashtrays and placards are installed on the airplane and when the provisions for the recurring inspections are incorporated into the FAA-approved inspection program [required by FAR 91.409 (14 CFR 91.409), "Inspections"]. The commenter contends that, in requiring the continuing inspection, the FAA has "gone counter to the commitment of the Administrator," who stated in the preamble to amendments 21-3 and 39-106, "The agency * * * will not issue AD's as a substitute for enforcing maintenance rules." Revising the proposal in accordance with the commenter's request, the commenter states that the FAA would "correct its error" with respect to enforcement of maintenance rules.

The FAA does not concur with the commenter's request. First, according to § 39.1 of the FAR (14 CFR 39.1), the issuance of an AD is based on the finding that an unsafe condition exists or is likely to develop in aircraft of a particular type design. The responsibilities placed on the FAA by the Federal Aviation Act do not limit it from making any unsafe condition—whether resulting from maintenance, design defect, or otherwise—the proper subject of an AD. Therefore, regardless of the cause or the source of an unsafe condition, the FAA has the authority to issue an AD when it is found that an unsafe condition is likely to exist or develop on other products of the same type design.

Second, it is within the FAA's authority to issue AD's to require actions to address unsafe conditions that are not otherwise being addressed (or addressed adequately) by normal maintenance procedures. This AD has not been issued as a substitute for enforcement of maintenance rules. On the contrary, it establishes the maintenance rule. Currently, there is no other rule that imposes the 1,000-hour inspection of the waste receptacle doors. Based on in-service history of problems encountered, it is especially important that the requirement for these repetitive inspections continue in this AD in order to ensure that the problem addressed is not reintroduced in the fleet.

As for providing terminating action for the requirements of AD 74-08-09, the FAA has not approved any action or modification that would constitute an

appropriate "terminating action." Specifically:

a. With regard to the required installation of placards and ashtrays, those are one-time actions, requiring no additional "repetitive" installations. Once they are installed, operators merely need to document the appropriate maintenance records to indicate this.

b. With regard to the required procedure for announcements to aircraft occupants, this, too, would be a one-time action. Once a procedure is established, the operator would need only document the appropriate records to indicate this; no further documentation would be required.

c. With regard to the required repetitive inspections, data currently available to the FAA indicate that the majority of U.S. operators of transport category airplanes are conducting these inspections every 1,000 hours, as specified by the AD, and some are conducting the inspections more frequently. Many operators have found discrepancies at the 1,000-hour inspection interval. There currently is no in-service data to substantiate that any action or modification exists that would preclude the need for a 1,000-hour inspection. These repetitive inspections are appropriate, since they ensure that any discrepancy will be identified and corrected in a timely manner.

Further, the FAA does not concur with the commenter's request to allow operators to incorporate the provisions for these recurring inspections into the FAA-approved inspection program as "terminating action" for the AD. Incorporating the repetitive inspection program into the operator's maintenance or inspection program would allow escalation of inspection intervals, which the FAA finds inappropriate without adequate control.

Additionally, while the vast majority of affected U.S.-registered airplanes are operated under FAA-approved maintenance/inspection programs, there are some airplanes that are not so operated, namely, certain airplanes that are excepted from the requirements of FAR part 125 by § 125.1. Because the applicability of the rule includes *all* transport airplanes, those "excepted" airplanes would still be subject to the AD's requirements; however, because they are not operated under an FAA-approved maintenance/inspection program, their operators would not be able to comply with an AD that required a revision to that program. Moreover, in accordance with existing bilateral airworthiness agreements with foreign countries, the FAA recognizes that one

of the purposes of this AD action is to advise foreign authorities of the addressed unsafe condition, and to provide them with guidance as to appropriate methods for correcting it. Again, while revising the FAA-approved maintenance/inspection programs may be effective for many U.S. carriers, other countries do not regulate carriers in the same way. Specifically, foreign authorities may not have the same regulatory system of "approved maintenance programs" as in the U.S. Since the AD is formulated to address a worldwide system for preventing potential fires, the FAA considers that it would not be appropriate to change the requirement for the inspections as the commenter has requested.

Request To Permit Removal of Ashtrays

One commenter requests that the proposal be revised to allow the removal of lavatory door ashtrays, especially on air carriers that prohibit smoking, or on flights for which smoking is prohibited under the appropriate portions FAR section 252 (14 CFR 252, "Smoking aboard aircraft"). This commenter points out that the existing AD requires that ashtrays be installed, while other parts of the FAR prohibit smoking in the passenger cabin and lavatories for certain flights. This commenter, a U.S. operator, notes that it has, on occasion, experienced delays due to missing lavatory door ashtrays, even though smoking is not permitted during the flight. The commenter recommends that lavatory door ashtrays be considered "passenger convenience items" and, as such, be dispositioned under the provision of the appropriate Minimum Equipment List (MEL).

The FAA does not concur. The requirement for the presence of an ashtray on or near the lavatory door provides a convenient disposal location for cigarettes (or other smoking material), and thereby ensures that there is a place to dispose of such material in the event that the "no smoking" policy is not adhered to. Further, the installation of an ashtray on or near the lavatory door will ensure that uninformed persons who find themselves with lighted smoking materials on the airplane will have an obvious location to dispose of smoking materials before entering the lavatory. Previous experience and reports have shown that there is a high probability that these persons may deposit the lighted smoking material in the lavatory paper or linen receptacle when no safe and convenient place to dispose it exists; such actions can result in an in-flight fire aboard the airplane. Accordingly, while the "no smoking"

policy is a positive feature that may contribute to safety, it is not meant to be a substitute for required equipment.

Additionally, the FAA does not concur with the commenter's request to consider ashtrays as "passenger convenience items" that can be dispositioned under the MEL. As explained above, ashtrays do serve a safety function and, therefore, must be considered required equipment.

Request To Revise Estimated Cost of Compliance

One commenter requests that the FAA revise its economic impact estimate relative to the cost of compliance with the AD. This commenter states that FAA's analysis of the cost may be reasonably representative of the recurring inspections currently required, but it does not consider the cost of research and recordkeeping involved when determining whether or not an airplane is fitted with lavatories or receptacles subject to the AD. The commenter contends that research and recordkeeping needed just to confirm that an airplane is not subject to the AD results in costs approximating the 1.5 work hours that the FAA indicates is the time required to accomplish the inspections.

The FAA does not concur with the commenter's request. The applicability statement of the AD clearly limits the AD to those transport category airplanes that have one or more lavatories equipped with paper or linen waste receptacles. If an operator is not certain whether its airplane has lavatories so equipped, it may simply review the type design (drawings) of the airplane to determine this. A one-time check of a drawing to determine whether or not the AD is applicable should not create an undue burden on any operator.

Conclusion

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

Economic Impact

Since this action only provides for an alternative method of complying with an existing rule, it does not add any new additional economic burden on affected operators. The current costs associated with this AD are reiterated below for the convenience of affected operators:

The costs associated with the currently required placard installations entail approximately 1 work hour per airplane, at an average labor rate of \$60 per work hour. The cost of required parts is negligible. Based on these

figures, the total cost impact of the installation requirements of the AD on U.S. operators is estimated to be \$60 per airplane.

The costs associated with the currently required inspections entail approximately 1.5 work hours per airplane per inspection, at an average labor rate of \$60 per work hour. Based on these figures, the total cost impact of the inspection requirements of this AD on U.S. operators is estimated to be \$90 per airplane per inspection.

Regulatory Impact

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

For the reasons discussed above, I certify that this action (1) is not a "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. App. 1354(a), 1421 and 1423; 49 U.S.C. 106(g); and 14 CFR 11.89.

§ 39.13 [Amended]

2. Section 39.13 is amended by removing amendment 39-1917, and by

adding a new airworthiness directive (AD), amendment 39-9214, to read as follows:

74-08-09 R1 Transport Category Aircraft:

Amendment 39-9214. Docket 94-NM-44-AD. Revises AD 74-08-09, Amendment 39-1917.

Applicability: All transport category airplanes, certificated in any category, that have one or more lavatories equipped with paper or linen waste receptacles.

Note: The following is a partial list of aircraft, some or all models of which are type certificated in the transport category and have lavatories equipped with paper or linen waste receptacles:

Aerospatiale Models ATR42 and ATR72 series airplanes;
Airbus Models A300, A310, A300-600, A320, A330, and A340 series airplanes;
Boeing Models 707, 720, 727, 737, 747, 757, and 767 series airplanes;
Boeing Model B-377 airplanes;
British Aircraft Models BAC 1-11 series, BAe-146 series, and ATP airplanes;
CASA Model C-212 series airplanes;
Convair Models CV-580, 600, 640, 880 and 990 series airplanes;
Convair Models 240, 340, and 440 series airplanes;
Curtiss-Wright Model CW 46;
de Havilland Models DHC-7 and DHC-8 series airplanes;
Fairchild Models F-27 and C-82 series airplanes;
Fairchild-Hiller Model FH-227 series airplanes;
Fokker Models F27 and F28 series airplanes;
Grumman Model G-159 series airplanes;
Gulfstream Model 1159 series airplanes;
Hawker Siddeley Model HS-748;
Jetstream Model 4101 series airplanes;
Lockheed Models L-1011, L-188, L-1049, and 382 series airplanes;
Martin Model M-404 airplanes;
McDonnell Douglas Models DC-3, -4, -6, -7, -8, -9, and -10 series airplanes;
Model MD-88 airplanes; and Model MD-11 series airplanes;
Nihon Model YS-11;
Saab Models SF340A and SAAB 340B series airplanes;
Short Brothers and Harlin Model SC-7 series airplanes;
Short Brothers Models SD3-30 and SD3-60 series airplanes;

Compliance: Required as indicated, unless accomplished previously.

To prevent possible fires that could result from smoking materials being dropped into lavatory paper or linen waste receptacles, accomplish the following:

(a) Within 60 days after August 6, 1974 (the effective date of amendment 39-1917, AD 74-08-09), or before the accumulation of any time in service on a new production aircraft after delivery, whichever occurs later, except that new production aircraft may be flown in accordance with §§ 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to a base where compliance may be accomplished, accomplish the requirements of paragraphs (a)(1) and (a)(2) of this AD:

(1) Install a placard either on each side of each lavatory door over the door knob, or on each side of each lavatory door, or adjacent to each side of each lavatory door. The placards must either contain the legible words, "No Smoking in Lavatory" or "No Smoking;" or contain "No Smoking" symbology in lieu of words; or contain both wording and symbology; to indicate that smoking is prohibited in the lavatory. The placards must be of sufficient size and contrast and be located so as to be conspicuous to lavatory users.

(2) Install a placard on or near each lavatory paper or linen waste disposal receptacle door, containing the legible words or symbology indicating "No Cigarette Disposal."

(b) Within 30 days after August 6, 1974, establish a procedure that requires that no later than a time immediately after the "No Smoking" sign is extinguished following takeoff, an announcement be made by a crewmember to inform all aircraft occupants that smoking is prohibited in the aircraft lavatories; except that, if the aircraft is not equipped with a "No Smoking" sign, the required procedure must provide that the announcement be made prior to each takeoff.

(c) Within 180 days after August 6, 1974, or before the accumulation of any time in service on a new production aircraft, whichever occurs later, except that new production aircraft may be flown in accordance with §§ 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to a base where compliance may be accomplished, install a self-contained, removable ashtray on or near the entry side of each lavatory door. One ashtray may serve more than one lavatory door if the ashtray can be seen readily from the cabin side of each lavatory door served.

(d) Within 30 days after August 6, 1974, and thereafter at intervals not to exceed 1,000 hours time-in-service from the last inspection; accomplish the following:

(1) Inspect all lavatory paper and linen waste receptacle enclosure access doors and disposal doors for proper operation, fit, sealing, and latching for the containment of possible trash fires.

(2) Correct all defects found during the inspections required by paragraph (d)(1) of this AD.

(e) Upon the request of an operator, the FAA Principal Maintenance Inspector may adjust the 1,000 hour repetitive inspection interval specified in paragraph (d)(1) of this AD to permit compliance at an established inspection period of the operator if the request contains data to justify the requested change in the inspection interval.

(f) This amendment becomes effective on June 1, 1995.

Issued in Renton, Washington, on April 26, 1995.

James V. Devany,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 95-10709 Filed 5-1-95; 8:45 am]

BILLING CODE 4910-13-U

14 CFR Part 71

[Airspace Docket No. 95-ASO-2]

Amendment of Class D and E4 Airspace, and Establishment of Class E2 Airspace; Louisville, KY

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; request for comments.

SUMMARY: This amendment modifies the Louisville Bowman Field Class D and E4 airspace areas at Louisville, KY. The VOR RWY 19 Standard Instrument Approach (SIAP) for Bowman Field has been cancelled. Therefore, a portion of the Class D and E4 airspace areas currently designated north-northeast of Bowman Field is no longer needed. Additionally, this amendment establishes Class E2 airspace for Bowman Field during the hours the tower is not in operation. The intended effect of this action is to provide adequate Class E airspace for instrument approach procedures when the tower is closed.

DATES: *Effective Date:* 0901 UTC, July 20, 1995.

Comments: Comments must be received on or before May 25, 1995.

ADDRESSES: Send comments on the proposal in triplicate to: Federal Aviation Administration, Docket No. 95-ASO-2, Manager, System Management Branch, ASO-530, P.O. Box 20636, Atlanta, Georgia 30320.

The official docket may be examined in the Office of the Assistant Chief Counsel for Southern Region, Room 550, 1701 Columbia Avenue, College Park, Georgia 30337, telephone (404) 305-5586.

FOR FURTHER INFORMATION CONTACT: Steve McDuffee, System Management Branch, Air Traffic Division, Federal Aviation Administration, P.O. Box 20636, Atlanta, Georgia 30320; telephone (404) 305-5570.

SUPPLEMENTARY INFORMATION:

Request for Comments on the Rule

On February 6, 1995, the FAA proposed to amend part 71 of the Federal Aviation Regulations (14 CFR part 71) by modifying the Class D and E4 airspace areas at Louisville, KY. (60 FR 6975). This action would reduce the size of the Class D and E4 airspace areas for Bowman Field. No comments objecting to the proposal were received. However, the proposed amendment inadvertently failed to recognize the airspace requirements for an airport without a tower, or when the tower is not in operation, and IFR service is

provided by another ATC facility. Accordingly, the rule needs to provide Class E2 airspace for instrument approach procedures at Bowman Field when the tower is closed and air traffic control service is provided for IFR operations at Bowman Field by Standiford Tower. Comments are invited specifically on the establishment of Class E2 airspace for Bowman Field during the hours the Bowman tower is not in operation. This rule will become effective on the date specified in the **DATES** section. However, after the review of any comments and, if the FAA finds that further changes are appropriate, it will initiate rulemaking proceedings to extend the effective date or to amend the regulation.

Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in evaluating the effects of the rule and in determining whether additional rulemaking is needed. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the rule that might suggest the need to modify the rule.

The Rule

This amendment to part 71 of the Federal Aviation Regulations (14 CFR part 71) modifies the Class D and E4 airspace areas, and establishes Class E2 airspace at Louisville, KY, for Bowman Field. The VOR RWY 19 SIAP has been cancelled. Therefore, a portion of the Class D and E4 airspace areas currently designated north-northeast of Bowman Field is no longer needed. Additionally, this amendment establishes Class E2 airspace for Bowman Field during the hours the tower is not in operation. The intended effect of this action is to provide adequate Class E Airspace for instrument approach procedures when the tower is closed. This action improves air safety for participating and non-participating traffic. Class D airspace designations, Class E airspace areas designated as a surface area for an airport, and Class E airspace areas designated as an extension to a Class D surface area are published in Paragraphs 5000, 6002 and 6004 respectively of FAA Order 7400.9B dated July 18, 1994, and effective September 16, 1994. The Class D and E airspace designations listed in this document will be published subsequently in the Order.

Under the circumstances presented, the FAA concludes that there is an immediate need to establish Class E2 airspace for Bowman Field when the tower is not in operation to ensure that participating and non-participating traffic will be able to comply with

appropriate federal regulations governing controlled airspace. Without this additional provision the rule would be incomplete and defective, and have an adverse impact on safety. Therefore, I find that notice and public procedure under 5 U.S.C. 553(b) specifically regarding the establishment of the Class E2 airspace area are impracticable and contrary to the public interest.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore, (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) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—[AMENDED]

1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. app. 1348(a), 1354(a), 1510; EO 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389; 49 U.S.C. 106(g); 14 CFR 11.69.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order 7400.9B, Airspace Designations and Reporting Points, dated July 18, 1994, and effective September 16, 1994, is amended as follows:

Paragraph 5000 Class D Airspace

* * * * *

ASO KY D Louisville Bowman Field, KY [Revised]

Louisville Bowman Field, KY
(Lat. 38°13'41" N, long. 85°39'48" W.)
Louisville Standiford Field, KY
(Lat. 38°10'29" N, long. 85°44'11" W.)

That airspace extending upward from the surface to but not including 2,200 feet MSL within a 3.9-mile radius of Bowman Field,

excluding that portion within the Louisville Standiford Field Class C Airspace Area, and excluding that portion south of the 081° bearing from Standiford Field, and also excluding that portion north of the Louisville Standiford Field Class C Airspace Area and west of a line drawn from lat. 38°11'28" N, long. 85°42'01" W direct thru the point where the 030° bearing from Standiford Field intersects the 5-mile radius from Standiford Field to the point of intersection with the 3.9-mile radius from Bowman Field. This Class D airspace area is effective during the specific days and times established in advance by a Notice to Airmen. The effective days and times will thereafter be continuously published in the Airport/Facility Directory.

* * * * *

Paragraph 6002 Class E Airspace Areas Designated as a Surface Area for an Airport

* * * * *

ASO KY E2 Louisville Bowman Field, KY [Revised]

Louisville Bowman Field, KY
(Lat. 38°13'41" N, long. 85°39'48" W.)
Louisville Standiford Field, KY
(Lat. 38°10'29" N, long. 85°44'11" W.)

Within a 3.9-mile radius of Bowman Field, excluding that portion within the Louisville Standiford Field Class C Airspace Area, and excluding that portion south of the 081° bearing from Standiford Field, and also excluding that portion north of the Louisville Standiford Field Class C Airspace Area and west of a line drawn from lat. 38°11'28" N, long. 85°42'01" W direct thru the point where the 030° bearing from Standiford Field intersects the 5-mile radius from Standiford Field to the point of intersection with the 3.9-mile radius from Bowman field. This Class E Airspace area is effective during the specific days and times established in advance by a Notice to Airmen. The effective days and times will thereafter be continuously published in the Airport/Facility Directory.

* * * * *

Paragraph 6004 Class E Airspace Areas Designated as an Extension to a Class D Surface Area

* * * * *

ASO KY E4 Louisville Bowman Field, KY [Revised]

Louisville Bowman Field, KY
(Lat. 38°13'41" N, long. 85°39'48" W.)
Bowman VOR/DME
(Lat. 38°13'49" N, long. 85°39'53" W.)

That airspace extending upward from the surface within 2.4 miles each side of the Bowman VOR/DME 067° radial, extending from the 3.9-mile radius of Bowman Field to 7 miles east of the Bowman VOR/DME. This Class E airspace area is effective during the specific days and times established in advance by a Notice to Airmen. The effective days and times will thereafter be continuously published in the Airport/Facility Directory.

* * * * *

Issued in College Park, Georgia, on April 20, 1995.

Stephen W. McDuffee,

*Acting Manager, Air Traffic Division,
Southern Region.*

[FR Doc. 95–10770 Filed 5–1–95; 8:45 am]

BILLING CODE 4910–13–M

14 CFR Part 71

[Airspace Docket No. 94–ACE–16]

Amendment to Class E Airspace; Monticello, MO

AGENCY: Federal Aviation
Administration (FAA), DOT.

ACTION: Final rule; correction.

SUMMARY: This action corrects an error in the geographic coordinates of a final rule that was published in the **Federal Register** on December 28, 1994. (59 FR 66671), Airspace Docket No. 94–ACE–16.

EFFECTIVE DATE: Effective on May 2, 1995.

FOR FURTHER INFORMATION CONTACT:

Kathy J. Randolph, Airspace Technician, Air Traffic Operations Branch, ACE–530c, Federal Aviation Administration, 601 East 12th Street, Kansas City, Missouri 64106; telephone number: (816) 426–3408.

SUPPLEMENTARY INFORMATION:

History

Federal Register Document 94–31921, Airspace Docket No. 94–ACE–16, published on December 28, 1994 (59 FR 66671), established Class E airspace at Monticello, MO. An error was discovered in the geographic coordinates for the Monticello-Lewis County Regional Airport, MO, Class E airspace area. This action corrects that error.

Correction to Final Rule

Accordingly, pursuant to the authority delegated to me, the geographic coordinates for the Class E airspace area at Monticello-Lewis County Regional Airport, MO as published in the **Federal Register** on December 28, 1994, (59 FR 66671), (Federal Register Document 94–31921; page 66672, Column 1) are corrected as follows:

§ 71.71 [Corrected]

* * * * *

ACE MO E5 Monticello, MO [Corrected]

By removing "(lat. 40°07'47"N., long. 91°16'44"W.)" and substituting "(lat. 40°07'45"N., long. 91°40'42"W.)"

* * * * *

Herman J. Lyons, Jr.,

Acting Manager, Air Traffic Division, Central Region.

[FR Doc. 95-10773 Filed 5-1-95; 8:45 am]

BILLING CODE 4910-13-M

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[T.D. 7636]

Contributions to Pension, Profit-Sharing, etc., Plans on Behalf of Self-Employed Individuals and Shareholders-Employees; Correction

AGENCY: Internal Revenue Service, Treasury.

ACTION: Correcting amendment.

SUMMARY: This document contains a correction to the final regulations (T.D. 7636), which were published in the **Federal Register** Friday, August 10, 1979 (44 FR 47046), relating to contributions to pension, profit-sharing, etc., plans on behalf of self-employed individuals and shareholder-employees.

EFFECTIVE DATE: May 2, 1995.

FOR FURTHER INFORMATION CONTACT: Brant Goldwyn (202) 622-6090, (not a toll-free call).

SUPPLEMENTARY INFORMATION:

Background

The final regulations that are the subject of this correction clarify the applicability of the \$100,000 limitation of section 401(a)(17) to certain plans maintained by an aggregated employer group.

Need for Correction

As published, T.D. 7636 contains an error which may prove to be misleading and is in need of clarification.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Accordingly, 26 CFR part 1 is corrected by making the following correcting amendment:

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

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

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

§ 1.401(e)-5 [Corrected]

Par. 2. The first sentence of § 1.401(e)-5 (a)(1) is amended by removing the "(1)" following the paragraph heading "(a) *General rules—(1) General rule.*".

Cynthia E. Grigsby,

Chief, Regulations Unit, Assistant Chief Counsel (Corporate).

[FR Doc. 95-10688 Filed 5-1-95; 8:45 am]

BILLING CODE 4830-01-P

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 944

Utah Regulatory Program

AGENCY: Office of Surface Mining Reclamation and Enforcement (OSM), Interior.

ACTION: Final rule; approval of amendment.

SUMMARY: OSM is approving a proposed amendment to the Utah regulatory program (hereinafter referred to as the "Utah program") under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). Utah proposed revisions to its civil penalty rules with the intent of making them consistent with recently promulgated revisions to the Utah Coal Reclamation Act of 1979.

EFFECTIVE DATE: May 2, 1995.

FOR FURTHER INFORMATION CONTACT: Thomas E. Ehmet, Telephone: (505) 766-1486.

SUPPLEMENTARY INFORMATION:

I. Background on the Utah Program

On January 21, 1981, the Secretary of the Interior conditionally approved the Utah program. General background information on the Utah program, including the Secretary's findings, the disposition of comments, and the conditions of approval of the Utah program can be found in the January 21, 1981, **Federal Register** (46 FR 5899). Subsequent actions concerning Utah's program and program amendments can be found at 30 CFR 944.15, 944.16, and 944.30.

II. Submission of Proposed Amendment

By letter dated February 10, 1995, Utah at its own initiative submitted a proposed amendment to its program (administrative record No. UT-1019) pursuant to SMCRA (30 U.S.C. 1201 *et seq.*). Utah proposed to amend the Utah Coal Mining Rules at Utah Administrative Rules (Utah, Admin. R.) 645-401-120, 410, 430, 721, 810, 830,

and 910, concerning civil penalties, and Utah Admin. R. 645-402-120, 420, and 422, concerning individual civil penalties. Utah did so with the intent of making them consistent with recently promulgated revisions to the Utah Coal Reclamation Act of 1979 (UCA 40-10 *et seq.*).

OSM announced receipt of the proposed amendment in the February 27, 1995, **Federal Register** (60 FR 10531; administrative record No. UT-1029) and in the same document opened the public comment period and provided an opportunity for a public hearing on the substantive adequacy of the proposed amendment. The public comment period closed on March 29, 1995. The public hearing, scheduled for March 24, 1995, was not held because no one requested an opportunity to testify.

III. Director's Findings

As discussed below, the Director, in accordance with SMCRA and 30 CFR 732.15 and 732.17, finds that the proposed Utah program amendment submitted by Utah on February 10, 1995, is no less effective than the corresponding Federal regulations. Thus, the Director approves the proposed amendment.

1. Nonsubstantive Revision to Utah's Rules

Utah proposed a revision to previously-approved Utah Admin. R. 645-401-430, concerning assessment of violations and unabated violations, that is nonsubstantive in nature and consists of the addition of the acronym "UCA" prior to referenced provisions of Utah's statute.

Because the proposed revision to this previously-approved rule is nonsubstantive in nature, the Director finds that the proposed revision to Utah Admin. R. 645-401-430 is no less effective than the corresponding Federal regulation at 30 CFR 845.15(b)(2). The Director approves this proposed revision.

2. Substantive Revisions to Utah's Rules That Are Substantively Identical to the Corresponding Provisions of the Federal Regulations

Utah proposed revisions to the following rules that are substantive in nature and contain language that is substantively identical to the requirements of the corresponding Federal regulations (listed in parentheses). The rules include revisions that transfer power for assessing civil penalties from the Board of Oil, Gas, and Mining (Board) to the Division of Oil, Gas, and Mining (Division). These rule revisions

implement previously approved statutory revisions at UCA 40-10-20 (1)(a) and (3)(a) that had the same effect (see finding No. 4, 59 FR 49185, 49187, September 27, 1994).

Utah Admin. R. 645-401-120 (30 CFR 845.11), concerning information on civil penalties;

Utah Admin. R. 645-401-410 (30 CFR 845.15(a)), concerning assessments of separate violations for each day;

Utah Admin. R. 645-401-721, 645-401-723.100, and 645-401-742 (30 CFR 845.18(b)(1), 845.18(b)(3)(i), and 845.18(d)(2)), concerning procedures for informal assessment conferences;

Utah Admin. R. 645-401-810 (30 CFR 845.19(a)), concerning requests for formal hearings; and

Utah Admin. R. 645-402-420 and 645-402-422 (30 CFR 846.17(b) and 846.17(b)(2)), concerning procedures for assessment of individual civil penalties.

Because these proposed revisions of the Utah rules are substantively identical to the corresponding provisions of the Federal regulations, the Director finds that they are no less effective than the Federal regulations. The Director approves these proposed rules.

3. *Utah Admin. R. 645-401-830, Formal Review of the Violation Fact or the Civil Penalty*

Utah proposed to revise Utah Admin. R. 645-401-830 to specify that formal review of the violation fact or penalty will be conducted by the Board under the provisions of the "procedural rules of the Board (R641 Rules)." The "procedural rules of the Board (R641 Rules)" are entitled "Rules of Practice and Procedure of the Utah Board of Oil, Gas and Mining."

The corresponding Federal regulations at 30 CFR 845.19(a) state that the person charged with the violation may contest the fact of a violation or the proposed penalty for a violation by submitting, among other things, a petition to the Office of Hearings and Appeals. The procedural requirements that apply to these appeals are included in the Federal program at 43 CFR 4.1150 through 4.1171.

Utah's proposed reference to its "procedural rules of the Board (R641 Rules)" in proposed Utah Admin. R. 645-401-830 corresponds to the general reference in the Federal regulation at 30 CFR 845.19(a) to the Office of Hearings and Appeals. OSM previously approved, in Utah's original program, Utah's procedural requirements at Utah Admin. R. Part 641, the "Rules of Practice and Procedure of the Utah

Board of Oil, Gas and Mining." (see finding No. 4(q), 46 FR 5899, 5910, January 21, 1981).

On this basis, the Director finds that the proposed revision to Utah Admin. R. 645-401-830 is no less effective than the Federal regulations at 845.19(a) and approves it.

4. *Utah Admin. R. 645-401-910, Final Civil Penalty Assessment and Payment of Penalty*

Utah proposed to revise Utah Admin. R. 645-401-910 to require that, if the permittee fails to request a hearing as provided in Utah Admin. R. 645-401-810, the proposed civil penalty assessment will become a final order of the Division, rather than the Board. Utah also proposed revising Utah Admin. R. 645-401-910 to require that the penalty assessed will become due and payable upon expiration of the time allowed to request a hearing and "upon the Division fulfilling its responsibilities under UCA 40-10-20(3)(e)." Utah proposed to add the quoted language as part of this amendment.

The counterpart Federal regulation at 30 CFR 845.20(a) requires that if the person to whom a notice of violation or cessation order is issued fails to request a hearing as provided for in 30 CFR 845.19, the proposed assessment shall become a final order of the Secretary and the penalty assessed shall become due and payable upon expiration of the time allowed to request a hearing.

The Federal regulation at 30 CFR 845.20(a) differs from proposed Utah Admin. R. 645-401-910 only in that (1) it addresses the final order of the Secretary of the Interior and (2) it does not reference section 518(b) of SMCRA which is substantively identical to the Utah's referenced statutory provision at UCA 40-10-20(3)(e).

Utah's referenced statutory provision at UCA 40-10-20(3)(e) provides that, if the person charged with a violation fails to avail himself of the opportunity for a public hearing, a civil penalty shall be assessed by the Division after it has (1) determined that a violation did occur, (2) determined the amount of the penalty that is warranted, and (3) issued an order requiring that the penalty be paid. These provisions of Utah's statute are implemented in Utah Admin. R. 645-401-730, which states that the assessment conference officer will promptly serve the permittee with a notice of his or her action (i.e., an assessment notice) and will include a worksheet if the penalty has been lowered or raised from the original assessment.

Proposed Utah Admin. R. 645-401-910 therefore requires that, if the

permittee fails to request a hearing as provided in Utah Admin. R. 645-401-810, the proposed civil penalty assessment (i.e., the assessment notice required in Utah Admin. R. 645-401-730) will become a final order of the Division.

The Director finds that proposed Utah Admin. R. 645-401-910 is no less effective than the Federal regulation at 30 CFR 845.20(a) and approves it.

5. *Utah Admin. R. 645-402-120, Information on Individual Civil Penalties*

Utah proposed to revise Utah Admin. R. 645-402-120 to require that a Division-appointed, rather than a Board-appointed, assessment officer will assess individual civil penalties.

Proposed Utah Admin. R. 645-402-120 has no direct counterpart in the Federal regulations. However, the generally corresponding Federal regulation at 30 CFR 846.1 establishes the scope of OSM's individual civil penalty regulations when it states that 30 CFR Part 846 covers the assessment of individual civil penalties under section 518(f) of SMCRA.

Utah's statutory provision which corresponds to, and is substantively identical to, section 518(f) of SMCRA is UCA 40-10-20(6). As discussed in finding No. 2 above, OSM previously approved Utah's statutory provisions at UCA 40-10-20 that transferred power for assessment of civil penalties from the Board to the Division. It naturally follows that Utah also has the discretion to select the same State entity to be responsible for assessments of individual civil penalties.

On this basis, the Director finds that proposed Utah Admin. R. 645-402-120 is consistent with its statute as well as the Federal regulation at 30 CFR 846.1. Therefore, the Director approves proposed Utah Admin. R. 645-402-120.

IV. Summary and Disposition of Comments

Following are summaries of all substantive comments on the proposed amendment that were received by OSM, and OSM's responses to them.

1. *Public Comments*

OSM invited public comments on the proposed amendment, but none were received.

2. *Federal Agency Comments*

Pursuant to 732.17(h)(11)(i), OSM solicited comments on the proposed amendment from various Federal agencies with an actual or potential interest in the Utah program.

The U.S. Bureau of Mines responded on March 3, 1995, by telephone conversation, that it had no comments on the proposed amendment (administrative record No. UT-1028).

The U.S. Army Corps of Engineers responded on March 14, 1995, that the changes to the Utah program were satisfactory (administrative record No. UT-1032).

The U.S. Mine Safety and Health Administration (MSHA) responded on April 3, 1995, that no conflict could be found between the amendment and current MSHA regulations (administrative record No. UT-1040).

3. Environmental Protection Agency (EPA) Concurrence and Comments

Pursuant to 30 CFR 732.17(h)(11)(ii), OSM is required to solicit the written concurrence of EPA with respect to those provisions of the proposed program amendment that relate to air or water quality standards promulgated under the authority of the Clean Water Act (33 U.S.C. 1251 *et seq.*) or the Clean Air Act (42 U.S.C. 7401 *et seq.*).

None of the revisions that Utah proposed to make in its amendment pertain to air or water quality standards. Therefore, OSM did not request EPA's concurrence.

Pursuant to 732.17(h)(11)(i), OSM solicited comments on the proposed amendment from EPA (administrative record No. UT-1021). EPA responded on March 3, 1995, that it had no comments on the proposed amendment and did not believe that there would be any impacts to water quality standards promulgated under the Clean Water Act (administrative record No. UT-1031).

4. State Historic Preservation Officer (SHPO)

Pursuant to 30 CFR 732.17(h)(4), OSM solicited comments on the proposed amendment from the SHPO (administrative record No. UT-1021). The SHPO did not respond to OSM's request.

V. Director's Decision

Based on the above findings, the Director approves the proposed amendment as submitted by Utah on February 10, 1995.

The Director approves, as discussed in: finding No. 1, Utah Admin. R. 645-401-430, concerning a nonsubstantive editorial revision; finding No. 2, Utah Admin. R. 645-401-120, Utah Admin. R. 645-401-410, Utah Admin. R. 645-401-721, 723.100, and 742, Utah Admin. R. 645-401-810, and Utah Admin. R. 645-402-420 and 422, concerning substantive revisions that

are substantively identical to the corresponding Federal regulations; finding No. 3, Utah Admin. R. 645-401-830, concerning the formal review of the violation fact or the civil penalty; finding No. 4, Utah Admin. R. 645-401-910, concerning the final civil penalty assessment and payment of penalty; and finding No. 5, Utah Admin. R. 645-402-120, concerning information on individual civil penalties.

The Director approves the rules as proposed by Utah with the provision that they be fully promulgated in identical form to the rules submitted to and reviewed by OSM and the public.

The Federal regulations at 30 CFR part 944, codifying decisions concerning the Utah program, are being amended to implement this decision. This final rule is being made effective immediately to expedite the State program amendment process and to encourage States to bring their programs into conformity with the Federal standards without undue delay. Consistency of State and Federal standards is required by SMCRA.

VI. Procedural Determinations

1. Executive Order 12866

This rule is exempted from review by the Office of Management and Budget (OMB) under Executive Order 12866 (Regulatory Planning and Review).

2. Executive Order 12778

The Department of the Interior has conducted the reviews required by section 2 of Executive Order 12778 (Civil Justice Reform) and has determined that this rule meets the applicable standards of subsections (a) and (b) of that section. However, these standards are not applicable to the actual language of State regulatory programs and program amendments since each such program is drafted and promulgated by a specific State, not by OSM. Under sections 503 and 505 or SMCRA (30 U.S.C. 1253 and 1255) and the Federal regulations at 30 CFR 730.11, 732.15, and 732.17(h)(10), decisions on proposed State regulatory programs and program amendments submitted by the States must be based solely on a determination of whether the submittal is consistent with SMCRA and its implementing Federal regulations and whether the other requirements of 30 CFR parts 730, 731, and 732 have been met.

3. National Environmental Policy Act

No environmental impact statement is required for this rule since section 702(d) of SMCRA (30 U.S.C. 1292(d)) provides that agency decisions on proposed State regulatory program

provisions do not constitute major Federal actions within the meaning of section 102(2)(C) of the National Environmental Policy Act (42 U.S.C. 4332(2)(C)).

4. Paperwork Reduction Act

This rule does not contain information collection requirements that require approval by OMB under the Paperwork Reduction Act (44 U.S.C. 3507 *et seq.*).

5. Regulatory Flexibility Act

The Department of the Interior has determined 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.*). The State submittal that is the subject of this rule is based upon counterpart Federal regulations for which an economic analysis was prepared and certification made that such regulations would not have a significant economic effect upon a substantial number of small entities. Accordingly, this rule will ensure that existing requirements previously promulgated by OSM will be implemented by the State. In making the determination as to whether this rule would have a significant economic impact, the Department relied upon the data and assumptions for the counterpart Federal regulations.

List of Subjects in 30 CFR Part 944

Intergovernmental relations, Surface mining, Underground mining.

Dated: April 25, 1995.

Peter A. Rutledge,

Acting Assistant Director, Western Support Center.

For the reasons set out in the preamble, title 30, Chapter VII, subchapter T of the Code of Federal Regulations is amended as set forth below:

PART 944—UTAH

1. The authority citation for part 944 continues to read as follows:

Authority: 30 U.S.C. 1201 *et seq.*

2. Section 944.15 is amended by adding paragraph (dd) to read as follows:

§ 944.15 Approval of amendments to the State regulatory program.

* * * * *

(dd) Revisions to the following Utah Administrative Rules, as submitted to OSM on February 10, 1995, are approved effective May 2, 1995.

- 645-401-120 ... How Civil Penalty Assessments Are Made.
- 645-401-410 and 430. Assessment of Separate Violations for Each Day.
- 645-401-721, 723.100, and 742. Procedures for Informal Assessment Conferences.
- 645-401-810 and 830. Request for Formal Hearings.
- 645-401-910 ... Final Civil Penalty Assessment and Payment of Penalty.
- 645-402-120 ... Information on Individual Civil Penalties.
- 645-402-420 and 422. Procedures for Assessment of Individual Civil Penalties.

[FR Doc. 95-10777 Filed 5-1-95; 8:45 am]

BILLING CODE 4310-05-M

DEPARTMENT OF EDUCATION

34 CFR Part 690

RIN 1840-AB73

Federal Pell Grant Program; Presidential Access Scholarship Program

AGENCY: Department of Education.

ACTION: Final regulations; correction.

SUMMARY: This document corrects an error in the final regulations published in the **Federal Register** on November 1, 1994 for the Federal Pell Grant Program (59 FR 54718). These regulations implement statutory changes in the Federal Pell Grant Program authorized by title IV of the Higher Education Act of 1965, as amended by the Higher Education Amendments of 1992, and the Higher Education Technical Amendments of 1993.

FOR FURTHER INFORMATION CONTACT: Greg Gerrans, Office of Student Financial Assistance Programs, Office of Postsecondary Education, U.S. Department of Education, 600 Independence Avenue, S.W., Room 3045, Regional Office Building 3, Washington, D.C. 20202-5447. Telephone (202) 708-4607. Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1-800-877-8339 between 8 a.m. and 8 p.m., Eastern Time, Monday through Friday.

Dated: April 24, 1995.

David A. Longanecker,

Assistant Secretary for Postsecondary Education.

§ 690.12 [Corrected]

1. The following correction is made in FR Doc. 94-26832, published on November 1, 1994 (59 FR 54718):

On page 54732, column 1,
§ 690.12(b)(2) "Mailing the paper

application form to the Secretary." is corrected to read "Sending an approved application form to the Secretary."

[FR Doc. 95-10665 Filed 5-1-95; 8:45 am]

BILLING CODE 4000-01-P

DEPARTMENT OF COMMERCE

Patent and Trademark Office

37 CFR Parts 1 and 10

[Docket No. 950403086-5086-01]

RIN 0651-AA72

Revisions of Patent Cooperation Treaty Provisions

AGENCY: Patent and Trademark Office, Commerce.

ACTION: Final rule.

SUMMARY: The Patent and Trademark Office (Office) is amending the rules of practice relating to applications filed under the Patent Cooperation Treaty (PCT) in accordance with revised regulations under the PCT. The changes will result in a procedure whereby international applications improperly filed with the United States Receiving Office (RO/US) will, for a fee, be forwarded for processing to the International Bureau as Receiving Office.

EFFECTIVE DATE: June 1, 1995.

FOR FURTHER INFORMATION CONTACT: Charles Pearson at (703) 308-6515.

SUPPLEMENTARY INFORMATION: In a Notice of Proposed Rulemaking published in the **Federal Register** at 59 FR 33707 (June 30, 1994) and in the Patent and Trademark Office Official Gazette at 1164 Off. Gaz. Pat. Office 77 (July 26, 1994), the Office proposed to amend several rules of practice in patent cases. Recent changes to the PCT Regulations include the addition of a new section (PCT Rule 19.4) which provides for transmittal of an international application to the International Bureau, acting in its capacity as Receiving Office, in certain instances. Under the regulations currently in effect, at least one applicant is required, on filing the international application in the United States, to be a resident or national of the United States.

The practice under the revised PCT Regulations permits an international application filed with the United States Receiving Office to be forwarded to the International Bureau for processing in its capacity as a Receiving Office if the international application does not name an applicant who is indicated as being a U.S. resident or national, but names an

applicant who is indicated as a resident or national of another PCT Contracting State or if the indication of residence or nationality of the applicant is missing. The Receiving Office of the International Bureau will consider the international application to be received as of the date accorded by the United States Receiving Office. This practice will avoid the loss of a filing date in those instances where the United States Receiving Office is not competent to act, but where the international application is filed by an applicant who is a national or resident of a PCT Contracting State. Where questions arise regarding residence and nationality, e.g., where residence and nationality are not clearly set forth, the application will be forwarded to the International Bureau as Receiving Office. If all applicants are indicated to be residents and nationals of non-PCT Contracting States, PCT Rule 19.4 does not apply and the application is denied an international filing date.

Discussion of Specific Rules

Section 1.412(c)(6) is added to reflect that the United States Receiving Office, where it is not a competent Receiving Office under PCT Rule 19.1 or 19.2, could transmit the international application to the International Bureau for processing in its capacity as a Receiving Office.

Section 1.421(a) is amended to clarify that applications filed by applicants who are not residents or nationals of the United States, but who are residents or nationals of a PCT Contracting State or who indicate no residence or nationality, will, upon timely payment of the proper fee, be forwarded to the International Bureau for processing in its capacity as a Receiving Office.

Section 1.445(a)(5) is added to establish a fee equivalent to the transmittal fee in paragraph (a)(1) of this section for transmittal of an international application to the International Bureau for processing in its capacity as a Receiving Office.

Section 10.9 is amended to add a new provision consistent with PCT Rule 90.1, clarifying that an attorney or agent having the right to practice before the International Bureau when acting as Receiving Office may represent the applicant before the U.S. International Searching Authority or the U.S. International Preliminary Examining Authority. An individual who has the right to practice before the International Bureau when acting as Receiving Office, and who is not registered under § 10.6, may not prosecute patent applications in the national stage in the Office.

Response to Comments on the Rules

The comments received in response to the notice of proposed rulemaking have been given careful consideration. The comments and responses are discussed below.

Comment: One comment was received which approved of the proposed rule changes but noted other aspects of the U.S. National Phase filing procedures that could be changed to make the PCT more user-friendly.

Response: The Office is interested in making the PCT more user friendly. Amendments to §§ 1.494 and 1.495, which were effective on May 1, 1993, removed many of the differences in practice involving the filing of a regular U.S. application under 35 U.S.C. 111 and the entry of the national stage under 35 U.S.C. 371. These regulations now provide for a notice of missing requirements, similar to a notice under § 1.53(d), where a defective oath or declaration or a defective translation is filed.

Comment: Regarding § 1.412(c), one comment suggested that the proposed rule should be made consistent with PCT Rule 19.4(b) which provides for the transmittal of international applications to the International Bureau as Receiving Office "unless prescriptions concerning national security prevent the international application from being so transmitted" by incorporating such language into the proposed rule.

Response: The Office has adopted the suggestion and modified the rule by incorporating the suggested language from PCT Rule 19.4(b) in the regulation.

Comment: One comment regarding § 1.445(a)(5) mentioned that the word "competent" should be deleted because it is not "necessary and may be inaccurate" when no applicant in an international application is a "resident or national of a PCT Contracting State."

Response: The Office has adopted the suggestion and modified the rule by deleting "competent" from § 1.445(a)(5). The second occurrence of the word "competent" has also been deleted from 37 CFR 1.412(c)(6), for the same reasons.

Comment: Regarding § 10.9(c), there were a few comments which focus on the wording. Specifically, one comment noted that the word "appointed" is confusing because it is not clear if it includes "an officer or employee of a legal-entity patent applicant" in cases where the United States of America is not designated. An example was provided which noted "if the only applicant was XYZ Company, would the president of the Company be authorized to prosecute the application before the USPTO as an International Searching

and Preliminary Examining Authority? In countries permitting assignee filing it is normal for any authorized officer or employee of the company to be able to represent the company without regard as to whether he is authorized to practice as an agent or attorney before the patent office."

Response: The proposed regulation is sufficiently clear on this point. If a person has the authority to represent an applicant, either a legal entity applicant or a real person, before the International Bureau as Receiving Office, then that person has the right to represent that applicant before the United States International Searching Authority and the United States International Preliminary Examining Authority.

Comment: Another comment about Rule 10.9(c) is that the word "only" is overlimiting and should be deleted from the Rule because it excludes Article 19 amendments filed before the International Bureau. It was suggested that the Rule be changed as follows: —* * * prosecute an International Application before the United States Patent and Trademark Office acting as an International Searching or Preliminary Examining Authority, * * *

Response: The Office will not adopt the suggestion. The word "only" in the Rule signifies that such persons may not prosecute an international application in the national stage before the USPTO. The rule is not meant to control who may practice before the International Bureau. Such a person would clearly be allowed to file Article 19 amendments with the International Bureau by virtue of PCT Rule 90.1(a).

Comment: A final comment made about Rule 10.9(c) is that the last phrase added is "too broad" because it does not recite who is entitled to act before the International Bureau. It was suggested that the rule should be changed to include the phrase—* * * for a national Office of a Contracting State of which an applicant is a resident or national—at the end of the rule.

Response: The Office has adopted the suggestion to the extent that an explicit reference to PCT Rule 83.1^{bis} has been inserted in the regulation. Since PCT Rule 83.1^{bis} clearly sets forth who may practice before the International Bureau, it is not necessary to repeat that information here. Thus, the regulation clearly sets forth who may practice before the United States International Searching and Preliminary Examining Authorities.

Other Considerations

The rule changes are in conformity with the requirements of the Regulatory

Flexibility Act, 5 U.S.C. 601 *et seq.*, Executive Order 12612, and the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 *et seq.* These rule changes have been determined to be not significant for the 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, Small Business Administration, that the rule changes will not have a significant economic impact on a substantial number of small entities (Regulatory Flexibility Act, 5 U.S.C. 605(b)), because the rules would affect only a small number of international applications and would provide more streamlined and simplified procedures for filing and prosecuting international applications under the PCT.

The Office has also determined that these rule changes have no federalism implications affecting the relationship between the National government and the States as outlined in Executive Order 12612.

These rule changes will not impose any additional burden under the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 *et seq.* The paperwork burden imposed by adherence to the PCT is currently approved by the Office of Management and Budget under control number 0651-0021.

List of Subjects

37 CFR Part 1

Administrative practice and procedure, Courts, Freedom of information, Inventions and patents, Reporting and recordkeeping requirements, Small businesses.

37 CFR Part 10

Administrative practice and procedure, Inventions and patents, Lawyers, Reporting and recordkeeping requirements, Trademarks.

For the reasons set forth in the preamble, 37 CFR parts 1 and 10 are amended to read as follows:

PART 1—RULES OF PRACTICE IN PATENT CASES

1. The authority citation for 37 CFR part 1 continues to read as follows:

Authority: 35 U.S.C. 6 unless otherwise noted.

2. Section 1.412 is amended by adding new paragraph (c)(6) to read as follows:

§ 1.412 The United States Receiving Office.

* * * * *

(c) * * *

(6) Reviewing and, where the United States Receiving Office is not the competent Receiving Office under § 1.421(a) and PCT Rule 19.1 or 19.2, transmitting the international application to the International Bureau for processing in its capacity as a Receiving Office unless prescriptions concerning national security prevent the application from being so transmitted (PCT Rule 19.4).

3. Section 1.421 is amended by revising paragraph (a) to read as follows:

§ 1.421 Applicant for international application.

(a) Only residents or nationals of the United States of America may file international applications in the United States Receiving Office. If an international application does not include an applicant who is indicated as being a resident or national of the United States of America, and at least one applicant:

(1) Has indicated a residence or nationality in a PCT Contracting State, or

(2) Has no residence or nationality indicated; applicant will be so notified and, if the international application includes a fee amount equivalent to that required by § 1.445(a)(5), the international application will be forwarded for processing to the International Bureau acting as a Receiving Office. (See also § 1.412(c)(6)).

* * * * *

4. Section 1.445 is amended by adding new paragraph (a)(5) to read as follows:

§ 1.445 International application filing, processing and search fees.

(a) * * *

(5) A fee equivalent to the transmittal fee in paragraph (a)(1) of this section for transmittal of an international application to the International Bureau for processing in its capacity as a Receiving Office (PCT Rule 19.4).

* * * * *

5. The authority citation for 37 CFR part 10 would continue to read as follows:

Authority: 5 U.S.C. 500; 15 U.S.C. 1123; 35 U.S.C. 6, 31, 32, 41.

6. Section 10.9 is amended by revising paragraph (c) to read as follows:

§ 10.9 Limited recognition in patent cases.

* * * * *

(c) An individual not registered under § 10.6 may, if appointed by applicant to do so, prosecute an international application only before the U.S. International Searching Authority and

the U.S. International Preliminary Examining Authority, provided: The individual has the right to practice before the national office with which the international application is filed (PCT Art. 49, Rule 90 and § 1.455) or before the International Bureau when acting as Receiving Office pursuant to PCT Rules 83.1^{bis} and 90.1.

Dated: April 25, 1995.

Lawrence J. Goffney, Jr.,

Acting Assistant Secretary of Commerce and Acting Commissioner of Patents and Trademarks.

[FR Doc. 95-10743 Filed 5-1-95; 8:45 am]

BILLING CODE 3510-16-M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[AZ 42-1-6916a; FRL-5186-7]

Approval and Promulgation of Implementation Plans; Arizona State Implementation Plan Revision, Pinal County Air Quality Control District; and Section 112(l) Approval of Pinal County Air Quality Control District Program for the Issuance of Permits Containing Voluntarily Accepted Federally Enforceable Conditions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: The EPA is taking direct final action on revisions to the Arizona State Implementation Plan. The revisions concern synthetic minor permit rules from the Pinal County Air Quality Control District (Pinal or District). The intended effect of approving these synthetic minor regulations is to allow facilities to voluntarily accept federally enforceable limits on their potential emissions. This approval action will incorporate these rules into the federally approved SIP. In order to extend the federal enforceability of conditions in permits to hazardous air pollutants (HAP), EPA is also approving Pinal's synthetic minor regulations pursuant to section 112 of the Act.

DATES: This final rule is effective on July 3, 1995 unless adverse or critical comments are received by June 1, 1995. If the effective date is delayed, a timely notice will be published in the **Federal Register**.

ADDRESSES: Copies of the rules and EPA's Technical Support Document for the synthetic minor program are available for public inspection at the following location:

Operating Permits Section (A-5-2), Air and Toxics Division, U.S.

Environmental Protection Agency, Region IX, 75 Hawthorne Street, San Francisco, CA 94105.

Air Docket (6102), U.S. Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460.

Copies of the submitted rules are also available for inspection at the following location:

Pinal County Air Quality Control District, 457 South Central Avenue, Florence, Arizona 85232.

Arizona Department of Environmental Quality, 3033 North Central Avenue, Phoenix, Arizona 85012.

FOR FURTHER INFORMATION CONTACT:

Regina Spindler, Operating Permits Section (A-5-2), Air and Toxics Division, U.S. Environmental Protection Agency, Region IX, 75 Hawthorne Street, San Francisco, CA 94105, Telephone: (415) 744-1251.

SUPPLEMENTARY INFORMATION:

Applicability

The rules being approved into the Arizona SIP include: Pinal County Air Quality Control District (Pinal) Code of Regulations, Chapter 1, Article 3, section 1-3-140, Definitions, subsections 5, 15, 21, 32, 33, 35, 50, 51, 58, 59, 103, and 123; Chapter 3, Article 1, section 3-1-081, Permit conditions, subsection (A)(8)(a); Chapter 3, Article 1, section 3-1-084, Voluntarily Accepted Federally Enforceable Emissions Limitations; Applicability; Reopening; Effective Date; and Chapter 3, Article 1, section 3-1-107, Public Notice and Participation. These rules were submitted by the Arizona Department of Environmental Quality to EPA on August 15, 1994 for approval into the State Implementation Plan. Pinal submitted these provisions for approval under section 112(l) on October 25, 1994.

Background

On June 28, 1989 (54 FR 27274), EPA published criteria for approving and incorporating into the SIP regulatory programs for the issuance of federally enforceable state operating permits (FESOP). Permits issued pursuant to an operating permit program approved into the SIP as meeting these criteria may be considered federally enforceable. On November 3, 1993, EPA announced in a guidance document entitled, "Approaches to Creating Federally Enforceable Emissions Limits," signed by John S. Seitz, Director, Office of Air Quality Planning and Standards, that this mechanism could be extended to create federally enforceable limits for

emissions of hazardous air pollutants (HAP) if the program were approved pursuant to section 112(l) of the Act. Approval under section 112(l) is necessary because SIP approval extends only to the control of criteria pollutants, i.e., those for which primary and secondary ambient air quality standards have been established by EPA pursuant to section 109 of the Act.¹ Federally enforceable limits on criteria pollutants may have the incidental effect of limiting certain HAP listed pursuant to section 112(b).² As a legal matter, no additional program approval by EPA is required in order for these criteria pollutant limits to be recognized as federally enforceable. However, section 112 of the Act provides the underlying authority for controlling all HAP emissions.

EPA Evaluation and Action

The Arizona Department of Environmental Quality submitted Pinal's synthetic minor permit program on August 15, 1994 for approval into the SIP. The EPA found this submittal to be complete on September 1, 1994. Pinal submitted the program for approval under section 112(l) on October 25, 1994. Pinal's synthetic minor permit program is based on provisions (adopted August 11, 1994) that allow a source to apply voluntarily for limits on emissions, production or operation to be placed in its permit to limit the source's total potential emissions. These provisions are contained within District permitting regulations (adopted November 3, 1993) that apply to both major and nonmajor sources and that provide for the issuance of integrated construction and operating permits. These permit regulations require sources that modify or construct to first obtain a permit that contains both preconstruction and operating requirements. The regulations also require all existing sources to apply for an operating permit. Therefore, new, modifying, and existing sources are eligible to obtain voluntary limits under Pinal's synthetic minor provisions.

The voluntary limits established pursuant to Pinal's synthetic minor provisions will be specifically designated as federally enforceable in the permit. When the permit is issued pursuant to either the District's EPA-

approved Title V or New Source Review program, the entire permit will be federally enforceable, except for those requirements that are enforceable only by the District and/or State and that Pinal specifically designates as not being federally enforceable. When the permit is issued to existing sources pursuant to the District's nonmajor source operating permit program, only federal applicable requirements and voluntary limits that are designated as such pursuant to section 3-1-084 will be federally enforceable since the District's nonmajor source operating permit program is not approved into the SIP by EPA. Pinal is not seeking to receive approval of its program such that all permits issued under the approved program are federally enforceable. Rather, Pinal is seeking approval of a rule that allows for federally enforceable terms and conditions, accepted voluntarily, to be placed in source construction and operating permits. The EPA interprets the June 28, 1989 **Federal Register** notice cited above to apply to approval of synthetic minor rules that provide for creating distinct federally enforceable limits in permits, as well as to approval of synthetic minor rules that provide for the issuance of permits that are federally enforceable in their entirety.

Though Pinal has submitted a number of regulations relating to the issuance of permits as a revision to its portion of the Arizona State Implementation Plan, today's action extends only to those provisions that pertain to the creation of voluntarily accepted federally enforceable emission limits. These provisions include section 3-1-084 which provides for establishing the federally enforceable emission, production, and operational limits in the source permit along with associated federally enforceable compliance requirements such as monitoring, recordkeeping, and reporting requirements. This provision also requires review of each permit by EPA as well as an opportunity for public comment pursuant to the public participation procedures in section 3-1-107. This action also extends to these public participation procedures as well as to a number of definitions in section 1-3-140 and to the requirement of section 3-1-081(A)(8)(a) that sources comply with the terms and conditions of the permit that contains the voluntarily accepted federally enforceable conditions. The EPA will take action on the remainder of the District's August 15, 1994 submittal at a future date.

The June 28, 1989 **Federal Register** notice specifies the following five

approval criteria for approving FESOP programs into the SIP: (1) The program must be submitted to and approved by EPA; (2) the program must impose a legal obligation on the operating permit holders to comply with the terms and conditions of the permit, and permits that do not conform with the June 28, 1989 criteria or EPA's underlying regulations shall be deemed not federally enforceable; (3) the program must contain terms and conditions that are at least as stringent as any requirements contained in the SIP, enforceable under the SIP, or any section 112 or other CAA requirement, and may not allow for the waiver of any CAA requirement; (4) permits issued under the program must contain conditions that are permanent, quantifiable, and enforceable as a practical matter; and (5) permits that are intended to be federally enforceable must be issued subject to public participation and must be provided to EPA in proposed form on a timely basis. The June 28, 1989 notice does not address HAP because it was written prior to the 1990 amendments to section 112, not because it establishes requirements unique to criteria pollutants. Hence, EPA believes that these five criteria are also appropriate for evaluating and approving synthetic minor permit programs under section 112(l).

In addition to meeting the criteria in the June 28, 1989 notice, a synthetic minor permit program that addresses HAP must meet the statutory criteria for approval under section 112(l)(5). Section 112(l) allows EPA to approve a program only if it: (1) Contains adequate authority to assure compliance with any section 112 standards or requirements; (2) provides for adequate resources; (3) provides for an expeditious schedule for assuring compliance with section 112 requirements; and (4) is otherwise likely to satisfy the objectives of the Act.

The EPA plans to codify the approval criteria for programs limiting potential to emit of HAP, such as FESOP programs, through amendments to Subpart E of Part 63, the regulations promulgated to implement section 112(l) of the Act. (See 58 FR 62262, November 26, 1993.) The EPA currently anticipates that these regulatory criteria, as they apply to FESOP programs, will mirror those set forth in the June 28, 1989 notice. The EPA also anticipates that since FESOP programs approved pursuant to section 112(l) prior to the planned Subpart E revisions will have been approved as meeting these criteria, further approval actions for those programs will not be necessary. The EPA believes it has authority under

¹ The following are considered criteria pollutants: oxides of nitrogen, lead, ozone precursors, sulfur dioxide, carbon monoxide, and PM-10.

² See "Options for Limiting the Potential to Emit of a Stationary Source Under Section 112 and Title V of the Clean Air Act," from John Seitz, dated January 25, 1995. EPA intends to issue further technical guidance on ensuring that the "effect" of limiting HAP is enforceable as a practical matter.

section 112(l) to approve programs to limit potential to emit of HAP directly under section 112(l) prior to this revision to Subpart E. The EPA is therefore approving Pinal's synthetic minor program now so that Pinal may begin to issue federally enforceable synthetic minor permits as soon as possible.

The EPA believes that Pinal's synthetic minor program meets the approval criteria specified in the June 28, 1989 **Federal Register** notice and in section 112(l)(5) of the Act. Please refer to the Technical Support Document for a thorough analysis of the June 28, 1989 criteria and the statutory criteria of section 112(l)(5) as applied to Pinal's synthetic minor program.

The EPA has evaluated the submitted rules and has determined that they are consistent with the CAA, EPA regulations, and EPA policy. Therefore, Pinal County Air Quality Control District Code of Regulations Chapter 1, Article 3, section 1-3-140, Definitions, subsections 5, 15, 21, 32, 33, 35, 50, 51, 58, 59, 103, and 123; Chapter 3, Article 1, section 3-1-081, Permit conditions, subsection (A)(8)(a); Chapter 3, Article 1, section 3-1-084, Voluntarily Accepted Federally Enforceable Emissions Limitations; Applicability; Reopening; Effective Date; and Chapter 3, Article 1, section 3-1-107, Public Participation, are being approved under section 110(k)(3) of the CAA as meeting the requirements of section 110(a) and Part D and under section 112(l) of the CAA as meeting the requirements of section 112(l)(5).

Pinal has already begun to issue permits containing voluntarily accepted limits pursuant to the regulations listed above. If the District followed its own procedures, each of these permits was subject to public notice and prior EPA review. Therefore, EPA will consider all voluntarily accepted limits in District permits that were processed in a manner consistent with the District regulations being acted upon today and the five June 28, 1989 criteria to be federally enforceable with the promulgation of this rule provided that any such permits containing the voluntarily accepted limits that the District wishes to make federally enforceable are submitted to EPA and accompanied by documentation that the procedures approved today have been followed. The EPA will expeditiously review any individual permits so submitted to ensure their conformity to the program requirements.

Nothing in this action should be construed as permitting or allowing or establishing a precedent for any future implementation plan. Each request for

revision to the state implementation plan shall be considered separately in light of specific technical, economic, and environmental factors and in relation to relevant statutory and regulatory requirements.

The EPA is publishing this notice without prior proposal because the Agency views this as a noncontroversial amendment and anticipates no adverse comments. However, in a separate document in this **Federal Register** publication, EPA is proposing to approve the SIP revision and section 112(l) submittal should adverse or critical comments be filed. This action will be effective July 3, 1995, unless by June 1, 1995, adverse or critical comments are received.

If EPA receives such comments, this action will be withdrawn before the effective date by publishing a subsequent notice that will withdraw the final action. All public comments received will then be addressed in a subsequent final rule based on this action serving as a proposed rule. The EPA will not institute a second comment period on this action. Any parties interested in commenting on this action should do so at this time. If no such comments are received, the public is advised that this action will be effective July 3, 1995.

Regulatory Process

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

Application for limits under Pinal's synthetic minor provisions is voluntary and therefore this approval under sections 110 and 112 of the Act does not create any new requirements. Therefore, because the federal SIP-approval and section 112(l) approval does not impose any new requirements, I certify that it does not have a significant impact on any small entities affected. Moreover, due to the nature of the federal-state relationship under the CAA, preparation of a regulatory flexibility analysis would constitute federal inquiry into the economic reasonableness of state action. The CAA forbids EPA to base its actions concerning SIPs on such grounds. *Union Electric Co. v. U.S. E.P.A.*, 427 U.S. 246, 256-66 (S. Ct. 1976); 42 U.S.C. 7410 (a)(2).

The OMB has exempted this action from review under Executive Order 12866.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Reporting and recordkeeping requirements.

Note: Incorporation by reference of the State Implementation Plan for the State of Arizona was approved by the Director of the Federal Register on July 1, 1982.

Dated: March 28, 1995.

Felicia Marcus,

Regional Administrator.

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

PART 52—[AMENDED]

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

Authority: 42 U.S.C. 7401-7671q.

Subpart D—Arizona

2. Section 52.120 is amended by adding paragraphs (c)(71) to read as follows:

§ 52.120 Identification of plan.

* * * * *

(c) * * *

(71) New and amended regulations for the following agencies were submitted on August 15, 1994 by the Governor's designee.

(i) Incorporation by reference.

(A) Pinal County Air Quality Control District.

(1) Chapter 1, Article 3, section 1-3-140, subsections 5, 15, 21, 32, 33, 35, 50, 51, 58, 59, 103, and 123, adopted on November 3, 1993; Chapter 3, Article 1, section 3-1-081(A)(8)(a), adopted on November 3, 1993; Chapter 3, Article 1, section 3-1-084, adopted on August 11, 1994; and Chapter 3, Article 1, section 3-1-107, adopted on November 3, 1993.

* * * * *

[FR Doc. 95-10698 Filed 5-1-95; 8:45 am]

BILLING CODE 6560-50-W

40 CFR Part 52

[MS-20-1-6562a; FRL-5173-9]

Approval and Promulgation of Implementation Plans; Mississippi: Approval of Revisions to Construction and Operation Permit Regulations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is approving revisions to the Mississippi State Implementation Plan (SIP) to allow the State of Mississippi to issue Federally enforceable state operating permits (FESOP). On January 26, 1994, the State of Mississippi through the Mississippi Department of Environmental Quality (MDEQ) submitted a SIP revision fulfilling the requirements necessary for a state FESOP program to become Federally enforceable. In order to extend the Federal enforceability of Mississippi's FESOP program to hazardous air pollutants (HAP), EPA is also approving Mississippi's FESOP program pursuant to section 112 of the Clean Air Act as amended in 1990 (CAA) so that the State may issue FESOP for HAP.

DATES: This final rule will be effective July 3, 1995 unless adverse or critical comments are received by June 1, 1995. If the effective date is delayed, timely notice will be published in the **Federal Register**.

ADDRESSES: Written comments should be addressed to Scott Miller, at the EPA Regional Office listed below. Copies of the documents relative to this action are available for public inspection during normal business hours at the following locations. The interested persons wanting to examine these documents should make an appointment with the appropriate office at least 24 hours before the visiting day.

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

Environmental Protection Agency, Region 4, Air Programs Branch, 345 Courtland Street, NE, Atlanta, Georgia 30365

Mississippi Department of Environmental Quality, Bureau of Air Quality Control, Air Quality Division, Post Office Box 10385, Jackson, Mississippi 39285

FOR FURTHER INFORMATION CONTACT: Carla Pierce, Title V, Regional Program Manager, Air Programs Branch, Air, Pesticides & Toxics Management Division, Region 4, Environmental Protection Agency, 345 Courtland Street, NE., Atlanta, Georgia 30365. The telephone number is 404/347-2864.

SUPPLEMENTARY INFORMATION: On January 26, 1994, the State of Mississippi through the MDEQ submitted a SIP revision designed to make certain permits issued under Mississippi's existing minor source operating permit program Federally enforceable pursuant to EPA requirements as specified in a **Federal**

Register notice, "Requirements for the preparation, adoption, and submittal of implementation plans; air quality, new source review; final rules," (see 54 FR 22274, June 28, 1989). The State will continue to issue permits which are not Federally enforceable under its existing minor source operating permit rules as it has done in the past. The SIP revision which is the subject of today's rulemaking adds additional requirements to the State's current minor source operating permit program which allows the State to issue FESOP. This voluntary SIP revision allows EPA and citizens under the CAA to enforce terms and conditions of Mississippi's FESOP program. Operating permits that are issued under the State's FESOP program that is approved into the State SIP and under section 112(l) will provide federally enforceable limits to an air pollution source's potential to emit. Limiting of a source's potential to emit through federally enforceable operating permits can affect a source's applicability to federal regulations such as title V operating permits, New Source Review (NSR) preconstruction permits, Prevention of Significant Deterioration (PSD) preconstruction permits for criteria pollutants and federal air toxics requirements mandated under section 112 of the CAA.

In the aforementioned June 28, 1989, **Federal Register** notice, EPA listed five criteria necessary to make a State's minor source operating permit program Federally enforceable and, therefore, approvable into the SIP. This revision satisfies the five criteria for Federal enforceability of the State's FESOP program.

The first criteria for a state's operating permit program to become Federally enforceable is that the permit program that the state wishes to be Federally enforceable must be approved into the SIP. On January 26, 1994, the State of Mississippi submitted through MDEQ a SIP revision designed to meet the five criteria for Federal enforceability. Today's action will approve these regulations into the Mississippi SIP, thereby, meeting the first criteria for Federal enforceability.

The second criteria for a state's operating permit program to become Federally enforceable is that the regulations approved into the SIP impose a legal obligation that operating permit holders adhere to the terms and limitations of such permits. Mississippi's regulations meet this criteria in Regulation APC-S-2, Section II of the State regulations by requiring the following:

In addition to the requirements contained herein, no permit shall be issued unless the

applicant has complied with applicable requirements including * * * and additional relevant Rules and Regulations promulgated by the Commission and/or Permit Board.

Hence, the second criteria for Federal enforceability is met.

The third criteria necessary for a state's operating permit program to be Federally enforceable is that the state operating permit program require that all emissions limitations, controls, and other requirements imposed by such permits will be at least as stringent as any other applicable limitations and requirements contained in the SIP or enforceable under the SIP, and that the program may not issue permits that waive, or make less stringent, any limitations or requirements contained in or issued pursuant to the SIP, or that are otherwise "Federally enforceable" (e.g. standards established under sections 111 and 112 of the Act). Mississippi satisfies this criteria in two regulations included in the State's SIP submittal. APC-S-2, Section II.B.5 requires that all permits to construct or operate shall specify in their application the air emission rate for each air pollutant subject to regulation under the Federal Clean Air Act that can be reasonably expected to be emitted from a facility. In addition, Regulation APC-S-2, Section VI.E.4 provides that the granting of a permit shall not relieve an air pollution source of the responsibility to comply with other applicable requirements of the permitting regulation or other applicable regulations or law. Taken together, these two regulations satisfy the third criteria for Federal enforceability.

The fourth criteria for a state's operating permit program to become Federally enforceable is that limitations, controls, and requirements in the operating permits are quantifiable, and otherwise enforceable as a practical matter. While a determination of what is practically enforceable will generally differ based on process type and emissions, the State has included several regulations designed to ensure that permit limitations are enforceable as a practical matter. APC-S-2, Section VII.B.2 requires that when performing stack tests to determine compliance with an applicable regulation that the results be expressed in units consistent with the emission standard of the applicable regulation for which the source is attempting to show compliance. In addition, this regulation requires that the stack test demonstration be reported in "units of mass per time" of the applicable regulation. Regulation APC-S-2, Section XI, provides that MDEQ may require in any permit the installation of

sampling ports with access and the installation, maintenance and use of monitoring equipment as well as be required to maintain records to show compliance with applicable emission standards. Therefore, the Mississippi FESOP program satisfies the fourth criteria for Federal enforceability.

The fifth criteria for a state's operating permit program to become Federally enforceable is to provide EPA and the public with timely notice of the proposal and issuance of such permits, and to provide EPA, on a timely basis, with a copy of each proposed (or draft) and final permit intended to be federally enforceable. This process also must provide for an opportunity for public comment on the permit applications prior to issuance of the final permit. Regulation APC-S-2, Section V provides a 30 day opportunity for public comment period as well as the opportunity for a public hearing on any application where MDEQ believes there is sufficient interest. Regulation APC-S-2, Section V.C provides that "the Permit Board may provide notice to the public and provide opportunity for public comment on any application for a Construction Permit or Operating Permit." EPA notes that any permit which has not gone through an opportunity for public comment and EPA review in the Mississippi FESOP program will not be Federally enforceable.

In addition to requesting approval into the SIP, Mississippi has also requested approval of its FESOP program under section 112(l) of the Act for the purpose of creating Federally enforceable limitations on the potential to emit of HAP through the issuance of FESOP. Approval under section 112(l) is necessary because the proposed SIP approval discussed above only extends to the control of criteria pollutants. Federally enforceable limits on criteria pollutants (i.e., VOC's or PM-10) may have the incidental effect of limiting certain HAP listed pursuant to section 112(b).¹ However, section 112 of the Act provides the underlying authority for controlling all HAP emissions.

EPA believes that the five approval criteria for approving FESOP programs into the SIP, as specified in the June 28, 1989, **Federal Register** notice, are also appropriate for evaluating and approving the programs under section 112(l). The June 28, 1989, notice does not address HAP because it was written prior to the 1990 amendments to section

112, not because it establishes requirements unique to criteria pollutants.

In addition to meeting the criteria in the June 28, 1989, notice, a FESOP program that addresses HAP must meet the statutory criteria for approval under section 112(l)(5). Section 112(l) allows EPA to approve a program only if it: (1) Contains adequate authority to assure compliance with any section 112 standards or requirements; (2) provides for adequate resources; (3) provides for an expeditious schedule for assuring compliance with section 112 requirements; and (4) is otherwise likely to satisfy the objectives of the CAA.

EPA plans to codify the approval criteria for programs limiting potential to emit of HAP, such as FESOP programs, through amendments to Subpart E of Part 63, the regulations promulgated to implement section 112(l) of the CAA. (See 58 FR 62262, November 26, 1993.) EPA currently anticipates that these regulatory criteria, as they apply to FESOP programs, will mirror those set forth in the June 28, 1989, notice. The EPA currently anticipates that since FESOP programs approved pursuant to section 112(l) prior to the planned Subpart E revisions will have been approved as meeting these criteria, further approval actions for those programs will not be necessary.

EPA believes it has authority under section 112(l) to approve programs to limit potential to emit of HAP directly under section 112(l) prior to this revision to Subpart E. Section 112(l)(5) requires the EPA to disapprove programs that are inconsistent with guidance required to be issued under section 112(l)(2). This might be read to suggest that the "guidance" referred to in section 112(l)(2) was intended to be a binding rule. Even under this interpretation, EPA does not believe that section 112(l) requires this rulemaking to be comprehensive. That is, it need not address every possible instance of approval under section 112(l). EPA has already issued regulations under section 112(l) that would satisfy any section 112(l)(2) requirement for rulemaking. Given the severe timing problems posed by impending deadlines set forth in "maximum achievable control technology" (MACT) emission standards under section 112 and for submittal of title V permit applications, EPA believes it is reasonable to read section 112(l) to allow for approval of programs to limit potential to emit prior to promulgation of a rule specifically addressing this issue. EPA is therefore approving Mississippi's FESOP program

so that Mississippi may begin to issue FESOP as soon as possible.

EPA believes that Mississippi's FESOP program meets the approval criteria specified in the June 28, 1989 **Federal Register** notice and in section 112(l)(5) of the CAA. As discussed previously in this notice, Mississippi's FESOP program meets the five criteria necessary for Federal enforceability.

Regarding the statutory criteria of section 112(l)(5) referred to above, EPA believes Mississippi's FESOP program contains adequate authority to assure compliance with section 112 requirements because the third criterion of the June 28, 1989, notice is met, that is, because the program does not allow for the waiver of any section 112 requirement. Sources that become minor through a permit issued pursuant to this program would still be required to meet section 112 requirements applicable to non-major sources.

Regarding the requirement for adequate resources, EPA believes Mississippi has demonstrated that it can provide for adequate resources to support the FESOP program. EPA expects that resources will continue to be adequate to administer that portion of the State's minor source operating permit program under which FESOP will be issued since Mississippi has administered a minor source operating permit program for several years. EPA will monitor Mississippi's implementation of its FESOP to ensure that adequate resources are in fact available. EPA also believes that Mississippi's FESOP program provides for an expeditious schedule for assuring compliance with section 112 requirements. This program will be used to allow a source to establish a voluntary limit on potential to emit to avoid being subject to a CAA requirement applicable on a particular date. Nothing in Mississippi's FESOP program would allow a source to avoid or delay compliance with a CAA requirement if it fails to obtain an appropriate federally enforceable limit by the relevant deadline. Finally, EPA believes it is consistent with the intent of section 112 and the CAA for states to provide a mechanism through which sources may avoid classification as a major source by obtaining a Federally enforceable limit on potential to emit.

With the addition of these provisions, Mississippi's FESOP program satisfies all the requirements listed in the June 28, 1989, **Federal Register** notice. EPA is approving this revision to the State of Mississippi's SIP thus making the State's FESOP program Federally enforceable.

¹ The EPA intends to issue guidance addressing the technical aspects of how these criteria pollutant limits may be recognized for purposes of limiting a source's potential to emit of HAP to below section 112 major source levels.

Final Action

In this action, EPA is approving the Mississippi FESOP program. EPA is publishing this action without prior proposal because the Agency views this as a noncontroversial amendment and anticipates no adverse comments. However, in a separate document in this **Federal Register** publication, EPA is proposing to approve the SIP revision should adverse or critical comments be filed. This action will be effective July 3, 1995 unless, within 30 days of its publication, adverse or critical comments are received. If EPA receives such comments, this action will be withdrawn before the effective date by publishing a subsequent document that will withdraw the final action. All public comments received will then be addressed in a subsequent final rule based on this action serving as a 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. If no such comments are received, the public is advised that this action will be effective July 3, 1995.

The Agency has reviewed this request for revision of the federally-approved SIP for conformance with the provisions of the 1990 Amendments enacted on November 15, 1990. EPA has determined that this action conforms with those requirements.

Under section 307(b)(1) of the CAA, 42 U.S.C. 7607(b)(1), petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by July 3, 1995. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for 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) of the CAA, 42 U.S.C. 7607(b)(2).) The Office of Management and Budget has exempted this action from review under Executive Order 12866.

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

Under the Regulatory Flexibility Act, 5 U.S.C. 600 *et seq.*, EPA must prepare

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

SIP approvals under section 110 and subchapter I, part D of the CAA do not create any new requirements, but simply approve requirements that the State is already imposing. Therefore, because the federal SIP-approval does not impose any new requirements, I certify that it does not have a significant impact on any small entities affected. Moreover, due to the nature of the federal-state relationship under the CAA, preparation of a regulatory flexibility analysis would constitute federal inquiry into the economic reasonableness of state action. The CAA forbids EPA to base its actions concerning SIPs on such grounds. *Union Electric Co. v. U.S. E.P.A.*, 427 U.S. 246, 256-66 (S.Ct. 1976); 42 U.S.C. 7410(a)(2).

List of Subjects in 40 CFR Part 52

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

Dated: March 1, 1995.

Patrick M. Tobin,

Acting Regional Administrator.

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

PART 52—[AMENDED]

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

Authority: 42 U.S.C. 7401-7671q.

Subpart Z—Mississippi

2. Section 52.1270 is amended by adding paragraph (c)(25) to read as follows:

§ 52.1270 Identification of plan.

* * * * *

(c) * * *

(25) Revisions to minor source operating permit rules submitted by the Mississippi Department of Environmental Quality on January 26, 1994.

(i) Incorporation by reference.

(A) Regulation APC-S-2, effective January 9, 1994.

(ii) Other material. None.

[FR Doc. 95-10700 Filed 5-1-95; 8:45 am]

BILLING CODE 6560-50-P

40 CFR Part 52

[KY-86-1-6932a; FRL-5189-6]

Approval and Promulgation of Implementation Plans State: Kentucky; Approval of Revisions to State Implementation Plan Regarding Emission Statements

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is approving the State Implementation Plan (SIP) revision submitted by the Commonwealth of Kentucky through the Natural Resources and Environmental Protection Cabinet (Cabinet) for the purpose of implementing an emission statement program. The SIP was submitted by the Cabinet on January 15, 1993. As a result of EPA comments, the Cabinet submitted another SIP on December 29, 1994, to satisfy the Federal requirements for an emission statement program.

DATES: This final rule will be effective June 16, 1995 unless adverse or critical comments are received by June 1, 1995. If the effective date is delayed, timely notice will be published in the **Federal Register**.

ADDRESSES: Written comments on this action should be addressed to Scott Southwick at the EPA Regional Office listed below.

Copies of the documents relative to this action are available for public inspection during normal business hours at the following locations. The interested persons wanting to examine these documents should make an appointment with the appropriate office at least 24 hours before the visiting day.

Air and Radiation Docket and Information Center (Air Docket 6102), U.S. Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460.
Environmental Protection Agency, Region 4, Air Programs Branch, 345 Courtland Street, NE., Atlanta, Georgia 30365.

Division for Air Quality, Department for Environmental Protection, Natural Resources and Environmental Protection Cabinet, 316 St. Clair Mall, Frankfort, Kentucky 40601.

FOR FURTHER INFORMATION CONTACT: Scott Southwick, Regulatory Planning and Development Section, Air Programs Branch, Air, Pesticides & Toxics Management Division, Region 4

Environmental Protection Agency, 345 Courtland Street, NE, Atlanta, Georgia 30365. The telephone number is 404/347-3555, X4207. Reference file KY-86-1-6932a.

SUPPLEMENTARY INFORMATION: A SIP revision was submitted by the Commonwealth on January 15, 1993, to satisfy section 182(a)(B) of the Clean Air Act as amended in 1990 (CAA). A second SIP revision was submitted on December 29, 1994 and replaces the first SIP submittal. The second SIP addresses deficiencies of the first SIP revision.

The January 15, 1993, SIP revision was reviewed by EPA to determine completeness shortly after its submittal, in accordance with the completeness criteria set out at 40 CFR part 51, appendix V (1991), as amended by 57 FR 42216 (August 26, 1991). The submittal was found to be complete and a letter dated April 27, 1993, was sent to Mr. John Hornback, Director of the Division for Air Quality, indicating the submittal is administratively complete. The December 29, 1994, SIP revision was reviewed by EPA to determine completeness and a letter dated March 3, 1995, was sent to Mr. John Hornback, Director of the Division for Air Quality, indicating the submittal is administratively complete.

There are several key general and specific components of an acceptable emission statement program. Specifically, the state must submit a revision to its SIP and the emission statement program must meet the minimum requirements for reporting. In general, the program must include, at a minimum, provisions for applicability, compliance, and specific source requirements detailed below.

A. SIP Revision Submission

The Commonwealth of Kentucky submitted their emission statement regulation on January 15, 1993, which meets the emission statement requirement.

B. Program Elements

The Commonwealth emission statement program must, at a minimum, include provisions covering applicability of the regulations, a compliance schedule for sources covered by the regulations, and the specific reporting requirements for sources—including a certification that the information is accurate to the best knowledge of the individual certifying the statement. Kentucky included all of the above, except for certification that the information is accurate, within regulation 401 KAR 50:037 Emission fee. The Cabinet revised their emissions statement program to include a

certification statement. The final revised emission statement program was submitted on December 29, 1994, within regulation 401 KAR 50:035 Permits regulation. This regulation contained all of the required program elements.

C. Applicability

Section 182(a)(3)(B) requires that states with areas designated as nonattainment for ozone require emission statement data from sources of volatile organic compounds (VOCs) or oxides of nitrogen (NO_x) in the nonattainment areas. This requirement applies to all ozone nonattainment areas, regardless of the classification (Marginal, Moderate, etc.). Kentucky's regulation applies to each air pollution source required to have a permit to operate and emits either twenty-five (25) tons per year of NO_x or VOCs.

The states may waive, with EPA approval, the requirement for emission statements for classes or categories of sources with less than 25 tons per year of actual plant-wide of both NO_x and VOC emissions in nonattainment areas if the class or category is included in the base year and periodic inventories and emissions are calculated using emission factors established by EPA (such as those found in EPA publication AP-42) or other methods acceptable to EPA. The Kentucky submittal waives the emission statement requirement for sources with less than 25 tons per year of actual plant-wide of both NO_x and VOC emissions in their 1990 Base Year Emissions Inventory.

Final Action

EPA is approving the plan revision submitted by the Commonwealth of Kentucky on December 29, 1994. This submittal meets all of the requirements of emission statements outlined in section 182(a)(3)(B).

The EPA is publishing this action without prior proposal because the Agency views this as a noncontroversial amendment and anticipates no adverse comments. However, in a separate document in this **Federal Register** publication, the EPA is proposing to approve the SIP revision should adverse or critical comments be filed. This action will be effective June 16, 1995 unless, by June 1, 1995, adverse or critical comments are received.

If the EPA receives such comments, this action will be withdrawn before the effective date by publishing a subsequent document that will withdraw the final action. All public comments received will then be addressed in a subsequent final rule based on this action serving as a proposed rule. The EPA will not

institute a second comment period on this action. Any parties interested in commenting on this action should do so at this time. If no such comments are received, the public is advised that this action will be effective June 16, 1995.

Under section 307(b)(1) of the CAA, 42 U.S.C. 7607(b)(1), petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by July 3, 1995. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for 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) of the Act, 42 U.S.C. 7607(b)(2)).

The OMB has exempted these actions from review under Executive Order 12866.

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

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

SIP approvals under section 110 and subchapter I, part D of the CAA do not create any new requirements, but simply approve requirements that the State is already imposing. Therefore, because the Federal SIP-approval does not impose any new requirements, I certify that it does not have a significant impact on any small entities affected. Moreover, due to the nature of the Federal-state relationship under the CAA, preparation of a regulatory flexibility analysis would constitute Federal inquiry into the economic reasonableness of state action. The CAA forbids EPA to base its actions concerning SIPs on such grounds. *Union Electric Co. v. U.S. E.P.A.*, 427

U.S. 246, 256–66 (S.Ct. 1976); 42 U.S.C. section 7410(a)(2).

List of Subjects in 40 CFR Part 52

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

Dated: April 3, 1995.

Patrick M. Tobin,

Acting Regional Administrator.

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

PART 52—[AMENDED]

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

Authority: 42 U.S.C. 7401–7671q.

Subpart S—Kentucky

2. Section 52.920 is amended by adding paragraph (c)(77) to read as follows:

§ 52.920 Identification of plan.

* * * * *

(c) * * *

(77) Revisions to the Commonwealth of Kentucky State Implementation Plan (SIP) concerning emission statements were submitted on December 29, 1994, by the Kentucky Natural Resources and Environmental Protection Cabinet.

(i) Incorporation by reference.

(A) Regulation 401 KAR 50:035 Permits. Section 1, Section 2(1) and Section 10. Regulation became effective September 28, 1994.

(ii) None.

[FR Doc. 95–10696 Filed 5–1–95; 8:45 am]

BILLING CODE 6560–50–P

40 CFR Part 52

[MN29–1–6203a; FRL–5174–7]

Approval and Promulgation of Implementation Plans; Minnesota

AGENCY: United States Environmental Protection Agency (USEPA).

ACTION: Direct final rule.

SUMMARY: USEPA is approving a revision to the Minnesota State Implementation Plan (SIP) to incorporate new permitting regulations. This revision consists of the State Rules in Chapter 7007, entitled “Air Emission Permits,” in conjunction with other rule changes relating to the repeal of prior air permitting rules. Although these rules have been submitted previously to

satisfy the requirements of Title V of the Clean Air Act, the purpose of this submittal is (1) to support federally enforceable permit conditions for limiting sources’ potential to emit, (2) to allow the use of permits as vehicles for future SIP revisions, and (3) to update the procedural rules governing the issuance of air permits in Minnesota. USEPA concludes that all three purposes are satisfied.

DATES: This action will be effective July 3, 1995 unless adverse or critical comments are received by June 1, 1995. If the effective date is delayed, timely notice will be published in the **Federal Register**.

ADDRESSES: Written comments should be sent to:

William L. MacDowell, Chief,
Regulation Development Section (AE–17J), U.S. Environmental Protection Agency, 77 West Jackson Boulevard, Chicago, Illinois 60604.

Copies of the SIP revision request and USEPA’s analysis are available for inspection at the following addresses: (It is recommended that you telephone John Summerhays at (312) 886–6067, before visiting the Region 5 Office.)

United States Environmental Protection Agency, Region 5, Air and Radiation Division, 77 West Jackson Boulevard (AE–17J), Chicago, Illinois 60604; and Office of Air and Radiation (OAR) Docket and Information Center (Air Docket 6102), Room M1500, United States Environmental Protection Agency, 401 M Street, S.W., Washington, D.C., 20460.

FOR FURTHER INFORMATION CONTACT: John Summerhays, Regulation Development Section, Air Enforcement Branch, U.S. Environmental Protection Agency, Region 5, Chicago, Illinois 60604.

SUPPLEMENTARY INFORMATION:

I. Summary of State Submittal

On November 23, 1993, the Minnesota Pollution Control Agency (MPCA) submitted revised air permitting rules for approval as part of the State Implementation Plan (SIP). These rules represent Minnesota’s consolidated permitting regulations, which include provisions for operating permits for major sources pursuant to Title V of the Clean Air Act, construction permits for major new sources and major source modifications pursuant to Parts C and D of Title I, and operating and construction permits for minor sources and minor modifications pursuant to State law. Thus, this submittal complements Minnesota’s submittal dated November 15, 1993, seeking USEPA approval of the same regulations

as satisfying Title V requirements. Separate rulemaking is being conducted with respect to whether these regulations satisfy Title V requirements. (See the **Federal Register** of September 13, 1994, at 59 FR 46948.)

Minnesota’s submittal of November 23, 1993, does not seek to satisfy any specific mandate under the Clean Air Act. As noted above, a separate submittal seeks to satisfy the requirements of Title V. A pair of submittals dated August 5, 1992, and August 26, 1993, have been found to satisfy nonattainment area major new source review requirements (see 59 FR 8578, dated February 23, 1994). The State has not sought to provide State regulations to supersede Federal regulations on attainment area new source review (prevention of significant deterioration).

Instead, the State’s submittal of November 23, 1993, seeks approval of updated State permitting regulations which have superseded previously approved regulations, including several provisions to help the State implement its Title V and Title I programs. Minnesota intended with this submittal: (1) to provide a mechanism for intermediate size sources to obtain federally enforceable limitations to become “minor sources,” (2) to facilitate future SIP revisions, and (3) to update the federally approved regulations to reflect the updated State permitting regulations. Each of these purposes requires evaluation under different criteria. These purposes and the associated United States Environmental Protection Agency (USEPA) criteria for approval are discussed individually in subsequent sections.

A. Federally Enforceable Limitations on Potential To Emit

The first purpose of Minnesota’s submittal was to provide a mechanism for intermediate size sources to obtain federally enforceable limitations such that the sources’ potential to emit would be below the size thresholds at which major source permits are required. This mechanism involves federally enforceable State operating permits (FESOPs) incorporating the relevant limitations. The State intends to write such permits both in the context of new source review and in the context of Title V permitting. As clarified in a letter from Charles Williams to Valdas Adamkus dated November 21, 1994, the State is requesting this authority with respect to hazardous air pollutants (HAPs) as well as for pollutants with air quality standards (“criteria pollutants”).

Criteria for USEPA approval of FESOP programs are given in the **Federal**

Register of June 28, 1989 (54 FR 27274). FESOP programs must satisfy five principal requirements: (1) the regulations must be approved into the SIP, (2) sources must have a legal obligation to comply with permit terms and USEPA must be authorized to deem as "not federally enforceable" those permits which it finds fail to satisfy applicable requirements, (3) the program must require all limits to be at least as stringent as other applicable requirements, (4) the permit provisions must be permanent, quantifiable, and otherwise enforceable as a practical matter, and (5) the permits must have been subject to public notice and review. Use of FESOPs for limiting hazardous air pollutants is further subject to requirements in section 112(l) of the Clean Air Act, which is also discussed below. Also discussed below is a policy memorandum entitled "Guidance on Limiting Potential to Emit in New Source Permitting," dated June 13, 1989, and a policy memorandum entitled "Options for Limiting the Potential to Emit (PTE) of a Stationary Source Under Section 112 and Title V of the Clean Air Act (Act)," dated January 25, 1995.

The first requirement for approval of Minnesota's FESOP program is satisfied by virtue of today's approval of Minnesota's regulations into the SIP.

The second requirement contains two parts. With respect to sources' legal obligations, Minnesota's rules satisfy the requirement by requiring each permit to state that "Any [noncompliance with permit conditions] constitutes a violation of the state law and, if the provision is federally enforceable, of the [Clean Air Act, and] is grounds for enforcement action."

With respect to the authority granted to USEPA to deem permits "not federally enforceable," the technical support document provides a detailed interpretation of Minnesota's rules on this issue both for the time period during permit review and for the time period subsequent to permit issuance. For the permit review period, the State rules specify that Minnesota "shall not issue [such a permit] if the administrator objects to its issuance in writing [during the specified review period]." For the period after the permit has been issued, USEPA interprets Minnesota's rules to allow avoidance of otherwise applicable permitting requirements only if a permit condition provides a federally enforceable limit on a source's potential to emit, which USEPA would be authorized to determine. Thus, in summary, USEPA is authorized to deem permits not

federally enforceable both during and after the permit review period.

With respect to the third requirement, Rule 7007.0800 ("Permit Content") explicitly requires that permits "shall include emissions limitations, operational requirements, and other provisions needed to ensure compliance with all applicable requirements * * *." No provision in the State rules authorizes any relaxation from any applicable requirement.

With respect to the fourth requirement, enforceability is mostly to be provided on a permit-by-permit basis, particularly by writing practical and quantitative enforcement procedures into each permit. USEPA will review enforceability of permits using the above cited memorandum entitled "Guidance on Limiting Potential to Emit in New Source Permitting," which describes the types of limitations that reduce potential to emit in a federally enforceable manner. Nevertheless, enforceability also requires proper permit program design. Minnesota's regulations (for example Rule 7007.0800 quoted above) provide for fully enforceable limitations. Concerning permanence, Rule 7007.0450 (2) expressly provides for permanence of "title I conditions," thereby assuring permanence of conditions relating to new source review. Pursuant to Rule 7007.0800 (15), Title I conditions in each permit will be identified as such. Other conditions have the duration provided for under Title V, i.e., they expire with permit expiration but are typically renewed with permit reissuance. Consequently, Minnesota's rules provide for the degree of permanence necessary for enforcement of the applicable provisions, and more generally provide for permit limitations to be fully enforceable.

With respect to the fifth requirement, Minnesota's rules have explicit requirements for public notice and review of proposed permitting actions. Of particular concern here are provisions that apply to permitting actions that establish limits to avoid major source permitting requirements ("synthetic minor permits"), both with respect to new source and to existing source permitting requirements. In both cases, Rule 7007.0850 provides for a 30-day public comment period. For most minor source permits, including existing source "synthetic minor permits," Rule 7007.0850 (2) allows the State to publish notice in the State Register rather than in a local newspaper. This approach is provided for in USEPA regulations for major existing source permits under Title V

(i.e., the regulations published at 40 CFR 70), and so this approach is also considered acceptable for synthetic minor existing source permits. For minor source permitting that involves "title I conditions," defined in Rule 7007.0100 (25) to include major new source permit conditions, permit conditions established to help meet air quality standards, and synthetic minor permit conditions, further requirements apply. Specifically, Rule 7007.0850 (4) requires that such permit actions "comply with all other federal requirements for public participation." The Federal requirements for new source permitting include prominent advertisement of the proposed permit, i.e., newspaper publication, which would thus also be a requirement of Rule 7007.0850. Rule 7007.0850 (2)(B) also stipulates that major amendments to State permits (including "major modifications" as defined in USEPA's new source review regulations as well as "synthetic minor modifications"), have the same notice and comment requirements as State permit issuance, "if authorized or required by the administrator." USEPA clearly authorizes and requires full notice and opportunity for public comment in cases of major and synthetic minor modifications. In summary, newspaper notice is a requirement for major and synthetic minor new source permitting under Federal regulations and therefore also under Minnesota Rule 7007.0850(4). In addition, USEPA "authorizes and requires" full notice and opportunity for public comment for major and synthetic minor modifications, which is therefore also required in these cases under Minnesota Rule 7007.0850 (2)(B). Given these interpretations, Minnesota's rules require full satisfaction of relevant notice and comment requirements.

In addition to meeting the criteria in the June 28, 1989, notice, a FESOP program for HAPs must meet the statutory criteria for approval under section 112(l)(5). This section allows USEPA to approve a program only if it (1) contains adequate authority to assure compliance with any section 112 standard or requirement, (2) provides for adequate resources, (3) provides for an expeditious schedule for assuring compliance with section 112 requirements, and (4) is otherwise likely to satisfy the objectives of the Act. The memorandum cited above dated January 25, 1995, provides further discussion of these criteria and of the extent to which limits on criteria pollutants such as volatile organic compounds and

particulate matter may be considered to limit sources' potential to emit HAPs.

Minnesota satisfies these additional requirements for HAPs. (1) The State has adequate authority to assure compliance with section 112 requirements since the third criterion of the June 28, 1989, notice is met, that is, the program does not allow waiving any section 112 requirement. Nonmajor sources would still be required to meet applicable section 112 requirements. (2) Minnesota has committed to provide adequate resources to implement and enforce the program, which it will obtain from fees collected under Title V. USEPA believes that this mechanism will provide sufficient resources to implement this program. USEPA will monitor the State's implementation of the program to assure that adequate resources continue to be available. (3) Minnesota's permitting program also meets the requirement for an expeditious schedule for assuring compliance. A source seeking a voluntary limit on potential to emit is probably doing so to avoid a Federal requirement applicable on a particular date. Nothing in this program would allow a source to avoid or delay compliance with the Federal requirement if it fails to obtain the appropriate federally enforceable limit by the relevant deadline. (4) Finally, Minnesota's permitting rules are consistent with the objectives of the section 112 program since its purpose is to enable sources to obtain federally enforceable limits on potential to emit to avoid major source classification under section 112. USEPA believes that this purpose is consistent with the overall intent of section 112. Accordingly, USEPA finds that Minnesota's program satisfies applicable criteria for establishing federally enforceable limitations on potential to emit both criteria and hazardous air pollutants.

Minnesota has requested that eligibility for Federal enforceability extend not only to permits issued after the effective date of this rule but also extend to permits issued under the State's current rule prior to the effective date of today's rulemaking. If the State followed its own procedures, each permit issued under this regulation to establish a Title I condition (e.g. for a source to have minor source potential to emit) was subject to public notice and prior USEPA review. Therefore, USEPA will consider all such operating permits issued which were processed in a manner consistent with both the State regulations and the five criteria to be federally enforceable with the promulgation of this rule provided that

any permits that the State wishes to make federally enforceable are submitted to USEPA and accompanied by documentation that the procedures approved today have been followed. USEPA will expeditiously review any individual permits so submitted to ensure their conformity to the program requirements.

B. Use of State Permits as SIP Revisions

The second purpose of Minnesota's submittal was to facilitate future SIP revisions. For cases when a single source or a small number of sources require limitations to bring about attainment or to meet other Title I requirements, Minnesota intends that such limitations could be incorporated into the source's permit. Minnesota would then submit the permit as a SIP revision in lieu of the current practice of developing and submitting an administrative order. Minnesota's submittal does not include any such permits for USEPA rulemaking. Thus, the following discussion expresses the approach and criteria that USEPA anticipates using in the future if and when Minnesota does provide such submittals.

The first criterion for USEPA approval of this approach is that the relevant permit conditions be nonexpiring and enforceable. Minnesota's rules address this criterion by defining such permit conditions as "Title I conditions." Minnesota's Rule 7007.0100 (25) defines this term to mean (1) any conditions in a permit which are based on new source review, (2) any conditions imposed to assure attainment, or (3) any conditions established to avoid being subject to new source review (i.e., limitations on potential to emit to become "synthetic minor sources"). Rule 7007.0450 declares that title I conditions are permanent "without regard to permit expiration or reissuance * * *." USEPA will review practical enforceability of permit-based SIP submittals on a permit by permit basis. Assuming that other relevant requirements are met (e.g., any attainment demonstration requirements), USEPA anticipates that well written permits would satisfy the substantive requirements for SIP revisions.

The second criterion for USEPA approval of permits as SIP revisions is that administrative requirements for the adoption of SIP revisions be met. These requirements are specified in 40 CFR 51, particularly Subpart F (Procedural Requirements) and Appendix V (Completeness Criteria). Most notably, any SIP revision must have been subject to proper public notice and opportunity for comment. In particular, the State

must have published a newspaper notice of the intended SIP revisions and have provided a 30-day opportunity for comments and opportunity for a public hearing.

Minnesota's rules have different public notice provisions depending on applicability of Title V permitting requirements, i.e., for major versus minor sources. For sources obtaining or amending a Title V permit, Rule 7007.0850 (Public Notice and Comment) subpart 2 dictates satisfaction of the SIP notice and comment requirements discussed previously. It is less clear whether Minnesota's rules mandate satisfaction of these requirements in the case of minor sources. Rule 7007.0850 subpart 4 states that Minnesota "shall also comply with all other federal requirements for public participation applicable to permits and permit amendments which include Title I conditions [including establishment of attainment-based limitations], including requirements in [40 CFR 51.102, 51.161, and 51.166(Q)]." On the other hand, Rule 7007.1500 subpart 3 indicates (seemingly inadvertently) that such amendments need not be subject to notice and comment. However, it is not necessary to determine here exactly what Minnesota's rules require. Instead, the real issue is whether each permit submitted for SIP revision purposes has been issued in accordance with the notice and comment requirements applicable to SIP revisions (as described above), irrespective of what notice and comment provisions are mandated by Minnesota rules. USEPA will conduct a submittal-by-submittal review of whether the notice and comment requirements for SIP revisions have been satisfied at the time it rulemakes on each submittal.

The above discussion addresses Minnesota's request that USEPA accept permits as the enforceable elements of future SIP revisions. Minnesota's submittal also requested that administrative orders currently in the SIP be replaced with permits. USEPA cannot grant this request now; no Title V permits have yet been issued and so none are available to replace the existing administrative orders. When such permits do become available, the substitution of a permit for an administrative order will not occur on an automatic basis, but rather will be reviewed as a SIP revision following the normal SIP review process.

C. Review of Updated New Source Review Requirements

A third purpose of Minnesota's submittal was to update the federally approved regulations to reflect the

updated State permitting regulations. In adopting a single set of air permitting regulations incorporating both construction permits and operating permits, the State updated numerous new source review provisions in conjunction with its adoption of the regulations required under Title V. These rules specify criteria for what sources must have Title V permits (namely, major sources), what sources must have State permits, and what sources do not need a permit. Further rules specify application requirements, permit content, and procedures for permit processing. Criteria are given for treating modifications as insignificant and for treating activities as insignificant. Separate requirements are established for administrative amendments, minor amendments, moderate amendments, and major amendments. Criteria for reopening of permits, criteria for Federal enforceability, criteria for coverage by a permit shield, and exemptions for emergency circumstances are defined. Additional revisions include modified permit processing provisions (e.g. specific public comment provisions), provisions which exempt certain defined modifications and activities from permitting due to insignificance, provision of raised size thresholds for State permits, and provision for trading of emissions increases and decreases at "minor" sources.

The technical support document provides a rule-by-rule review of the updated Minnesota regulations. A few rules present ambiguities requiring further interpretation. Previous discussion has described USEPA's interpretation of Minnesota's rules concerning notice and comment, concluding that USEPA authorizes and requires and therefore Rule 7007.0850 requires full opportunity for public comment and newspaper notice for synthetic minor and major new source and modification permits. Rule 7007.0750 allows construction prior to permit issuance in some cases for minor sources (provided State authorization is granted), but prohibits preissuance construction for major sources; USEPA interprets this rule to prohibit preissuance construction for prospective synthetic minor sources since such sources are major sources until the permit is issued. Rule 7007.1750 provides that conditions required under Chapter 7007 rules are federally enforceable, but is ambiguous as to whether permit conditions adopted to avoid "major source" size thresholds qualify as federally enforceable. Since such conditions may be considered a

means of satisfying Title I permitting requirements, and since Federal enforceability is a prerequisite for such limits to be effective in avoiding categorization as a major source, USEPA interprets such permit conditions as federally enforceable.

Numerous provisions governing new source review in Minnesota are unaffected by the State's submittal. Minnesota's offset rules, recodified as Rules 7007.4000 through 7007.4030, continue to provide substantive requirements for major new sources and major modifications in nonattainment areas. The State has not sought approval of State regulations for prevention of significant deterioration (i.e. new source review in attainment areas) to replace the Federal regulations at 40 CFR 52.21, so the Federal regulations remain applicable.

In its action on previous Minnesota permitting regulations, published at 53 FR 17033 (May 13, 1988), USEPA disapproved the rules with respect to sources with new source performance standards but exempted by the State as being below permitting size thresholds. The rules providing these exemptions have been repealed and replaced with regulations that require a permit for any source to which new source performance standards apply. Thus the prior partial disapproval may be rescinded. USEPA further concludes that these rules satisfy applicable new source permitting requirements.

II. Rulemaking Action

Today's rulemaking addresses Minnesota's air permitting regulations as submitted November 23, 1993. USEPA approves these regulations. Furthermore, USEPA concludes that Minnesota's three purposes in submitting these regulations have been fulfilled. First, USEPA concludes that Minnesota has satisfied the criteria for issuing federally enforceable state operating permits. Second, USEPA finds that Minnesota has established a suitable mechanism for use of permits as the basis of SIP submittals. Although no such permits have yet been issued or submitted, USEPA anticipates being able to approve future permit-based SIP submittals provided that SIP-related public notice requirements and other relevant SIP requirements (e.g. any attainment demonstration criteria) have been satisfied. Third, USEPA concludes that these new permitting regulations continue to satisfy relevant new source review requirements. Finally, USEPA is rescinding the partial disapproval applicable to Minnesota's previous permitting regulations.

Because USEPA considers this action noncontroversial and routine, we are approving it without prior proposal. The action will become effective on July 3, 1995, unless adverse or critical comments are received by June 1, 1995. This action will authorize Minnesota to issue federally enforceable state operating permits limiting the potential to emit criteria and/or hazardous air pollutant emissions. If the effective date is delayed, timely notice will be published in the **Federal Register**.

Most of the rules approved by this rulemaking are in Chapter 7007 of Minnesota's rules. Specifically, USEPA is approving Rules 7007.0050 through 7007.1850, including Rules 7007.0050, .0100, .0150, .0200, .0250, .0300, .0350, .0400, .0450, .0500, .0550, .0600, .0650, .0700, .0750, .0800, .0850, .0900, .0950, .1000, .1050, .1100, .1150, .1200, .1250, .1300, .1350, .1400, .1450, .1500, .1600, .1650, .1700, .1750, .1800, and .1850. In addition, USEPA is approving the repeal of previous Rules 7001.1200, 7001.1205, 7001.1210, 7001.1215, and 7001.1220, amendments to Rules 7001.0020, 7001.0050, 7001.0140, 7001.0180, 7001.0550, 7001.3050, 7002.0005, and 7002.0015 that accompany this repeal, and new definitions in Rule 7005.0100. USEPA will address Rule 7019.3000 (a portion of the State's emissions inventory rules) in separate rulemaking.

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

This action has been classified as a Table 2 action by the Regional Administrator under the procedures published in the **Federal Register** on January 19, 1989 (54 FR 2214-2225), as revised by an October 4, 1993 memorandum from Michael H. Shapiro, Acting Assistant Administrator for Air and Radiation. The Office of Management and Budget has exempted this rule from the requirements of section 6 of Executive Order 12866.

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

SIP approvals under section 110 and subchapter I, Part D of the Act do not create any new requirements, but simply approve requirements that the State is already imposing. Therefore, because the federal SIP approval does not impose any new requirements, I certify that it does not have a significant impact on any small entities affected. Moreover, due to the nature of the Federal-State relationship under the Act, preparation of a regulatory flexibility analysis would constitute federal inquiry into the economic reasonableness of state action. The Act forbids USEPA to base its actions concerning SIPs on such grounds. *Union Electric Co. v. USEPA*, 427 U.S. 246, 256–66 (S.Ct. 1976); 42 U.S.C. 7410(a)(2).

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 July 3, 1995. 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

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

Note: Incorporation by reference of the State Implementation Plan for the State of Minnesota was approved by the Director of the Federal Register on July 1, 1982.

Dated: March 8, 1995.

David A. Ullrich,

Acting Regional Administrator.

Title 40 of the Code of Federal Regulations, chapter I, part 52 is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

Authority: 42 U.S.C. 7401–7671q.

Subpart Y—[Amended]

2. Section 52.1220 is amended by adding paragraph (c)(37) to read as follows:

§ 52.1220 Identification of plan.

* * * * *

(c) * * *

(37) On November 23, 1993, the State of Minnesota submitted updated air permitting rules.

(i) Incorporation by reference.

(A) Rules 7007.0050 through 7007.1850, effective August 10, 1993.

(B) Rules 7001.0020, 7001.0050, 7001.0140, 7001.0180, 7001.0550, 7001.3050, 7002.0005, 7002.0015, and 7005.0100, effective August 10, 1993.

§ 52.1225 [Amended]

3. Section 52.1225 is amended by removing and reserving paragraphs (c) and (d).

§ 52.1233 [Added]

4. Section 52.1233 is added to read as follows:

§ 52.1233 *Operating permits.*

Emission limitations and related provisions which are established in Minnesota permits as federally enforceable conditions in accordance with Chapter 7007 rules shall be enforceable by USEPA. USEPA reserves the right to deem permit conditions not federally enforceable. Such a determination will be made according to appropriate procedures, and be based upon the permit, permit approval procedures or permit requirements which do not conform with the permit program requirements or the requirements of USEPA's underlying regulations.

[FR Doc. 95–10702 Filed 5–1–95; 8:45 am]

BILLING CODE 6560–50–P

40 CFR Part 52

[VA20–1–5996a; FRL–5178–9]

Approval and Promulgation of Air Quality Implementation Plans; for the Commonwealth of Virginia—Emission Statement Program

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is approving a State Implementation Plan (SIP) revision submitted by the Commonwealth of Virginia. This revision establishes and requires an emission statement program for stationary sources of volatile organics compounds (VOCs) and/or nitrogen oxides (NO_x). The intended effect of this action is to approve a regulation for annual reporting of actual emissions by sources that emit VOC and/or NO_x applicable to all ozone nonattainment areas in accordance with section 182(a)(3)(B) of the 1990 Clean

Air Act Amendments (CAAA). This action is being taken under section 110 of the CAA.

DATES: This final rule will become effective July 3, 1995 unless notice is received on or before June 1, 1995 that adverse or critical comments will be submitted. If the effective date is delayed, timely notice will be published in the **Federal Register**.

ADDRESSES: Comments must be mailed to Thomas J. Maslany, Director, Air, Radiation, and Toxics Division, U.S. Environmental Protection Agency, Region III, 841 Chestnut Building, Philadelphia, Pennsylvania, 19107. Copies of the Commonwealth's submittal and other information are available for public inspection during normal business hours at the following location: Environmental Protection Agency, Region III, Air, Radiation, and Toxics Division, 841 Chestnut Building, Philadelphia, PA 19107; the Air and Radiation Docket and Information Center, U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460; and the Virginia Department of Environmental Quality, 629 East Main Street, Richmond, Virginia, 23219.

FOR FURTHER INFORMATION CONTACT: Enid A. Gerena (3AT14), U.S. Environmental Protection Agency, Air, Radiation, and Toxics Division, 841 Chestnut Building, Philadelphia, PA 19107, (215) 597–8239.

SUPPLEMENTARY INFORMATION: On November 4, 1992, the Virginia Department of the Environment Quality (VDEQ) submitted a formal revision to the Commonwealth of Virginia's SIP which among other things, requires owners of stationary sources that emit VOCs and NO_x, above specified actual emission applicability thresholds, and within the ozone nonattainment areas, to submit annual statements certifying emissions. This notice only addresses those portions of the November 4, 1992 SIP submittal related to the Commonwealth of Virginia's emission statement program. The other SIP revisions included in the submittal are the subjects of separate rulemaking notices.

I. Background

The air quality planning and State Implementation Plan (SIP) requirements for ozone nonattainment and transport areas are set out in subparts I and II of Part D of Title I of the Clean Air Act, as amended by the Clean Air Act Amendments of 1990. EPA published a "General Preamble" describing EPA's preliminary views on how the Agency intends to review SIP's and SIP revisions submitted under Title I of the

CAA, including those State submittals for ozone transport areas within the States {see 57 FR 13498 (April 16, 1992) ["SIP: General Preamble for the Implementation of Title I of the Clean Air Act Amendments of 1990"], 57 FR 18070 (April 28, 1992) ["Appendices to the General Preamble"], and 57 FR 55620 (November 25, 1992) ["SIP: NO_x Supplement to the General Preamble"]}.

EPA also issued a draft guidance document describing the requirements for the emission statement programs discussed in this action, entitled "Guidance on the Implementation of an Emission Statement Program" (July, 1992). The Agency is also conducting a rulemaking process to modify Title 40, Part 51 of the CFR to reflect the requirements of the emission statement program.

Section 182 of the Act sets out a graduated control program for ozone nonattainment areas. Section 182(a) sets out requirements applicable in marginal ozone nonattainment areas, which are also made applicable by section 182 (b), (c), (d), and (e) to all other ozone nonattainment areas. Among the requirements in section 182(a) is a program for stationary sources to prepare and submit to the State each year emission statements certifying their actual emissions of VOCs and NO_x. This section of the Act provides that the States are to submit a revision to their SIPs by November 15, 1992 establishing this emission statement program.

If a source emits either VOC or NO_x at or above the designated minimum reporting level, the other pollutant should be included in the emission statement, even if it is emitted at levels below the specified cutoffs.

States may waive, with EPA approval, the requirement for an emission statement for classes or categories of sources with less than 25 tons per year of actual plant-wide NO_x or VOC emissions in nonattainment areas if the class or category is included in the base year and periodic inventories and emissions are calculated using emission factors established by EPA (such as those found in EPA publication AP-42) or other methods acceptable to EPA. Emissions from stationary sources that emit less than 25 tons per year of VOC and NO_x are included in Virginia's base year emission inventory and must be also included in the periodic emission inventories.

At minimum, the emission statement data should include:

- Certification of data accuracy;
- Source identification information;
- Operating schedule;

- Emissions information (to include annual and typical ozone season day emissions);
- Control equipment information; and
- Process data.

EPA developed emission statements data elements to be consistent with other source and State reporting requirements. This consistency is essential to assist States with quality assurance for emission estimates and to facilitate consolidation of all EPA reporting requirements.

II. EPA's Evaluation of the Commonwealth's Submittal

A. Procedural Background

The Commonwealth of Virginia held public hearings on July 22, 1992, for the purpose of soliciting public comment on proposed regulatory revisions concerning emission statements for stationary sources. The regulatory revisions were adopted on October 30, 1992, submitted to EPA on November 4, 1992 as a proposed revision to the SIP, and became effective in the Commonwealth of Virginia on January 1, 1993.

B. Components of Virginia's Emission Statement Program

There are several key and specific components of an acceptable emission statement program. Specifically, the State must submit a revision to its SIP which consists of an emission statement program which meets the minimum requirements for reporting by the sources and the State. For the emission statement program to be approvable, the state's SIP must include, at a minimum, definitions and provisions for applicability, compliance, and specific source reporting requirements and reporting forms.

Virginia's revision consists of amendments to Title VR 120-01 Regulations for the Control and Abatement of Air Pollution, specifically to add paragraph B to section 120-02-31, Registration, and to add Appendix S, which cross-references document AQP-8, Procedures for Preparing and Submitting Emission Statements for Stationary Sources.

Section 120-02-31, requires that owners of stationary sources report the levels of emissions from the sources emitting VOCs and NO_x, in order to assess compliance with emission and air quality standards and to track emission reductions necessary to attain the ozone National Ambient Air Quality Standard (NAAQS). This requirement applies to existing, modified, or new stationary sources that emit 25 tons per year (TPY) or more of VOCs or NO_x, and are

located in any ozone nonattainment area. The upper portion of White Top Mountain is the only area in Smyth County which is an ozone nonattainment area. Because there are no emission sources in this nonattainment area, the Commonwealth has excluded it from emission statement requirements.

Under the Commonwealth's regulation, sources' annual emission statements are due by April 15 of each year, beginning in 1993, for the emissions discharged during the previous calendar year. Section 120-02-31, Appendix S, Air Quality Program Policies and Procedures describes specifically how emission statements shall be prepared.

C. Enforceability

The Commonwealth of Virginia has a provision in its SIP which ensures that the emission statement requirements of Section 182(a)(3)(B) and Sections 184(b)(2) and 182(f) of the CAA as required by VR 120-01, section 120-02-31, are adequately enforced. Once EPA completes the rulemaking process approving the Virginia's Emission Statement program as part of the SIP, it will be federally enforceable.

EPA has determined that the submittal made by the Commonwealth of Virginia satisfies the relevant requirements of the CAA and EPA's guidance document, "Guidance on the Implementation of an Emission Statement Program" (July 1992). EPA's detailed review of Virginia's Emission Statement is contained in a Technical Support Document (TSD) which is available, upon request, from the EPA Regional Office listed in the ADDRESSES section of this notice.

EPA is approving this SIP revision without prior proposal because the Agency views this as a noncontroversial amendment and anticipates no adverse comments. However, in a separate document in this **Federal Register** publication, EPA is proposing to approve the SIP revision should adverse or critical comments be filed. This action will be effective July 3, 1995 unless, by June 1, 1995, adverse or critical comments are received.

If EPA receives such comments, this action will be withdrawn before the effective date by publishing a subsequent notice that will withdraw the final action. All public comments received will then be addressed in a subsequent final rule based on this action serving as a 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. If no such

comments are received, the public is advised that this action will be effective on July 3, 1995.

III. Final Action

EPA is approving revisions to the Commonwealth of Virginia SIP to include an Emission Statement Program. These revisions consist of amendments to Title VR 120-01 Regulations for the Control and Abatement of Air Pollution, the addition of paragraph B to section 120-02-31, Registration, and the addition of Appendix S including the document referenced therein, AQP-8.

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

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

SIP approvals under section 110 and subchapter I, Part D of the Act do not create any new requirements, but simply approve requirements that the State is already imposing. Therefore, because the Federal SIP-approval does not impose any new requirements, the Administrator certifies that it does not have a significant impact on small entities. Moreover, due to the nature of the federal-state relationship under the CAA, preparation of a regulatory flexibility analysis would constitute federal inquiry into the economic reasonableness of state action. The CAA forbids EPA to base its actions concerning SIPs on such grounds. *Union Electric Co. v. U.S. E.P.A.*, 427 U.S. 246, 256-66 (S.Ct. 1976); 42 U.S.C. section 7410 (a)(2).

This action has been classified as a Table 2 action for signature by the Regional Administrator under the procedures published in the **Federal Register** on January 19, 1989 (54 FR 2214-2225), as revised by an October 4, 1993 memorandum from Michael H. Shapiro, Acting Assistant Administrator for Air and Radiation. The OMB has exempted this regulatory action from E.O. 12866 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 July 3, 1995. 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 approving Virginia's Emission Statement SIP submittal requirements may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Hydrocarbons, Incorporation by reference, Intergovernmental relations, Oxides of nitrogen, Ozone, Reporting and recordkeeping requirements, and SIP requirements.

Dated: January 25, 1995.

Peter H. Kostmayer,

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. 7401-7671q.

Subpart VV—Virginia

2. Section 52.2420 is amended by adding paragraph (c)(103) to read as follows:

§ 52.2420 Identification of plan.

* * * * *

(c) * * *

(103) Revisions to the Commonwealth of Virginia Regulations State Implementation Plan submitted on November 4, 1992 by the Virginia Department of Environmental Quality:

(i) Incorporation by reference.

(A) Letter of November 4, 1992 from the Virginia Department of Environmental Quality transmitting a revised regulation to require owners of stationary sources in emissions control areas to submit emission statements annually.

(B) Amendments to Title VR 120-01, addition of paragraph B to section 120-02-31 and the addition of Appendix S including referenced document AQP-8, procedures for Preparing and submitting Emission Statements for Stationary Sources. Effective on January 1, 1993.

(ii) Additional Material.

(A) Remainder of November 4, 1992 State submittal related emission statements.

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40 CFR Part 52

[DC23-1-6790a; FRL-5181-2]

Approval and Promulgation of Air Quality Implementation Plans; District of Columbia; GSA Central and West Heating Plants

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is approving a State implementation plan (SIP) revision submitted by the District of Columbia. This revision will limit air pollution from two steam-generating facilities located in the District of Columbia. The intended effect of this action is to approve a permit-to-operate issued by the District of Columbia to General Services Administration for its Central and West Heating Plants. This action is being taken under section 110 of the Clean Air Act.

DATES: This final rule is effective July 3, 1995, unless notice is received on or before June 1, 1995, that adverse or critical comments will be submitted. If the effective date is delayed, timely notice will be published in the **Federal Register**.

ADDRESSES: Comments may be mailed to Marcia L. Spink, Associate Director, Air Programs (3AT00), U.S. Environmental Protection Agency, Region III, 841 Chestnut Building, Philadelphia, Pennsylvania 19107. Copies of the documents relevant to this action are available for public inspection during normal business hours at the Air, Radiation, and Toxics Division, U.S. Environmental Protection Agency, Region III, 841 Chestnut Building, Philadelphia, Pennsylvania 19107; the Air and Radiation Docket and Information Center, U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460; and District of Columbia Department of Consumer and Regulatory Affairs, 2100 Martin Luther King Ave, S.E., Washington, DC 20020.

FOR FURTHER INFORMATION CONTACT:

David J. Campbell, Technical Assessment Section (3AT22), U.S. Environmental Protection Agency, Region III, 841 Chestnut Building, Philadelphia, Pennsylvania 19107, phone: (215) 597-9781.

SUPPLEMENTARY INFORMATION: On October 24, 1994, the District of

Columbia submitted a request that EPA approve a revision to the District of Columbia SIP. The revision consists of a September 8, 1994 operating permit issued by the District of Columbia to GSA for its Central and West Heating Plants. The permit establishes general operating procedures at GSA's Central Heating Plant (CHP) and West Heating Plant (WHP), including the exclusive combustion of natural gas (with the provision for the combustion of low-sulfur oil in the event of a natural gas service interruption).

The permit also defines annual and short-term emission limitations for SO₂, particulate matter (PM-10), nitrogen oxides (NO_x), volatile organic compounds (VOCs), and carbon monoxide (CO) for both of the plants. Since this permit establishes more stringent emission limitations than the existing SIP or applicable new source performance standards (NSPS), the ambient air quality with respect to each of the criteria pollutants mentioned above shall be significantly improved.

The permit-to-operate issued to GSA promotes continued maintenance of the national ambient air quality standards (NAAQS) for SO₂, PM-10, and NO_x in the areas surrounding the CHP and WHP. The District of Columbia is currently designated as nonattainment for the NAAQS for CO. Although the emissions limits established in the permit for CO will not affect the attainment status of the District, they do provide for CO emissions reductions at these two facilities which were previously uncontrolled for CO. The permit also regulates particulate matter and VOC emissions.

In order to achieve these emission reductions, GSA is restricted by its September 8, 1994 operating permit to the combustion of natural gas. The District restricted the fuel capabilities at the two facilities primarily to minimize SO₂ emissions from the Plants. Modeling analyses performed in 1990 as part of the permitting process for GSA's proposed refurbishment of various boilers at CHP and WHP indicated that elevated ambient concentrations of SO₂ were predicted for the areas immediately surrounding the two facilities when the Plants burned coal under typical winter day conditions.

Along with the restrictions on fuel usage, the permit limits the hourly and annual emissions of various pollutants from the facilities. The permit drastically reduces SO₂ emissions from the plant to the point where such emissions present negligible potential for impact on the surrounding areas. For instance, the average annual SO₂ emissions from CHP and WHP were 523

and 626 tons per year, respectively, during the period of 1980 to 1990, inclusive. The current permit-to-operate restricts annual SO₂ emissions to 4 tons per year at CHP and 5 tons per year at WHP. This is an average overall reduction of 1140 tons per year of SO₂ emissions in the vicinity of the two facilities. Annual emissions of PM-10, NO_x, CO, and VOCs from the two plants are restricted to a degree that further limits the potential for violation of the relevant annual NAAQS in the vicinity of these facilities.

The operating permit is also protective of the short-term NAAQS. For each of the pollutants discussed above, hourly emission limitations are established in the permit. These hourly emission limits are, in every instance, as stringent or more restrictive than the applicable limits in the District's existing SIP or new source performance standards (NSPS) limits.

As mentioned above, the operating permit requires the combustion of natural gas at all times at GSA's CHP and WHP. However, there is a provision for the use of No. 2 "on-road diesel" with a maximum sulfur content of five hundredths weight percent (0.05%_w) during periods of service interruptions by the supplier. It should be noted that GSA must comply with its annual and short-term emission rates regardless of the fuel it uses. In the event of a service interruption, the permit contains explicit instructions for the notification of the District of this event and recordation of pertinent information.

The permit also requires GSA to report an extensive amount of information to ensure continuous compliance with the annual and short-term emission limits. The principal means for compliance determination is the use of continuous emissions monitoring data collected at the facilities. The District relies primarily on the procedures established in 40 CFR part 60 for monitor operation and data quality assurance. Daily emissions reports that provide hourly emission rates for SO₂, NO_x, VOCs, and CO are to be prepared by GSA. GSA must also submit a quarterly report documenting the hourly status of each boiler at CHP and WHP including: hours of service, types and quantities of fuel combusted, fuel composition and heat content, service interruptions, and total tons of SO₂, NO_x, PM-10, VOCs, and CO emitted on a monthly basis and as part of a rolling, 12-month annual average. A monthly report is to be prepared demonstrating GSA's maintenance of the NAAQS for SO₂ in the vicinity of the two facilities. Sulfur-in-fuel reports are due each month detailing specific

information about the fuel oil, if any, that was burned during the month. The level of reporting detailed above provides adequate assurances that the compliance status of GSA can be quickly and accurately tracked at all times.

EPA Evaluation

EPA has evaluated the District of Columbia's SIP revision request and concluded the following: (1) The operational and emission limitations imposed on GSA's Central and West Heating Plants adequately promote continued maintenance of the NAAQS; (2) the operational and emission limitations are clearly enforceable; and (3) the applicable requirements of CFR part 51 have been met. A more detailed evaluation is provided in the Technical Support Document for this action which is available upon request from the EPA Region III office listed in the ADDRESSES section of this document.

EPA is approving this SIP revision without prior proposal because the Agency views this as a noncontroversial amendment and anticipates no adverse comments. However, in a separate document in this **Federal Register** publication, EPA is proposing to approve the SIP revision should adverse or critical comments be filed. This action will be effective July 3, 1995, unless, by June 1, 1995, adverse or critical comments are received.

If EPA receives such comments, this action will be withdrawn before the effective date by publishing a subsequent notice that will withdraw the final action. All public comments received will then be addressed in a subsequent final rule based on this action serving as a 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. If no such comments are received, the public is advised that this action will be effective on July 3, 1995.

Final Action

EPA is approving the District of Columbia's October 24, 1994 submittal consisting of a permit-to-operate for GSA's Central and West Heating Plants as a revision to the District of Columbia SIP.

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

relation to relevant statutory and regulatory requirements.

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

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

This action has been classified as a Table 3 action for signature by the Regional Administrator under the procedures published in the **Federal Register** on January 19, 1989 (54 FR 2214–2225), as revised by an October 4, 1993 memorandum from Michael H. Shapiro, Acting Assistant Administrator for Air and Radiation. The OMB has exempted this regulatory action from E.O. 12866 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 July 3, 1995. Filing a petition for reconsideration by the Administrator of this final rule to approve the permit-to-operate issued to GSA for its Central and West Heating Plants as a revision to the District of Columbia SIP 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, Nitrogen dioxide, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides.

Dated: March 21, 1995.

Stanley L. Laskowski,

Acting 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. 7401–7671q.

Subpart J—District of Columbia

2. Section 52.470 is amended by adding paragraph (c)(33) to read as follows:

§ 52.470 Identification of plan.

* * * * *

(c) * * *

(33) Permit-to-operate issued by the District of Columbia to General Services Administration for its Central and West Heating Plants submitted on October 24, 1994 by the Environmental Regulation Administration:

(i) Incorporation by reference.

(A) Letter of October 24, 1994 from the Environmental Regulation Administration transmitting a permit-to-operate issued by the District of Columbia to GSA for its Central and West Heating Plants.

(B) September 8, 1994 permit-to-operate issued by the District of Columbia to GSA for its Central and West Heating Plants requiring the combustion of natural gas and establishing annual and short-term emission limits for SO₂, NO_x, PM–10, VOCs, and CO. The permit was effective upon its issuance.

(ii) Additional material.

(A) Remainder of the District of Columbia's October 24, 1994 submittal.

[FR Doc. 95–10706 Filed 5–1–95; 8:45 am]

BILLING CODE 6560–50–P

40 CFR Part 52

[CA 125–1–6903; FRL–5190–9]

Approval and Promulgation of Implementation Plans; California State Implementation Plan Revision, San Diego County Air Pollution Control District

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is finalizing the approval of revisions to the California State Implementation Plan (SIP) proposed in the **Federal Register** on December 9, 1994. The revisions concern rules from the San Diego County Air Pollution Control District (SDCAPCD). This approval action will incorporate these rules into the federally approved SIP. The intended effect of approving these rules is to regulate emissions of volatile organic compounds (VOCs) in accordance with the requirements of the Clean Air Act, as amended in 1990 (CAA or the Act). The revised rule controls VOC emissions from the surface coating of miscellaneous metal parts and products. Thus, EPA is finalizing the approval of these revisions into the California SIP under provisions of the CAA regarding EPA action on SIP submittals, SIPs for national primary and secondary ambient air quality standards and plan requirements for nonattainment areas.

EFFECTIVE DATE: This action is effective on June 1, 1995.

ADDRESSES: Copies of the rule revisions and EPA's evaluation report for each rule are available for public inspection at EPA's Region IX office during normal business hours. Copies of the submitted rule revisions are available for inspection at the following locations: Rulemaking Section (A–5–3), Air and Toxics Division, U.S. Environmental Protection Agency, Region IX, 75 Hawthorne Street, San Francisco, CA 94105.

Environmental Protection Agency, Air Docket (6102), 401 M Street, S.W., Washington, D.C. 20460.
San Diego County Air Pollution Control District, 9150 Chesapeake Drive, San Diego, CA 92123–1096.

FOR FURTHER INFORMATION CONTACT: Helen Liu, Rulemaking Section, Air and Toxics Division, U.S. Environmental Protection Agency, Region IX, 75 Hawthorne Street, San Francisco, CA 94105, Telephone: (415) 744–1199.

SUPPLEMENTARY INFORMATION:

Background

On December 9, 1994 in 59 FR 63724, EPA proposed to approve the following rule into the California SIP: SDCAPCD's Rule 67.3, Coating of Metal Parts and Products. Rule 67.3 was adopted by the SDCAPCD on November 1, 1994. The rule was submitted by the California Air Resources Board (CARB) to EPA on November 23, 1994. These rules were submitted in response to EPA's 1988 SIP-Call and the CAA section 182(a)(2)(A) requirement that nonattainment areas fix their reasonably available control technology (RACT)

rules for ozone in accordance with EPA guidance that interpreted the requirements of the pre-amendment Act. A detailed discussion of the background for the above rule and nonattainment area is provided in the NPRM cited above.

EPA has evaluated the above rule for consistency with the requirements of the CAA, EPA regulations, and EPA interpretation of these requirements as expressed in the various EPA policy guidance documents referenced in the NPRM cited above. EPA has found that the rule meets the applicable EPA requirements. A detailed discussion of the rule provisions and evaluations has been provided in 59 FR 63724 and in a technical support document (TSD) available at EPA's Region IX office (dated December 2, 1994).

Response to Public Comments

A 30-day public comment period was provided in 59 FR 3274. EPA received no adverse comments.

EPA Action

EPA is finalizing action to approve SDCAPCD Rule 67.3 for inclusion into the California SIP. EPA is approving the submittal under section 110(k)(3) as meeting the requirements of section 110(a) and Part D of the CAA. This approval action will incorporate these rules into the federally approved SIP. The intended effect of approving these rules is to regulate emissions of VOCs in accordance with the requirements of the CAA.

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

Regulatory Process

The OMB has exempted this action from review under Executive Order 12866.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Hydrocarbons, Incorporation by reference, Intergovernmental relations, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Note: Incorporation by reference of the State Implementation Plan for the State of California was approved by the Director of the Federal Register on July 1, 1982.

Dated: March 31, 1995.

Felicia Marcus,

Regional Administrator.

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

PART 52—[AMENDED]

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

Authority: 42 U.S.C. 7401-7671q.

Subpart F—California

2. Section 52.220 is amended by adding paragraph (c)(206) to read as follows:

§ 52.220 Identification of plan.

* * * * *

(c) * * *

(206) Amended rule for the following APCD was submitted on November 23, 1994, by the Governor's designee.

(i) Incorporation by reference.

(A) San Diego County Air Pollution Control District.

(1) Rule 67.3, adopted on November 1, 1994.

* * * * *

[FR Doc. 95-10695 Filed 5-1-95; 8:45 am]

BILLING CODE 6560-50-P

40 CFR Parts 52 and 81

[OH50-1-6077a, FRL-5176-8]

Approval and Promulgation of Implementation Plans and Designation of Areas for Air Quality Planning Purposes: State of Ohio

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: USEPA is approving, through "direct final" procedure, a redesignation request and maintenance plan for the Toledo, Ohio area (Lucas and Wood Counties) as a revision to Ohio's State Implementation Plan (SIP) for ozone. The revision is based on a request from the State of Ohio to redesignate this area from a moderate nonattainment area to an attainment area for ozone, and to approve the maintenance plan for the area. The State has met the requirements for redesignation contained in the Clean Air Act (the Act), as amended in 1990. The redesignation request is based on ambient monitoring data that show no violations of the ozone National Ambient Air Quality Standard (NAAQS) during the three-year period from 1990 through 1992. In the proposed rules section of this **Federal Register**, USEPA is proposing approval of and soliciting

public comment on this requested redesignation and SIP revision. If adverse comments are received on this direct final rule, USEPA will withdraw this final rule and address these comments in a final rule based on the related proposed rule which is being published in the proposed rules section of this **Federal Register**.

DATES: This action will be effective on July 3, 1995 unless adverse or critical comments are received by June 1, 1995. If the effective date is delayed, timely notice will be published in the **Federal Register**.

ADDRESSES: Copies of the SIP revision and USEPA's analysis are available for inspection at the following address: (It is recommended that you telephone Angela Lee at (312) 353-5142 before visiting the Region 5 Office.) United States Environmental Protection Agency, Region 5, Air and Radiation Division, 77 West Jackson Boulevard, Chicago, Illinois 60604.

A copy of this SIP revision is available for inspection at the following location: Office of Air and Radiation Docket and Information Center, Room M1500, United States Environmental Protection Agency, 401 M Street SW., Washington, DC 20460, (202) 260-7548.

Written comments can be mailed to: William MacDowell, Chief, Regulation Development Section, Air Enforcement Branch (AE-17J), United States Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois, 60604.

FOR FURTHER INFORMATION CONTACT: Angela Lee, Regulation Development Section, Air Enforcement Branch (AE-17J), United States Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 353-5142.

SUPPLEMENTARY INFORMATION: On September 17, 1993, Ohio submitted a redesignation request and section 175A maintenance plan for Lucas and Wood Counties. The USEPA reviewed these submittals against the redesignation criteria set forth by section 107(d)(3)(E) of the Act, which are discussed in a September 4, 1992, memorandum from the Director of the Air Quality Management Division, Office of Air Quality Planning and Standards, to Directors of Regional Air Divisions entitled, "Procedures for Processing Requests to Redesignate Areas to Attainment" (Calcagni Memorandum). A second memorandum dated September 17, 1993, signed by Michael Shapiro, Acting Assistant Administrator for Air and Radiation, entitled, "State Implementation Plan (SIP) Requirements for Areas Submitting

Requests for Redesignation to Attainment of the Ozone and Carbon Monoxide NAAQS on or after November 15, 1992" was also used to evaluate Ohio's request. An analysis of these submittals is contained in a Technical Support Document (TSD), dated December 9, 1994, and an addendum to this TSD dated March 7, 1995.

I. Background

The 1977 Act required areas that were designated nonattainment to develop SIPs with sufficient control measures to expeditiously attain and maintain the standard. For Ohio, Lucas and Wood Counties were designated nonattainment for ozone, see 43 FR 8962 (March 3, 1978), 43 FR 45993 (October 5, 1978), and 40 CFR Part 81.

After enactment of the amended Act on November 15, 1990, the nonattainment designation of the Toledo area continued by operation of law according to section 107(d)(1)(C)(i) of the Act; furthermore, it was classified by operation of law as moderate for ozone pursuant to section 181(a)(1) (56 FR 56694, November 6, 1991), codified at 40 CFR 81.336.

More recently, the Toledo area has ambient monitoring data that show no violations of the ozone NAAQS, during the period from 1990 through 1992. The area, therefore, became eligible for redesignation from nonattainment to attainment consistent with the amended Act. On September 17, 1993, Ohio requested redesignation of the area to attainment with respect to the ozone NAAQS. To ensure continued attainment of the ozone standard, Ohio submitted an ozone maintenance SIP for the Toledo area with the redesignation request. On November 1, 1993, Ohio held a public hearing on the maintenance plan and redesignation request.

II. Evaluation Criteria

The 1990 Amendments revised section 107(d)(3)(E) to provide five specific requirements that an area must meet in order to be redesignated from nonattainment to attainment.

1. The area must have attained the applicable NAAQS.

2. The area has met all applicable requirements under section 110 and part D of the Act.

3. The area has a fully approved SIP under section 110(d) of the Act.

4. The air quality improvement must be permanent and enforceable.

5. The area must have a fully approved maintenance plan pursuant to section 175A of the Act.

Each of these requirements are addressed below.

A. Section 107(d)(3)(E)(i). The Administrator determines that the area has attained the National Ambient Air Quality Standard (NAAQS). For ozone, an area is considered in attainment of the NAAQS if there are no violations, as determined in accordance with 40 CFR 50.9, based on quality assured monitoring data for three complete, consecutive calendar years. A violation of the NAAQS occurs when the annual average number of expected exceedances is greater than 1.0 at any site in the area at issue. An exceedance occurs when the maximum hourly ozone concentration exceeds 0.124 ppm. The data should be collected and quality-assured in accordance with 40 CFR Part 58, and recorded in the Aerometric Information Retrieval System (AIRS) in order for it to be available to the public for review. The monitors should have remained at the same location for the duration of the monitoring period required for demonstrating attainment.

Ohio submitted ozone monitoring data recorded in the Lucas and Wood Counties Metropolitan Area (LWCMA) during the years 1984 through August 31, 1993. No violations were monitored for the three-year period 1990 through 1992 upon which the redesignation request was based. Furthermore, no violations have been monitored since then. Monitored exceedances (one-hour averaged) of 0.127 ppm in 1991, 0.126 ppm in 1993, and 0.142 ppm occurred at the Yondota Avenue monitor in 1994. An exceedance of 0.136 ppm occurred at the Friendship Park monitor in 1993. The USEPA used data stored in AIRS to determine the annual average expected exceedances for the years 1990, 1991, 1992, 1993, and 1994. Since the annual average expected exceedances for each monitor during these years is less than 1.0, Lucas and Wood Counties are considered to have attained the standard.

B. Section 107(d)(3)(E)(iii). The Administrator determines that the improvement in air quality is due to permanent and enforceable measures. Ohio estimated emission reductions from a nonattainment year (1988) to an attainment year (1990), and found that emission reductions from federally mandated control on fuel volatility and new automobiles reduced volatile organic compound (VOC) emissions by 25,843 lbs/day. In 1989, fuel volatility was restricted to 10.5 pounds per square inch (psi) in the Toledo area. Currently, the fuel volatility standard is 9.0 psi. This standard was established in 1992. The USEPA considers the emissions reductions from the Federal Motor Vehicle Control Program (FMVCP) and

Federal volatility standards to be permanent and enforceable and to have contributed to the improvement in air quality.

Controls placed on a wastewater ditch which was used to transport wastewater from the British Petroleum (BP) refinery to a wastewater treatment system also provided VOC emissions reductions during this period. This wastewater ditch, which measured about 3600 feet in length and an average of about 10 feet in width, is referred to as the "oily ditch." Prior to 1990, this "oily ditch" was uncontrolled and was one of the largest single sources of VOCs in the LWCMA with emissions of 19,802 lbs/summer day. The USEPA reviewed the methodology used to calculate these emissions and agrees with the amount of emissions estimated from this source. A major portion of the open ditch was converted to a hard pipe to minimize VOC emissions. Ohio estimates that the enclosure of 3000 feet of the "oily ditch" which was completed on March 15, 1990, resulted in an emission reduction of 11,225 lbs/summer day of VOCs. Since the USEPA is approving the Director's Findings and Orders requiring this control into the SIP as part of the maintenance plan, the emission reductions from the enclosure of the "oily ditch" at the BP Toledo Refinery are considered permanent and enforceable and to have contributed to the improvement in air quality.

C. Section 107(d)(3)(E)(iv). The Area must have a fully approved maintenance plan meeting the requirements of Section 175A. Section 175A of the CAA sets forth the elements of a maintenance plan for areas seeking redesignation from nonattainment to attainment. The maintenance plan is a SIP revision which provides for maintenance of the relevant NAAQS in the area for at least 10 years after redesignation. The Calcagni Memorandum provides further guidance on the required content of a maintenance plan.

An ozone maintenance plan should address the following five areas: the attainment inventory, maintenance demonstration, monitoring network, verification of continued attainment and a contingency plan. The attainment emissions inventory identifies the emissions level in the area which is sufficient to attain the ozone NAAQS, and includes emissions during the time period which had no monitored violations. Maintenance is demonstrated by showing that future emissions will not exceed the level established by the attainment inventory. Provisions for continued operation of an appropriate air quality monitoring network are to be

included in the maintenance plan. The State must show how it will track and verify the progress of the maintenance plan. Finally, the maintenance plan must include contingency measures which ensure prompt correction of any violation of the ozone standard.

1. Attainment Inventory

The State has developed an adequate attainment emission inventory for 1990 that identifies the level of emissions in the Toledo area sufficient to attain the ozone NAAQS. The 1990 attainment inventory was based on the comprehensive inventories of VOC and

nitrogen oxides (NO_x) emissions from area, stationary, and mobile sources for 1990. The 1990 base year emission inventory represents 1990 average summer day actual emissions for the Toledo area and was prepared in accordance with USEPA guidance. USEPA's TSD prepared for the 1990 base year emission inventory SIP revision contains a detailed analysis of this inventory. The USEPA approved this inventory as satisfying the requirements of section 182(a)(1) for an emissions inventory on March 22, 1995 (60 FR 15053).

2. Maintenance Demonstration

To demonstrate continued attainment, Ohio projected point, area, and mobile source emissions from the year 1990 to the year 2005. These projections show that the level of emissions established by the attainment inventory will not be exceeded during the maintenance period, 1990–2005. Table 1 lists the emissions for the year 1990 and projected emissions for the year 2005. Total point, mobile, and area emissions are expected to be lower in 2005 than total emissions in the 1990 attainment inventory.

TABLE 1.—MAINTENANCE DEMONSTRATION

Source category	1990	1996	2000	2005
VOC Emissions (pounds per day)				
Point	120,154	78,978	78,611	77,742
Mobile (on-road)	132,659	102,560	82,494	57,412
Area	74,502	74,693	75,119	75,209
Total	327,315	256,231	236,224	210,363
NO _x Emissions (pounds per day)				
Point	147,943	146,793	80,294	81,376
Mobile (on-road)	75,630	65,128	58,126	49,374
Area	20,522	20,547	20,563	20,584
Total	244,095	232,468	158,983	151,334

3. Emission projections

Point source emissions were projected by accounting for known changes to sources for each year between 1990 and 2005, and applying a growth factor based on manufacturing employment data provided by the Bureau of Economic Analysis, United States Department of Commerce, to derive inventories for all ensuing years. The stationary source emission projections incorporate existing control measures. The known stationary source emission reductions came from the British Petroleum (BP) Refinery reductions documented in annual Reasonable Further Progress Reports, and stationary source shutdowns.

Some of the emission reductions from the BP refinery during the maintenance period result from controls included in Ohio's non-control technology guideline (non-CTG) Reasonably Available Control Technology (RACT) rules, Ohio Administrative Code 3745–21–09(UU) and 3745–21–04(c)(55). Additional VOC reductions at the BP Refinery result from the conversion of two cooling towers to non-VOC emitting processes and the removal of the Crude Vacuum blow down drum. Emission reductions from source shutdowns can be considered permanent and enforceable to the extent that those shutdowns have

been reflected in the SIP and all applicable permits have been modified accordingly. Once the maintenance plan is approved into the SIP, these emission reductions will be provided for by the SIP. Consequently, resumption of operation of these sources would be treated as operation of a new source and would be subject to preconstruction review under Part C of the Prevention of Significant Deterioration (PSD) program. The net reduction in VOC emissions at the BP refinery during the maintenance period is estimated to be 40,582 lbs/day.

Stationary source emissions of nitrogen oxides (NO_x) are projected to decline from 1990 levels. This reduction is caused by shutdowns of utility units, "low-NO_x burner" requirements of Title IV of the Clean Air Act, and declining growth in stationary sources. In 1992, Toledo Edison permanently retired all units at its Acme Generating Station other than Unit 16. The operating permits for the retired units have been surrendered, making the resulting emission reductions permanent and enforceable. These shutdowns reduced 1990 levels of NO_x emission by 15,403 lbs/day. A negative growth factor of 2.3 percent based on manufacturing employment from 1990 and 2005, reduces NO_x emissions by 973 lbs/day.

Mobile source emissions were projected by forecasting vehicle miles travelled (VMT) for the year 2005. This was done by considering the future highway networks and forecasts of socio-economic data. Growth parameters for the year 2005 were developed from the travel forecasting modeling programs and VMTs from the transportation modeling growth factors and 1990 Highway Performance Modeling System data.

Area source emissions were projected using growth factors consistent with Table III.3 in USEPA's guidance document entitled "Procedures for Preparing Emissions Projections," dated July 1991.

4. Emissions Budgets

The emissions budget to be used for determining the conformity status of transportation plans and transportation improvement plans is 29.85 tons VOC/day and 24.69 tons NO_x/day. On November 28, 1994, the USEPA received a request from Ohio to add 1.142 tons VOC/day of the "safety margin" to the year 2005 VOC emissions (28.71 tons/day) for purposes of conformity. This is provided for by section 51.456(b) of the conformity rule (58 FR 62188). (The safety margin is the difference between the attainment

inventory level of mobile source emissions from the projected levels of mobile source emissions in the out year (i.e. 2005) of the maintenance plan.) The USEPA is approving this submittal as part of the maintenance plan.

5. Contingency Plan

Ohio has committed to adopt and implement various contingency measures following various triggering events. The contingency plan is summarized in Table 3. If three exceedances at one monitor occur in the same year, Stage II Vapor Recovery (Stage II) would be implemented. Stage II and the vehicle inspection and maintenance (I/M) program would be implemented after a violation has been monitored. If a violation occurred after both Stage II and the I/M program have been implemented, NO_x RACT would be adopted and implemented. If an emissions inventory meeting the requirements of USEPA guidance shows that total area-wide VOC emissions exceed 95 percent of the 1990 emissions inventory, then either one or both Stage

II and the I/M program would be implemented. The implementation schedules for each contingency measure are detailed in Table 4. If more violations were to occur, Ohio has committed to identify and develop the legislative authority to implement additional contingency measures.

Ohio has the legislative authority to implement the I/M program in Toledo. Ohio's Stage II rule allows for the implementation of Stage II as part of a maintenance and/or a contingency plan. The Director of the Ohio Environmental Protection Agency (OEPA) issued a Director's Findings and Orders on September 17, 1993, suspending Stage II in the Toledo area. This suspension will continue until there are three monitored exceedances of the ozone standard in one year or a violation of the ozone standard is monitored. On October 20, 1994, the USEPA partially approved and partially disapproved Ohio's SIP revision for implementation of Stage II (58 FR 52911). As stated in that rulemaking action, with the exception of paragraph 3745-21-09 (DDD)(5),

USEPA considers Ohio's Stage II program to fully satisfy the criteria set forth in the USEPA guidance document for such programs entitled "Enforcement Guidance for Stage II Vehicle Refueling Control Programs." Ohio has adopted NO_x RACT rules for the Toledo area. The Director of OEPA has suspended the NO_x RACT rules in the Toledo area until a violation is monitored after the implementation of I/M and Stage II.

TABLE 3.—CONTINGENCY PLAN

Trigger	Control measure
3 exceedances of ozone standard in one year.	Stage II.
Violation	Stage II and I/M.
Violation after implementation of Stage II and I/M.	NO _x RACT.
VOC emissions greater than 95% of the 1990 level of VOC emissions.	Stage II and/or I/M.

TABLE 4.—CONTINGENCY PLAN SCHEDULE FOR ADOPTION AND IMPLEMENTATION

Activity	Completion time after triggering event
Stage II Vapor Recovery	
Identify and verify third excursion in one year or violation of ozone standard	1 month.
Initiate compliance schedules contained in Ohio Administrative Code (OAC) 3745-21-04	2 months.
Source demonstration of compliance or submittal of schedules to achieve compliance	3 months.
Achieve final compliance of non-independent facilities for which construction commenced after 11/15/90	6 months.
Achieve final compliance of non-independent facilities greater than 100,000 gallons per month	12 months.
Achieve final compliance of all other non-independent facilities	24 months.
Achieve final compliance of 33% of facilities owned by each marketer	12 months.
Achieve final compliance of 66% of facilities owned by each marketer	24 months.
Achieve final compliance of 100% of facilities owned by each marketer	36 months.
Activity	Time after triggering event
Vehicle Inspection and Maintenance	
Identify and verify violation of the ozone standard. Begin revisions to the Request for Proposals for centralized portion of program based on existing legislative authority.	1 month.
Begin drafting rules for contingency centralized I/M program, procedures and guidelines	1 month.
Release Request for Proposals for centralized contractor	2 months.
File draft program rules with Legislative Service Commission	3 months.
Public hearing on new program rules	4 months and 15 days.
Rules approved by Joint Committee on Agency Rule Review	4 months and 30 days.
Request for Proposal responses for centralized contract due	4 months and 30 days.
Begin evaluation of Request for Proposal responses	5 months.
Award centralized contract for each zone.	6 months and fifteen days.
Program rules become effective	6 months and 30 days.
Begin drafting Request for Proposal for Ohio Environmental Protection Agency (BAR90) approved analyzer certification, if necessary..	7 months.
Begin drafting Request for Proposal for inspector certification training in the Toledo metropolitan area	7 months.
Release Request for Proposal for analyzer certification services	8 months.
Release Request for Proposal for inspector certification training	8 months.
Proposals for analyzer certification services due	9 months and 15 days.
Proposals for inspector certification training due	9 months and 15 days.
Begin evaluation of proposals for analyzer certification services	9 months and 16 days.
Begin evaluation of proposals for inspector certification training	9 months and 16 days.
Award contract for analyzer certification services	10 months.
Award contract for inspector certification training	10 months.
Begin licensing process for reinspection stations. State will require Ohio Certified BAR90 (or better) equipment, on-line real-time systems, and ASE certified mechanics.	11 months.
New analyzer specifications issued, if necessary. Begin certifying four-gas analyzers	12 months.

Activity	Time after triggering event
Inspector certification begins	14 months.
Begin final licensing of reinspection stations	15 months.
Initiate PR program including media blitz	16 months.
Initiate motorist notification mailings	16 months and 15 days.
Begin limited voluntary inspections at centralized test stations. Allow first month motorist to receive valid test. Reinspection stations begin to perform retests.	17 months.
Begin mandatory testing at centralized test stations	18 months.
Activity	Completion time after triggering event
NO _x RACT	
Identify and verify violation following implementation of OAC 3745-21-09 and automobile inspection and maintenance.	1 month.
Source demonstration of compliance or submittal of schedule to achieve compliance	3 months.
Achieve compliance with requirements of OAC 3745-14-03 or request extension	18 months.

6. Tracking Maintenance

The State plans to track monitored levels of ozone. Emissions inventories will be prepared every 3 years beginning with the year 1993. The point source inventory will be updated annually with facility and permit data. OEPA will update emissions estimates from the BP refinery wastewater system on an annual basis. The mobile source inventory will be updated annually with new VMT estimates and revised mobile emissions models if appropriate. Area source inventories will be updated annually using new census data. The OEPA will submit annual progress reports to USEPA which will include available emissions data and a comparison of projected and actual emissions. The Toledo Division of Pollution Control has committed to continue operating and maintaining the four existing ozone monitors in a manner consistent with Federal and State monitoring guidelines.

The USEPA has determined that the maintenance plan for Lucas and Wood Counties meets the requirements set forth by the CAA.

D. Section 107(d)(3)(E)(v). The Area must have met all applicable requirements under Section 110 and Part D. Section 107(d)(3)(E) requires that, for an area to be redesignated, an area must have met all applicable requirements under section 110 and Part D. The USEPA interprets section 107(d)(3)(E)(v) to mean that for a redesignation to be approved, the State must have met all requirements that applied to the subject area prior to or at the time of the submission of a complete redesignation request. Requirements of the Act that come due subsequently continue to be applicable to the area at those later dates (see section 175A(c)) and, if the redesignation of the area is disapproved, the State remains obligated to fulfill those requirements.

1. Section 110 Requirements

General SIP elements are delineated in section 110(a)(2) of Title I, Part A. These requirements include but are not limited to submittal of a SIP that has been adopted by the State after reasonable notice and public hearing, provisions for establishment and operation of appropriate apparatus, methods, systems and procedures necessary to monitor ambient air quality, implementation of a permit program, provisions for Part C (PSD) and D (NSR) permit programs, criteria for stationary source emission control measures, monitoring, and reporting, provisions for modeling, and provisions for public and local agency participation. For purposes of redesignation, the Ohio SIP was reviewed to ensure that all requirements under the amended Act were satisfied. Although section 110 was amended in 1990, the Toledo area SIP meets the requirements of the amended section 110(a)(2). A number of the requirements did not change in substance and, therefore, USEPA believes that the pre-1990 amendment SIP meets those requirements. As to those requirements that were amended in 1990, many are duplicative of other requirements in the Act and USEPA has determined that the Toledo SIP is consistent with the requirements of section 110 of the amended Act.

2. Part D Requirements

Before the Toledo area may be redesignated to attainment, it must have fulfilled the applicable requirements of part D. Under part D, an area's classification determines the requirements to which it is subject. Subpart 1 of part D sets forth the basic nonattainment requirements applicable to all nonattainment areas. Subpart 2 of part D establishes additional requirements for nonattainment areas

classified under Table 1 of section 181(a). As described in the General Preamble for the Implementation of Title 1, specific requirements of subpart 2 may override subpart 1's general provisions (57 FR 13501 (April 16, 1992)). The Toledo area was classified as moderate (56 FR 56694). Therefore, in order to be redesignated, the State must meet the applicable requirements of subpart 1 of part D—specifically sections 172(c) and 176, as well as the applicable requirements of subpart 2 of part D.

a. Section 172(c) Requirements

Section 172(c) sets forth general requirements applicable to all nonattainment areas. Under section 172(b), the section 172(c) requirements are applicable as determined by the Administrator, but no later than 3 years after an area has been designated as nonattainment under the amended Act. Furthermore, as noted above, some of these section 172(c) requirements are superseded by more specific requirements in subpart 2 of part D. In the case of Toledo, the State has satisfied all of the section 172(c) requirements necessary for Toledo to be redesignated upon the basis of the November 8, 1993 redesignation request.

USEPA has determined that the section 172(c)(2) reasonable further progress (RFP) requirement (with parallel requirements for a moderate ozone nonattainment area under subpart 2 of part D, due November 15, 1993) was not applicable as the State of Ohio submitted this redesignation request on November 8, 1993. Also the section 172(c)(9) contingency measures and additional section 172(c)(1) non-RACT reasonable available control measures beyond what may already be required in the SIP are no longer necessary, since no earlier date was set for these measures

and as RFP was not due until November 15, 1993.

The section 172(c)(3) emissions inventory requirement has been met by the submission and approval of the 1990 base year inventory required under subpart 2 of part D, section 182(a)(1) (60 FR 15053).

As for the section 172(c)(5) NSR requirement, USEPA has determined that areas being redesignated need not comply with the NSR requirement prior to redesignation provided that the area demonstrates maintenance of the standard without part D NSR in effect. Memorandum from Mary Nichols, Assistant Administrator for Air and Radiation, dated October 14, 1994, entitled Part D New Source Review (part D NSR) Requirements for Areas Requesting Redesignation to Attainment. The rationale for this view is described fully in that memorandum, and is based on the Agency's authority to establish *de minimis* exceptions to statutory requirements. See *Alabama Power Co. v. Costle*, 636 F.2d 323, 360-61 (D.C. Cir. 1979). As discussed below, the State of Ohio has demonstrated that the Toledo area will be able to maintain the standard without part D NSR in effect and, therefore, the State need not have a fully-approved part D NSR program prior to approval of the redesignation request for Toledo. Ohio's part C PSD program will become effective in the Toledo area upon redesignation to attainment.

Finally, for purposes of redesignation, the Toledo SIP was reviewed to ensure that all requirements of section 110(a)(2), containing general SIP elements, were satisfied. As noted above, USEPA believes the SIP satisfies all of those requirements. Section 176 Conformity Plan Provisions Section 176(c) of the Act requires States to revise their SIPs to establish criteria and procedures to ensure that, before they are taken, Federal actions conform to the air quality planning goals in the applicable State SIP. The requirement to determine conformity applies to transportation plans, programs and projects developed, funded or approved under Title 23 U.S.C. or the Federal Transit Act (transportation conformity), as well as to all other Federal actions (general conformity). Section 176 further provides that the conformity revisions to be submitted by States must be consistent with Federal conformity regulations that the Act required EPA to promulgate. Congress provided for the State revisions to be submitted one year after the date for promulgation of final EPA conformity regulations. When that date passed without such promulgation, USEPA's General Preamble for the

Implementation of Title I informed States that its conformity regulations would establish a submittal date [see 57 FR 13498, 13557 (April 16, 1992)].

The USEPA promulgated final transportation conformity regulations on November 24, 1993 (58 FR 62188) and general conformity regulations on November 30, 1993 (58 FR 63214). These conformity rules require that States adopt both transportation and general conformity provisions in the SIP for areas designated nonattainment or subject to a maintenance plan approved under CAA section 175A. Pursuant to section 51.396 of the transportation conformity rule and section 51.851 of the general conformity rule, the State of Ohio is required to submit a SIP revision containing transportation conformity criteria and procedures consistent with those established in the Federal rule by November 25, 1994. Similarly, Ohio is required to submit a SIP revision containing general conformity criteria and procedures consistent with those established in the Federal rule by December 1, 1994. Because the deadlines for these submittals did not come due prior to the date the Toledo redesignation request was submitted, however, they are not applicable requirements under section 107(d)(3)(E)(v) and, thus, do not affect approval of this redesignation request.

b. Subpart 2 Requirements

The Toledo area is classified moderate nonattainment; therefore, part D, subpart 2, section 182(b) requirements apply. The requirements which came due prior to the submission of the request to redesignate the Toledo area must be fully approved into the SIP prior to redesignating the area to attainment. These requirements are discussed below:

(i) *1990 Base Year Emission Inventory*. The 1990 base year emission inventory was due on November 15, 1992. It was submitted to the USEPA on March 15, 1994. The USEPA approved this submittal on March 22, 1995 (60 FR 15053).

(ii) *Emission Statements*. The emissions statement SIP was due on November 15, 1992. It was submitted to the USEPA on March 15, 1994. The USEPA approved this SIP revision through a direct final rulemaking action published on October 13, 1994 (59 FR 51863).

(iii) *VOC RACT Fix-ups and Catch-ups*. Sections 182(a)(2)(A) and 182(b)(2) establish VOC RACT requirements applicable to moderate ozone nonattainment areas such as Toledo. Section 182(a)(2)(A) required the submission to USEPA of all rules and

corrections to existing VOC RACT rules that were required under the RACT provision of the pre-1990 CAA (referred to as RACT "fix-ups"). Section 182(b)(2) required the submission to USEPA of (1) VOC RACT rules for all VOC sources covered by a CTG issued before the date of enactment of the 1990 CAA amendments (a requirement that the State has previously met), (2) VOC RACT for each VOC source covered by a CTG issued between the enactment of the 1990 CAA and the attainment date (which is not an applicable requirement for purposes of this redesignation since the due date for these rules is November 15, 1994, a date after the submission of the redesignation request), and (3) VOC RACT for all other major stationary sources of VOC located in the area.

On June 9, 1988, August 24, 1990, and June 7, 1993, Ohio submitted VOC RACT rules. In a final rulemaking action, the USEPA partially approved, partially disapproved and granted partial limited approval/limited disapproval to portions of Ohio's VOC RACT rules on May 9, 1994 (see 58 FR 49458). The USEPA processed draft VOC RACT rules which addressed identified deficiencies in Ohio's VOC RACT rules in parallel with the ozone redesignation request. Ohio adopted these rules and submitted them to USEPA on February 14, 1995. Ohio's VOC RACT rules submittals have now been approved in a direct final notice published on March 23, 1995 (60 FR 15235). Thus, the State has now satisfied all of the VOC RACT requirements applicable to the Toledo area. (The approval of the redesignation is contingent upon the approval of the VOC RACT rules and the 1990 Base-Year Emissions Inventory. Thus, this redesignation will not become effective until the approval of the VOC RACT rules and the 1990 Base-Year Emissions Inventory become effective. Consequently, should the direct final notice approving the VOC RACT rules or 1990 Base-Year Inventory be withdrawn as a consequence of adverse comment, this direct final notice approving the redesignation will also be withdrawn and final action will be taken on the redesignation at a later date.)

(iv) *Stage II Vapor Recovery (Stage II)*. Section 182(b)(3) required States to submit Stage II rules to USEPA for moderate ozone nonattainment areas by November 15, 1992. Ohio submitted Stage II regulations as a SIP revision on June 7, 1993. However, as the USEPA promulgated onboard rules on April 6, 1994 (59 FR 16262), Stage II is no longer required for moderate ozone nonattainment areas (see section

202(a)(b). Thus, Stage II is not an applicable requirement for purposes of evaluating this redesignation.

(v) *Vehicle Inspection and Maintenance (I/M)*. On January 5, 1995, the USEPA revised the I/M Program Requirements promulgated on November 5, 1992 (60 FR 1735). See 60 FR 1735. The revision allows areas subject to the basic I/M program requirements and that otherwise qualify for redesignation from nonattainment to attainment for ozone or carbon monoxide NAAQS to defer adoption and implementation of some of the otherwise applicable requirements established in the original promulgation of the I/M rule. USEPA amended Subpart S to allow such areas to be redesignated if they submit a SIP that contains the following four elements: (1) Legal authority for a basic I/M program (or an enhanced program, as defined in the Federal rule, if the state chooses to opt up), meeting all of the requirements of Subpart S such that implementing regulations can be adopted without further legislation; (2) a request to place the I/M plan or upgrades, as defined in the Federal rule, (as applicable) in the contingency measures portion of the maintenance plan upon redesignation as described in the fourth element below; (3) a contingency measure to go into effect as soon as a triggering event occurs, consisting of a commitment by the Governor or the governor's designee to adopt regulations to implement the I/M program in response to the specified triggering event; and (4) a commitment that includes an enforceable schedule for adopting and implementing the I/M program, including appropriate milestones, in the event the contingency measure is triggered (milestones shall be defined in terms of months since the triggering event). USEPA believes that for areas that otherwise qualify for redesignation, a SIP meeting these four requirements would satisfy the obligation to submit "provisions to provide" for a satisfactory I/M program, as required by the statute.

Ohio has met each of the above four requirements. Section 3704.14(B) of Ohio's Administrative Code states "* * * The Director shall implement and supervise a basic or an enhanced motor vehicle inspection and maintenance program in a county that is within an area classified as nonattainment for carbon monoxide or ozone when such a program is included in the air quality maintenance plan or contingency plan for the nonattainment area that includes the county and that is submitted to the USEPA by the Director as required under section 175A of the CAAA as part of a request for

redesignation of the nonattainment area as attainment for carbon monoxide or ozone under section 107(d) of that Act, and the Director determines that the conditions requiring implementation of such a program and set forth in either such plan have been met." This provision allows the I/M program to be implemented in the Toledo area as part of a contingency plan. In addition, I/M programs in Ohio have been approved by USEPA (46 FR 31881). As noted in tables 3 and 4, Ohio has identified appropriate triggering events and submitted an enforceable implementation schedule for the I/M program. The commitment to implement I/M was contained in the letter from the Director of OEPA, the Governor's designee, requesting the redesignation of the Toledo area to attainment for ozone. This satisfies the remaining requirements of the I/M rule revision.

(vi) *1.15:1 VOC and NO_x Offsets Requirement for NSR*. As explained above, USEPA has determined that areas need not comply with the part D NSR requirements of the Act in order to be redesignated provided that the area is able to demonstrate maintenance without part D NSR in effect. As maintenance has been demonstrated for the Toledo area without part D NSR being in effect, USEPA is not requiring that the area have a fully-approved part D NSR plan meeting the requirements of sections 182(a) and (b) prior to redesignation.

(vii) *NO_x Requirement*. Section 182(f) establishes NO_x requirements for ozone nonattainment areas. However, it provides that it does not apply to an area such as Toledo if the Administrator determines that NO_x reductions would not contribute to attainment. The Administrator has made such a determination and has approved the State of Ohio's request to exempt the Toledo area from the section 182(f) NO_x requirements (60 FR 3760). Thus, the State of Ohio need not comply with the NO_x requirements of section 182(f) for Toledo to be redesignated. If a violation is monitored in the Toledo area, Ohio has committed to adopt and implement NO_x RACT rules as a contingency measure.

E. Section 107(d)(3)(E)(ii). The Administrator has fully approved the applicable implementation plan for the area under Section 110(k). USEPA has reviewed the SIP to ensure that it contains all measures that were due under the amended 1990 Act. Based on the approval of submittals under the pre-amended CAA, and USEPA's approval of SIP revisions under the amended CAA, USEPA has determined

that the Toledo area has a fully approved SIP under section 110(k), which also meets the applicable requirements of section 110 and part D as discussed above (45 FR 72122, 59 FR 51863, 60 FR 3760, 60 FR 15053, 60 FR 15235).

III. Transport of Ozone Precursors to Downwind Areas

Preliminary modeling results utilizing USEPA's regional oxidant model (ROM) indicate that ozone precursor emissions from various States west of the ozone transport region (OTR) in the northeastern United States contribute to increases in ozone concentrations in the OTR. The State of Ohio has provided documentation that VOC and NO_x emissions in the Toledo area will decrease 35 percent and 38 percent, respectively, from attainment levels by the year 2005. Given this decrease in emissions, the Toledo area's impact on ozone concentrations in the OTR will correspondingly be reduced. The USEPA is currently developing policy which will address long range impacts of ozone transport. The USEPA is working with the States and other organizations to design and complete studies which consider upwind sources and quantify their impacts. The USEPA intends to address the transport issue through Section 110 based on a domain-wide modeling analysis.

The USEPA notified Environment Canada of this action. The redesignation is not expected to have any adverse impact on Canada since emissions are expected to remain below levels associated with attainment conditions in the Toledo area.

IV. Final Rulemaking Action

The State of Ohio has met the requirements of the Act for revising the Ohio ozone SIP. The USEPA approves the redesignation of Lucas and Wood Counties to attainment areas for ozone. In addition, the USEPA approves the maintenance plan into the ozone SIP for these Counties. As noted earlier, this approval is contingent upon the direct final approval of Toledo's VOC RACT rules and 1990 Base-Year Emissions Inventory becoming effective.

Because USEPA considers this action to be noncontroversial and routine, USEPA is publishing this notice of approval without prior proposal. This action will become effective on July 3, 1995. However, if the USEPA receives adverse comments by June 1, 1995 on this action or by April 24, 1995, regarding the VOC RACT notice published at 60 FR 15235, or by April 21, 1995, regarding the 1990 Base-Year Emissions Inventory published at 60 FR

15053, then the USEPA will publish a notice that withdraws the action, and will address these comments in the final rule on the requested redesignation and SIP revision which has been proposed for approval in the proposed rules section of this **Federal Register**.

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

This action has been classified as a Table 2 action by the Regional Administrator under the procedures published in the **Federal Register** on January 19, 1989 (54 FR 2214-2225), as revised by an October 4, 1993 memorandum from Michael H. Shapiro, Acting Assistant Administrator for Air and Radiation. The Office of Management and Budget exempted this regulatory action from Executive Order 12866 review.

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

The SIP approvals under section 110 and subchapter I, part D, of the Act do not create any new requirements, but simply approve requirements that the State is already imposing. Therefore, because the Federal SIP approval does not impose any new requirements, I certify that it does not have a significant impact on small entities affected. Moreover, due to the nature of the Federal-State relationship under the Act, preparation of a regulatory

flexibility analysis would constitute Federal inquiry into the economic reasonableness of State action. The Act forbids USEPA to base its actions concerning SIPs on such grounds. *Union Electric Co. v. USEPA*, 427 U.S. 246, 256-66 (1976).

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 July 3, 1995. 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

40 CFR Part 52

Air pollution control, Hydrocarbons, Incorporation by reference, Intergovernmental relations, Ozone, Volatile organic compounds, Reporting and recordkeeping requirements.

40 CFR Part 81

Environmental protection, Air pollution control, National parks, Wilderness areas.

Dated: March 14, 1995.

Valdas V. Adamkus,
Regional Administrator.

40 CFR parts 52 and 81 are amended as follows:

PART 52—[AMENDED]

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

Authority: 42 U.S.C. 7401-7671q.

2. Section 52.1870 is amended by adding a new paragraph (c)(105) to read as follows:

§ 52.1870 Identification of plan.

* * * * *

(c) * * *

(105) On September 17, 1993, the Ohio Environmental Protection Agency requested the redesignation of Lucas and Wood Counties to attainment of the National Ambient Air Quality Standard for ozone. To meet the redesignation criteria set forth by section 107(d)(3)(E) (iii) and (iv), Ohio credited emissions reductions from the enclosure of the "oily ditch" at the British Petroleum Refinery in Oregon, Ohio. The USEPA is approving the Director's Finding and Order which requires the enclosure of the "oily ditch" into the SIP for Lucas and Wood Counties.

(i) Incorporation by reference.

Letter dated June 2, 1994, from Donald R. Schregardus, Director, Ohio Environmental Protection Agency, to Valdas Adamkus, Regional Administrator, USEPA, Region 5, and one enclosure which is the revised Director's Final Findings and Orders in the matter of BP Oil company, Toledo Refinery, 4001 Cedar Point Road, Oregon, Ohio, Fugitive Emissions from the Refinery Waste Water System "Oily Ditch", dated June 2, 1994.

3. Section 52.1885 is amended by adding paragraph (b) to read as follows:

§ 52.1885 Control strategy: Ozone.

* * * * *

(b) The maintenance plans for the following counties are approved:

(1)-(4) [Reserved].

(5) Lucas and Wood Counties.

* * * * *

PART 81—DESIGNATION OF AREAS FOR AIR QUALITY PURPOSES

1. The authority citation for part 81 continues to read as follows:

Authority: 42 U.S.C. 7401-7671q.

2. Section 81.336 is amended by revising the entry in the ozone table for Toledo area to read as follows:

§ 81.336 Ohio.

* * * * *

OHIO—OZONE

Designated area	Designation		Classification	
	Date ¹	Type	Date ¹	Type
* * * * *				
Toledo Area.				
Lucas County	July 3, 1995.	Attainment		
Wood County	July 3, 1995.	Attainment		
* * * * *				

¹ This date is November 15, 1990, unless otherwise noted.

[FR Doc. 95-10693 Filed 5-1-95; 8:45 am]
BILLING CODE 6560-50-P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 76

[MM Docket 92-264; FCC 95-147]

Cable Television Act of 1992—Vertical Ownership Rules

AGENCY: Federal Communications Commission.

ACTION: Order on reconsideration.

SUMMARY: On reconsideration of the cable television vertical ownership (or channel occupancy) rules adopted in its Second Report and Order, the Federal Communications Commission (the “Commission”) has adopted a Memorandum Opinion and Order on Reconsideration of the Second Report and Order (“Reconsideration Order”). The Reconsideration Order denies petitions for reconsideration filed by the Center for Media Education/Consumer Federation of America (collectively “CME”) and Bell Atlantic Corporation (“Bell Atlantic”). Specifically, the Reconsideration Order: Denies CME’s petition requesting that the Commission; reduce the percentage of activated channels that a cable operator may devote to video programming in which it has an attributable interest from 40% to 20%; reverse the Commission’s decision to include over-the-air broadcast, public, educational, governmental (“PEG”), and leased access channels when calculating total channel capacity; reverse the Commission’s decision to exempt local and regional networks from the channel occupancy limits; reverse the Commission’s decision not to apply channel occupancy limits beyond a system’s first 75 channels; and reverse the Commission’s decision to grandfather all vertically integrated programming services being carried as of the effective date of the 1992 Cable Act. The Reconsideration Order also denies Bell Atlantic’s petition asking that the Commission reconsider its decision to apply the vertical ownership limits to cable systems facing actual head-to-head competition.

EFFECTIVE DATE: April 6, 1995.

FOR FURTHER INFORMATION CONTACT: Rick Chessen, Cable Services Bureau, (202) 416-0800.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Memorandum Opinion and Order on Reconsideration of the Second Report and Order

(“Reconsideration Order”) in MM Docket 92-264, adopted April 5, 1995 and released April 6, 1995. This Reconsideration Order responds to petitions for reconsideration filed in response to the Commission’s Second Report and Order, 58 FR 60135 (November 15, 1993). The Second Report and Order was established pursuant to section 11(c)(2)(B) of the Cable Television Consumer Protection and Competition Act of 1992 (“1992 Cable Act”), Public Law 102-385, 106 Stat. 1460 (1992).

The complete text of this Reconsideration Order is available for inspection and copying during normal business hours in the FCC Reference Center (room 239), 1919 M Street, NW., Washington, DC, and also may be purchased from the Commission’s copy contractor, International Transcription Services, Inc. (“ITS, Inc.”) at (202) 857-3800, 2100 M Street, NW., Suite 140, Washington, DC 20037.

Synopsis of the Memorandum Opinion and Order on Reconsideration of the Second Report and Order

A. Background

Pursuant to section 11(c)(2)(B) of the Cable Television Consumer Protection and Competition Act of 1992 (“1992 Cable Act”), Pub. L. 102-385, 106 Stat. 1460 (1992), the Commission’s Second Report and Order, 58 FR 60135 (November 15, 1993), established cable channel occupancy rules, including the following rules relevant here: (1) Cable operators generally may devote no more than 40% of their activated channels to the carriage of programming services in which they have an attributable interest; (2) all activated channels will be included in calculating channel capacity, including broadcast, PEG and leased access channels; (3) channel occupancy limits will apply only to “national” programming services (i.e., local and regional programming services are exempt); (4) channel occupancy limits will apply to a maximum of 75 channels per system; (5) all vertically integrated programming services carried as of the effective date of the 1992 Cable Act (December 4, 1992) could continue to be carried; and (6) channel occupancy limits will not be eliminated in communities where actual head-to-head competition exists.

B. Petitions for Reconsideration

The Center for Media Education and the Consumer Federation of America (collectively “CME”) filed a joint Petition for Reconsideration asking the Commission to reconsider several issues decided in the Second Report and

Order. Specifically, CME asked the Commission to: (1) Reduce the channel occupancy limit from 40% to 20%; (2) require that broadcast, PEG, and leased access channels be subtracted from the number of activated channels before calculating total channel capacity; (3) eliminate the exemption for local and regional networks; (4) apply channel occupancy limits beyond a system’s first 75 channels; and (5) reverse the decision to grandfather all vertically integrated programming services carried as of December 4, 1992.

After consideration of the various submissions, the Commission declines to modify the 40% channel occupancy limit. In requiring the Commission to establish “reasonable” channel occupancy limits, Congress directed the Commission to balance the risks of vertical integration against benefits such as the development of diverse and high quality video programming. The Commission continues to believe that the 40% limit strikes the appropriate balance between these competing objectives.

Moreover, CME may have overstated the practical effect of must-carry, PEG and leased access requirements on unaffiliated programmers’ ability to obtain carriage. In the absence of record evidence on this point, the Commission examined an unscientific sampling of 25 Tele-Communications, Inc. (“TCI”) and Time Warner Entertainment Company, L.P. (“Time Warner”) cable systems (those being the most vertically integrated cable operators) in order to determine whether, in fact, broadcast, PEG and leased access channels occupied all, or nearly all, of the systems’ unaffiliated programming channels. Generally, the Commission found that, even after excluding broadcast, PEG and leased access channels (and even assuming the presence of two local or regional networks), all of the systems had capacity remaining for additional unaffiliated programming.

Next, CME claims that the Commission overstated the benefits of vertical integration. As proof, CME states that the Cable News Network, Inc. (“CNN”), Black Entertainment Television, Inc. (“BET”), and Nickelodeon were successful prior to their relationship with cable operators, and that “there has been no successful launch of an unaffiliated video programmer since the cable industry began the trend toward vertical integration.” Whether or not CNN, BET and Nickelodeon achieved some initial independent success, there is evidence in the record that these and other programmers would have had difficulty

sustaining their success had it not been for cable operator investment (see, e.g., Comments of Turner Broadcasting System, Inc., filed February 9, 1993, at 12 (at a time when TBS's "independence was very much at stake," cable operators were willing to provide long-term equity under terms others were not); Opposition of Black Entertainment Television, Inc. to Comments of Viacom International, Inc., filed February 22, 1994, at 2 ("[C]able investment has been crucial to establishing BET as a viable and valuable programming service.")). Likewise, CME's assertion that there has been no successful launch of an unaffiliated programmer since vertical integration has taken hold was disputed by TBS, citing the recent successes of ESPN2, FLIX and the SciFi Channel.

Similarly, there is no evidence in the record to substantiate CME's claim that the 40% limit will deter independent investors from investing in video programming, or that independent investors are currently deterred from investing in cable programming by the Commission's channel occupancy limits.

Finally, the Commission disagrees with CME's assertion that the Senate Report "suggested" a 20% channel occupancy limit. The Senate Report stated: "For example, the FCC may conclude that each MSO should control no more than 20 percent of the channels on any cable system * * *." Thus, the Report used the 20% figure for illustrative purposes only, while clearly acknowledging that the Commission was free to choose a different limit. This interpretation is supported by the actual wording of the statute, which simply requires the Commission to establish "reasonable" channel occupancy limits.

The Commission also denies CME's petition to reconsider the treatment of broadcast, PEG and leased access channels. CME correctly notes that the channel occupancy limits are intended to keep cable operators from filling every available channel with their own programming. But from this premise, CME draws the conclusion that channel occupancy limits must therefore be intended to give "independent commercial programmers a chance to get on the wire." The statute, however, does not distinguish between "independent" unaffiliated programmers and other types of unaffiliated programmers. Section 11 simply ensures that subscribers will have access to some kind of unaffiliated programming on a prescribed number of channels. CME does not dispute that broadcast, PEG and leased access channels are "unaffiliated" with cable

operators, or that the 1992 Cable Act requires cable operators to reserve channel space for such unaffiliated programming. Thus, the Commission reaffirms its holding in the Second Report and Order that it would be unreasonable to subtract such channels before calculating the system's channel capacity, since they provide the type of diverse, unaffiliated programming contemplated by the 1992 Cable Act. Further, as the Commission noted in the Second Report and Order, it would be unfair to penalize those cable operators who carried the widest array of broadcast, PEG and leased access channels by decreasing the number of channels available for affiliated programming.

Moreover, there is no evidence in the record that "independent" commercial programmers (i.e., those with no cable ownership interests at all) are unable to obtain carriage because of the Commission's treatment of broadcast, PEG and leased access channels. To the contrary, in the Commission's sampling of 25 TCI and Time Warner cable systems described above, the Commission found that all of the systems carried some "independent" unaffiliated programmers, with most systems carrying between 7 and 11 such channels.

In addition, although the Senate Report's sample calculation excluded broadcast and access channels in calculating channel capacity, CME's reliance on it as an expression of Congressional intent is misplaced. As the Commission stated in the Second Report and Order:

The Senate Report language (* * *) appears to be included merely as an example to illustrate how the Commission may decide to calculate channel occupancy limits and therefore does not prohibit the Commission from adopting an alternative approach if it finds such an approach to be reasonable to promote the legislative objectives. In any event, this language is not included in the statute itself.

Finally, the Commission does not believe that it is weakening Congress' statutory scheme by considering the impact of other provisions of the 1992 Cable Act in establishing channel occupancy limits. Section 11 expressly gives the Commission broad discretion to fashion "reasonable" channel occupancy limits. In the Commission's view, establishing "reasonable" limits requires it to consider all factors bearing on the dangers or benefits of vertical integration. Thus, for instance, the Commission believes that not only should it take into account the impact of broadcast, PEG and leased access channels, but also the impact of sections

12 and 19 in deterring the type of discriminatory conduct that may be caused by vertical integration. Only by considering the whole of Congress' scheme can the Commission determine the level of vertical structural limits that are "reasonable."

The Commission also denies CME's petition to reconsider the exception for local and regional programming. CME's approach overlooks Congress' direction that the Commission consider the benefits as well as the dangers of vertical integration in establishing "reasonable" channel occupancy limits. As the Commission stated in the Second Report and Order, the exception for local and regional networks was "an important means of encouraging continued MSO investment in the development of local cable programming, which is responsive to the needs and tastes of local audiences and serves Congress' objectives of promoting localism." (Second Report and Order at ¶ 78.) CME does not challenge the value of local and regional programming, or the Commission's conclusion that given the cost and limited appeal of such programming, an exception may be necessary to encourage continued MSO investment. The Commission continues to believe that consideration of these benefits of vertical integration more accurately reflects Congressional intent, and fully justifies the exception.

On reconsideration, the Commission also declines CME's invitation to eliminate the 75-channel cap. There is no evidence in the record to support CME's claim that "there is a strong likelihood that all of the newly available channels will be filled by services affiliated with the MSO." Indeed, the Commission notes that in its informal survey of 25 TCI and Time Warner cable systems, none of the systems were approaching the current 40% channel occupancy limit for affiliated programming. However, even if there were some basis for CME's prediction, the Commission still believes that the vast expansion of channel capacity may obviate the need for a rigid occupancy limit. As the Commission noted in the Second Report and Order, although information on how multichannel video distributors will use the additional capacity "is necessarily somewhat speculative," the record indicates that the capacity will likely be used to deliver targeted "niche" video programming services aimed at correspondingly smaller audience sizes, such as pay-per-view and "multiplexed" channels. (Second Report and Order at ¶¶ 83-84.) Occupancy limits in these

circumstances do not parallel occupancy limits for more restricted capacity systems where most services are distributed on discrete channels to a significant portion of a system's subscribership. Accordingly, the occupancy limits can be relaxed.

In sum, the Commission continues to believe that the introduction of advanced technologies such as signal compression and fiber optics will reduce the need for structural occupancy limits in order to ensure programming diversity and access for unaffiliated programmers. Nevertheless, as the Commission noted in the Second Report and Order, the 75-channel cap will be subject to periodic review and will be eliminated if developments warrant.

The Commission also denies CME's request to reconsider its decision to grandfather all vertically integrated programming services carried as of December 4, 1992 (the effective date of the 1992 Cable Act). The Commission still believes, as it held in the Second Report and Order, that the public interest would be disserved by requiring cable operators to delete vertically integrated programming services to comply with the channel occupancy caps. The Commission continues to believe that grandfathering existing arrangements will limit consumer confusion and the disruption of existing programming relationships, and is consistent with Congress' direction that our channel occupancy limits "take particular account of the market structure, ownership patterns, and other relationships of the cable television industry." (Communications Act, section 613(f)(2)(C).)

The Commission also rejects CME's contention that the decision to grandfather existing vertical arrangements "has rendered impotent" the intent of Congress to limit excessive vertical integration. First, the Commission reiterates that Congress directed it to establish "reasonable" channel occupancy limits based on competing interests; if Congress wished to require the divestiture of existing channels it could have done so. More importantly, the Commission did not grandfather non-compliance in perpetuity. Rather, the Second Report and Order provided that when a grandfathered cable system adds channel capacity, it cannot add an affiliated programming service until its system is in full compliance with the Commission's channel occupancy rules. Thus, the difference is more one of timing than of ultimate objectives. While CME suggests immediate divestiture of existing services to bring

systems into compliance, the Commission's approach is to grandfather existing services and remedy non-compliance prospectively. The Commission continues to believe that its approach better reflects the various interests at stake, and thus better reflects Congress' intent.

Bell Atlantic filed a Petition for Limited Reconsideration requesting that the Commission reconsider its decision to apply the channel occupancy limits to cable systems that face actual head-to-head competition. On reconsideration, the Commission declines to modify its decision to enforce channel occupancy limits in systems which face actual head-to-head competition. With respect to Bell Atlantic's argument that channel occupancy limits are even less necessary in markets where competition exists and one of the competitors is a video dialtone service, the Commission cannot find, at this time, that video dialtone will completely eliminate the problems caused by vertical integration. Under video dialtone, a telephone company must provide sufficient capacity to serve multiple video programmers, and must expand capacity as demand increases to the extent technically feasible and economically reasonable. At this point, there are only eight commercially licensed video dialtone services in the country. None of these systems is yet operational; until that time, it is unclear whether a video dialtone system will fully address the concerns raised by channel occupancy limits. In addition, the practical effect of several recent court cases is that certain telephone companies may now provide their own programming to subscribers in their service areas. Thus, the Commission does not believe that video dialtone in its current state can provide sufficient justification to reconsider the decision to enforce channel occupancy limits in systems which face actual head-to-head competition.

The remaining arguments raised by Bell Atlantic's Petition have already been considered and rejected in the Second Report and Order. In the Second Report and Order, the Commission concluded that it should not eliminate channel occupancy limits in communities where effective competition exists because the Commission found that the effective competition standard was not adopted for this specific purpose and because it is not clear that the presence of effective competition for any cable system will address all of the relevant concerns that Congress expressed in enacting section 11 of the 1992 Cable Act. For example, the Commission noted that if a

competing multichannel distributor is also vertically integrated, without channel occupancy limits, unaffiliated programming services may continue to be denied access from either outlet, thus frustrating the diversity and competition objectives of the 1992 Act.

Finally, the Commission also agrees that the statutory exemption from regulation for cable systems subject to effective competition is very limited: Congress explicitly stated in the statute that, in systems which faced effective competition, rate regulation would not be necessary. Thus, it is reasonable to assume that had Congress intended for all cable regulations to be eliminated where systems became subject to actual head-to-head competition, this statutory exemption would have been drafted much more broadly. Nowhere in either the language of section 11 or its legislative history does it state that the presence of actual head-to-head competition will render the channel occupancy limits unnecessary.

The Commission therefore concludes that there is insufficient evidence in the record before it to warrant elimination or modification of the channel occupancy limits in systems that face actual head-to-head competition. However, as the Commission indicated in the Second Report and Order, it remains aware that Congress has indicated that a primary objective of the 1992 Act was to rely on the marketplace to the maximum extent possible, and that the legislation was intended to protect consumer interests in the receipt of cable service where cable television systems are not subject to effective competition. Thus, as competition develops and the Commission gains more experience with the rules, the Commission will further analyze its rules and the industry as a whole to see whether vertical ownership limits should be phased out.

Administrative Matters

Regulatory Flexibility Act Analysis

Pursuant to sections 601-602 of the Regulatory Flexibility Act, Public Law 96-354, 94 Stat. 1164, 5 U.S.C. 601 *et seq.* (1981), the Commission's final analysis is as follows:

Need and Purpose for Action: This action is being taken to address petitions for reconsideration of the channel occupancy rules adopted by the Commission to implement section 11(c) of the 1992 Cable Act.

Summary of Issues Raised by the Public Comments in Response to the Initial Regulatory Flexibility Analysis: There were no comments received in

response to the Initial Regulatory Flexibility Analysis.

Significant Alternatives Considered: We have analyzed the comments submitted in light of our statutory directives and have, to the extent possible, minimized the regulatory burden on entities covered by the ownership provisions of the 1992 Cable Act.

Ordering Clauses

Accordingly, *it is hereby ordered* That pursuant to the authority in sections 1, 4 and 613 of the Communications Act of 1934, as amended, 47 U.S.C. 151, 154, and 533, the petitions for reconsideration filed in this proceeding by the Center for Media Education/ Consumer Federation of America and Bell Atlantic Corporation are denied. Federal Communications Commission.

William F. Caton,

Acting Secretary.

[FR Doc. 95-10719 Filed 5-1-95; 8:45 am]

BILLING CODE 6712-01-M

GENERAL SERVICES ADMINISTRATION

48 CFR Parts 502, 506, 513, and 552

[APD 2800.12A, CHGE 62]

RIN 3090-AF60

General Services Administration Acquisition Regulation; Miscellaneous Changes

AGENCY: Office of Acquisition Policy, GSA.

ACTION: Final rule.

SUMMARY: The General Services Administration Acquisition Regulation (GSAR) is amended to make miscellaneous changes by providing uniform procedures for contracting under the regulatory system.

EFFECTIVE DATE: May 8, 1995.

FOR FURTHER INFORMATION CONTACT: Paul Lynch, Office of GSA Acquisition Policy, (202) 501-1224.

SUPPLEMENTARY INFORMATION:

A. Background

The rule amends section 502.101 to revise the definitions of "Agency competition advocate," "Contracting activity competition advocate," and "Head of the contracting activity" to reflect current GSA organizational changes; to revise section 506.304 to delete reference to "concurrence by legal counsel" which is no longer required; to revise section 513.106 to make use of the GSA Form 2010, Small

Purchase Tabulation Source List/ Abstract optional rather than mandatory and to indicate that the form does not apply to purchases under \$2,500; and to revise section 552.225-72 to insert the words "Basin country" after "Caribbean" in paragraph (a)(1) to correct an inadvertent omission of the words in GSAR Change 59.

B. Public Comments

This rule was not published in the **Federal Register** for Public comment because it is not a significant revision as defined in FAR 1.501-1.

C. Executive Order 12866

The rule was not submitted to the Office of Management and Budget because it is not a significant rule as defined in Executive Order 12866, Regulatory Planning and Review.

D. Regulatory Flexibility Act

The Regulatory Flexibility Act does not apply because this rule is not a significant revision as defined in FAR 1.501-1.

E. Paperwork Reduction Act

This rule does not impose any information collection or recordkeeping requirements that require the approval of OMB under 44 U.S.C. 3501, et seq. Therefore, the requirements of the Paperwork Reduction Act do not apply.

List of Subjects in 48 CFR Parts 502, 506, 513 and 552

Government procurement, Reporting and recordkeeping requirements.

Accordingly, 48 CFR Parts 502, 506, 513 and 552 are amended as follows:

1. The authority citation for 48 CFR Parts 502, 506, 513 and 552 continues to read as follows:

Authority: 40 U.S.C. 486(c).

PART 502—DEFINITION OF WORDS AND TERMS

2. Section 502.101 is amended by revising the definitions for "Agency competition advocate," "Contracting activity competition advocate" and "Head of the contracting activity" to read as follows:

502.101 Definitions.

Agency competition advocate means the GSA Competition Advocate located in the Office of Acquisition Policy.

* * * * *

Contracting activity competition advocate means the individual designated in writing by the head of the contracting activity. This authority may not be redelegated. The HCA must ensure that the designated competition

advocate is not assigned any duty or responsibility that is inconsistent with the advocacy function. The identity of the designated official shall be communicated to procuring staff and the Senior procurement executive.

* * * * *

Head of the contracting activity means the Associate Administrator for Acquisition Policy, Commissioners of the Federal Supply Service (FSS), Information Technology Service (ITS), Public Buildings Service (PBS), or Regional Administrators. The Associate Administrator for Acquisition Policy serves as the HCA for Central Office contracting activity outside of FSS, ITS and PBS.

* * * * *

PART 506—COMPETITION REQUIREMENTS

3. Section 506.304 is amended by revising the introductory text to read as follows:

506.304 Approval of the justification.

The justification (except for contracts awarded under FAR 6.302-7) must be approved by:

* * * * *

PART 513—SMALL PURCHASE AND OTHER SIMPLIFIED PURCHASE PROCEDURES

3. Section 513.106 is amended by revising paragraph (c)(2) to read as follows:

513.106 Competition and price reasonableness.

* * * * *

(c) * * *

(2) The GSA Form 2010, Small Purchases Tabulation Source List/ Abstract, or an automated equivalent which provides substantially the same documentation, must be used to document written and oral quotations (except small purchases \$2,500 or less).

PART 552—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

4. Section 552.225-72 is amended by revising paragraph (a)(1) of the clause to read as follows:

552.225-72 Eligible Products from Nondesignated Countries—Waiver.

* * * * *

(a) * * *

(1) No responsive bid or technically acceptable offer from a responsible offeror is received offering U.S. or designated country end products, Caribbean Basin country end products, Canadian or Mexican end products

as defined in the clause entitled "Trade Agreement Act" in this solicitation; or

* * * * *

Dated: April 20, 1995.

Ida M. Ustad,

Associate Administrator for Acquisition Policy.

[FR Doc. 95-10547 Filed 5-1-95; 8:45 am]

BILLING CODE 6820-61-M

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 678

[Docket No. 950414106-5106-01; I.D. 121494A]

RIN 0648-AF63

Atlantic Shark Fisheries; Semiannual Quotas for Large Coastal and Pelagic Sharks

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Final rule.

SUMMARY: NMFS issues this final rule to establish semiannual commercial quotas for Atlantic large coastal sharks and Atlantic pelagic sharks under the framework provisions of the Fishery Management Plan for Sharks of the Atlantic Ocean (FMP), at 1994 levels. These quotas apply to permitted vessels for 1995 and, unless adjusted, for future years. This final rule is intended to reduce the probability of overfishing, by maintaining the current semiannual quotas for the pelagic shark species group and rejecting the planned 1995 increases in the semiannual commercial quotas increase for the large coastal species group.

EFFECTIVE DATE: May 1, 1995.

ADDRESSES: Requests for copies of the environmental assessment and regulatory impact review (EA/RIR) should be sent to Richard B. Stone, Chief, Highly Migratory Species Management Division, Office of Fisheries Conservation and Management (F/CM), National Marine Fisheries Service, 1315 East-West Highway, Silver Spring, MD 20910.

FOR FURTHER INFORMATION CONTACT: C. Michael Bailey, 301-713-2347, FAX 301-713-0596; Michael E. Justen, 813-570-5305 or Kevin B. Foster, 508-281-9260.

SUPPLEMENTARY INFORMATION: The fishery for Atlantic sharks is managed under the FMP prepared by NMFS

under authority of section 304(f)(3) of the Magnuson Fishery Conservation and Management Act (Magnuson Act), and implemented in April 1993 through regulations found at 50 CFR part 678.

For the reasons explained below, NMFS is implementing the following semiannual quotas: Large coastal species = 1,285 metric tons dressed weight (mtdw); Pelagic species = 290 mtdw. The notice of proposed rulemaking was published on January 6, 1995 (60 FR 2071), with a request for comments. The notice of proposed rulemaking contained background information which is not repeated here.

Comments and Responses

Commercial Quotas

Comments: Written comments on the proposed commercial quotas were provided by one Fishery Management Council, three conservation organizations, one directed commercial shark fishing organization (petition with 49 entries), one incidental commercial shark fishing organization, one seafood production company, and 64 individuals whose comments addressed the proposed commercial quotas. Commenters suggested four possible options: (1) Commercial quotas should be allowed to increase as scheduled in the FMP, (2) commercial quotas should be maintained at the current level until additional data on the status of the stocks can be evaluated, (3) commercial quotas should be significantly reduced, and (4) the commercial shark fishery should be closed until there are clear signs of stock recovery.

Response: NMFS has examined the four possible commercial quota options and has determined that the total allowable catch (TAC) for 1995 should remain at the 1994 level, as recommended by the 1994 Shark Evaluation Workshop (SEW) and members of the Shark Operations Team (OT). A new stock assessment and fishery evaluation (SAFE) report is currently in preparation and will be published in 1995. If appropriate, the Assistant Administrator for Fisheries, NOAA (AA) may reexamine the quota levels and make determinations on adjustments to future quotas.

Large Coastal and Pelagic Shark Quotas

The framework provisions of the FMP allow the AA to make adjustments in the management measures in order to achieve the objectives of the FMP. NMFS has determined that the 1994 semiannual quotas of 1,285 mt, which represented for the year only a 5 percent increase over 1993, should be set as the semiannual commercial quotas for the

large coastals group for 1995. This, in the opinion of NMFS, represents a reasonable compromise between alternatives, pending future scientific analyses that may suggest the need for different quotas.

The alternative of increasing the commercial quotas as planned in the FMP was rejected primarily on the basis of recommendations from the SEW and members of the OT. The SEW concluded that "the weight of evidence does not support the previous (FMP) recommendation that the 1994 or 1995 TAC should automatically increase." The OT met in July 1994, and generally agreed with this conclusion. Thus, the rebuilding plan outlined in the FMP has been determined to be inadequate to achieve the goal of rebuilding the large coastal sharks resource to a level consistent with the maximum sustainable yield (MSY). As a result, NMFS has rejected planned quota increases for 1995. Whether the selected semiannual quotas of 1,285 mt (equivalent to the 1994 semiannual quotas) will lead to rebuilding in 1995 and beyond is currently uncertain. The likelihood of stock rebuilding for this and other quota levels will be addressed in future stock assessments.

In terms of the semiannual quota increase that has already gone into effect, NMFS believes that the 5 percent reduction in quotas necessary to return to the 1993 level could have a large negative impact on the large coastal shark fishing industry, while it is unlikely to change substantially the future dynamics of the large coastal shark resource. Until recently, the fishing industry had anticipated that the scheduled increases in the FMP would take place, and had planned operations accordingly. Subsequently, the industry has had to replan and scale down projected production schedules. Further scaling down could result in greater negative consequences which, in the opinion of NMFS, may not be warranted.

In terms of benefits to the large coastal shark resource, NMFS believes that action to forestall the planned 30.3 percent increase of the 1995 semiannual quotas for the year over the 1993 quotas has far greater significance for the future viability of the various shark stocks. NMFS believes that it is not worth putting the industry at a disadvantage for the sake of a quota reduction of the order of 5 percent, which may have been within the margin of error of quota monitoring capabilities in the past.

Comments received from the Delaware Division of Fish and Wildlife through the Delaware Coastal Management Program recommended

that the quota for 1995 be further reduced. Three conservation organizations and numerous individuals also requested that the quota be reduced. Large reductions in the established quota would likely cause substantial financial hardship for vessels already commercially fishing for large coastal sharks. A complete closure of the established directed shark fishery for large coastal sharks would result in severe financial hardships for vessels already participating in the fishery, and could result in the displacement of vessels and crews from the large coastal shark fishery into other fisheries, including pelagic and small coastal sharks.

The Delaware Coastal Management Program has requested additional information concerning the basis for maintaining the quota at status quo, expressing a preference that the quota be further reduced. The AA has agreed to continue discussion on quota levels with Delaware officials, and Delaware officials have agreed that the proposed quota should be established by a final rule prior to a final resolution of this issue, because otherwise the fishery would be unrestricted.

While the 1994 SEW focused on the large coastal shark species group, declining catch per unit of effort and life history characteristics indicating low productivity for pelagics and small coastals also suggest that a prudent approach is warranted for these groups.

No new analyses were presented upon which to modify MSY or TAC of the pelagic and small coastal sharks. Accordingly, NMFS sets the semiannual commercial quotas for large coastal and pelagic sharks for 1995 at the 1994 levels. At present, no quota has been established for the small coastal species group. When analyses are presented, the AA may propose an appropriate quota for small coastal sharks.

NMFS also removes the specification of the year from those parts of the regulatory text referring to quotas. Thus, if a change in quota level from a previous year is not published, a change in the regulatory text will not be necessary to continue the previous level for the new year.

Classification

The AA has determined that this rule is necessary for conservation and management of shark resources in the Atlantic Ocean and is consistent with the national standards and other provisions of the Magnuson Act, and other applicable law. This final rule has been determined to be not significant for purposes of E.O. 12866. The quotas for 1995 are within the range analyzed in the Regulatory Flexibility Analysis (RFA) included in the EA/RIR prepared for the FMP and no new RFA has been prepared.

List of Subjects in 50 CFR Part 678

Fisheries, Fishing, Reporting and recordkeeping requirements.

Dated: April 26, 1995.

Gary Matlock,

Program Management Officer, National Marine Fisheries Service.

For the reasons set out in the preamble, 50 CFR part 678 is amended as follows:

PART 678—ATLANTIC SHARKS

1. The authority citation for part 678 continues to read as follows:

Authority: 16 U.S.C. 1801 *et seq.*

2. Section 678.24, paragraph (b) is revised to read as follows:

§ 678.24 Commercial quotas.

* * * * *

(b) *Semiannual quotas.* The following commercial quotas apply:

(1) For the period January 1 through June 30:

(i) Large coastal species—1,285 metric tons, dressed weight.

(ii) Pelagic species—290 metric tons, dressed weight.

(2) For the period July 1 through December 31:

(i) Large coastal species—1,285 metric tons, dressed weight.

(ii) Pelagic species—290 metric tons, dressed weight.

* * * * *

[FR Doc. 95-10738 Filed 4-27-95; 1:36 pm]

BILLING CODE 3510-22-F

Proposed Rules

Federal Register

Vol. 60, No. 84

Tuesday, May 2, 1995

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. 95–NM–03–AD]

Airworthiness Directives; Airbus Model A300–600 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes the adoption of a new airworthiness directive (AD) that is applicable to all Airbus Model A300–600 series airplanes. This proposal would require repetitive inspections to detect cracks in the bottom skin of the wing in the area of the cutout for the pylon rear attachment fitting, and repair, if necessary. This proposal is prompted by a report indicating that, during full-scale fatigue testing, a crack was found in the bottom skin of the wing at the cutout for the aft pylon attachment fitting due to fatigue-related stress. The actions specified by the proposed AD are intended to prevent such fatigue-related cracking, which could result in reduced structural integrity of the wing.

DATES: Comments must be received by June 12, 1995.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM–103, Attention: Rules Docket No. 95–NM–03–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056. Comments may be inspected at this location between 9:00 a.m. and 3:00 p.m., Monday through Friday, except Federal holidays.

The service information referenced in the proposed rule may be obtained from Airbus Industrie, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France. This information may be examined at the FAA, Transport Airplane

Directorate, 1601 Lind Avenue, SW., Renton, Washington.

FOR FURTHER INFORMATION CONTACT: Stephen Slotte, Aerospace Engineer, Standardization Branch, ANM–113, FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (206) 227–2797; fax (206) 227–1320.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications shall identify the Rules Docket number and be submitted in triplicate to the address specified above. All communications received on or before the closing date for comments, specified above, will be considered before taking action on the proposed rule. The proposals contained in this notice may be changed in light of the comments received.

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

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this notice must submit a self-addressed, stamped postcard on which the following statement is made: “Comments to Docket Number 95–NM–03–AD.” The postcard will be date stamped and returned to the commenter.

Availability of NPRMs

Any person may obtain a copy of this NPRM by submitting a request to the FAA, Transport Airplane Directorate, ANM–103, Attention: Rules Docket No. 95–NM–03–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056.

Discussion

The Direction Générale de l'Aviation Civile (DGAC), which is the airworthiness authority for France, recently notified the FAA that an unsafe condition may exist on all Airbus Model

A300–600 series airplanes. The DGAC advises that, during full scale fatigue testing, a crack was found in the bottom skin of the wing at the cut out for the aft pylon attachment fitting after the airplane accumulated approximately 58,650 total simulated flights. Investigation revealed that such cracking was caused by fatigue-related stress. Such fatigue-related cracking, if not detected and corrected in a timely manner, could result in reduced structural integrity of the wing.

Airbus has issued Service Bulletin A300–57–6028, Revision 3, dated September 13, 1994, which describes procedures for repetitive detailed visual inspections to detect cracks in the bottom skin of the wing in the area of the cut out for the pylon rear attachment fitting, and repair, if necessary. The DGAC classified this service bulletin as mandatory and issued French airworthiness directive 94–069–158(B), dated March 30, 1994, in order to assure the continued airworthiness of these airplanes in France.

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

Since an unsafe condition has been identified that is likely to exist or develop on other airplanes of the same type design registered in the United States, the proposed AD would require repetitive detailed visual inspections to detect cracks in the wing bottom skin of the wing in the area of the cut out for the pylon rear attachment fitting, and repair, if necessary. The inspection actions would be required to be accomplished in accordance with the service bulletin described previously. Any necessary repair of the wing bottom skin would be required to be accomplished in accordance with a method approved by the FAA.

As a result of recent communications with the Air Transport Association

(ATA) of America, the FAA has learned that, in general, some operators may misunderstand the legal effect of AD's on airplanes that are identified in the applicability provision of the AD, but that have been altered or repaired in the area addressed by the AD. The FAA points out that all airplanes identified in the applicability provision of an AD are legally subject to the AD. If an airplane has been altered or repaired in the affected area in such a way as to affect compliance with the AD, the owner or operator is required to obtain FAA approval for an alternative method of compliance with the AD, in accordance with the paragraph of each AD that provides for such approvals. A note has been included in this notice to clarify this long standing requirement.

The FAA estimates that 35 airplanes of U.S. registry would be affected by this proposed AD, that it would take approximately 6 work hours per airplane to accomplish the proposed actions, and that the average labor rate is \$60 per work hour. Based on these figures, the total cost impact of the proposed AD on U.S. operators is estimated to be \$12,600, or \$360 per airplane.

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

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

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

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

Airbus Industrie: Docket 95–NM–03–AD.

Applicability: All Model A300–600 series airplanes, certificated in any category.

Note 1: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must use the authority provided in paragraph (b) to request approval from the FAA. This approval may address either no action, if the current configuration eliminates the unsafe condition; or different actions necessary to address the unsafe condition described in this AD. Such a request should include an assessment of the effect of the changed configuration on the unsafe condition addressed by this AD. In no case does the presence of any modification, alteration, or repair remove any airplane from the applicability of this AD.

Compliance: Required as indicated, unless accomplished previously.

To prevent reduced structural integrity of the wing, accomplish the following:

(a) Prior to the accumulation of 24,000 total flight cycles since date of manufacture of the airplane, or within 750 flight cycles after the effective date of the AD, whichever occurs later, perform a detailed visual inspection to detect cracks in the bottom skin of the wing in the area of the cut out for the pylon rear attachment fitting, in accordance with Airbus Service Bulletin A300–57–6028, Revision 3, dated September 13, 1994. Repeat the inspection thereafter at intervals not to exceed 9,000 flight cycles. If any crack is detected, prior to further flight, repair the wing bottom skin in accordance with a method approved by the Manager, Standardization Branch, ANM–113, FAA, Transport Airplane Directorate.

(b) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be

used if approved by the Manager, Standardization Branch, ANM–113. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Standardization Branch, ANM–113.

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

(c) Special flight permits may be issued in accordance with §§ 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 April 26, 1995.

James V. Devany,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 95–10710 Filed 5–1–95; 8:45 am]

BILLING CODE 4910–13–U

14 CFR Part 39

[Docket No. 95–CE–20–AD]

Airworthiness Directives; Twin Commander Aircraft Corporation 680, 681, 690, and 695 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes to adopt a new airworthiness directive (AD) that would apply to certain Twin Commander Aircraft Corporation (Twin Commander) 680, 681, 690, and 695 series airplanes. The proposed action would require installing a placard warning the pilot to observe turbulent air penetration speeds. Two accidents involving Model 690 airplanes where the affected airplanes encountered turbulence while descending at high speeds prompted the proposed action. The actions specified by the proposed AD are intended to prevent structural damage to the airplane caused by excessive turbulence, which could result in loss of the airplane.

DATES: Comments must be received on or before June 28, 1995.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Central Region, Office of the Assistant Chief Counsel, Attention: Rules Docket No. 95–CE–20–AD, Room 1558, 601 E. 12th Street, Kansas City, Missouri 64106. Comments may be inspected at this location between 8 a.m. and 4 p.m., Monday through Friday, holidays excepted.

Service information that applies to the proposed AD may be obtained from the Twin Commander Aircraft Corporation, 19010 59th Drive, N.E., Arlington, Washington 98223. This information also may be examined at the Rules Docket at the address above.

FOR FURTHER INFORMATION CONTACT: Mr. Mike Pasion, Aerospace Engineer, FAA, Northwest Mountain Region, 1601 Lind Avenue S.W., Renton, Washington 98055-4056; telephone (206) 227-2594; facsimile (206) 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 should identify the Rules Docket number and be submitted in triplicate to the address specified above. All communications received on or before the closing date for comments, specified above, will be considered before taking action on the proposed rule. The proposals contained in this notice may be changed in light of the comments received.

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

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this notice must submit a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket No. 95-CE-20-AD." The postcard will be date stamped and returned to the commenter.

Availability of NPRMs

Any person may obtain a copy of this NPRM by submitting a request to the FAA, Central Region, Office of the Assistant Chief Counsel, Attention: Rules Docket No. 95-CE-20-AD, Room 1558, 601 E. 12th Street, Kansas City, Missouri 64106.

Discussion

Two Twin Commander Model 690C airplanes were recently involved in accidents where the pilot encountered excessive turbulence while descending at high speeds. In both of these

accidents the airplane was lost. Wind gusts associated with turbulence can result in increased loads on the wing, resulting in possible airplane structural damage and loss of the airplane.

Reducing airspeed in turbulence reduces the effect of these gust-induced loads during turbulence. Maintaining airspeed at Turbulent Air Penetration speed or Maneuvering speed provides an increase in structural margin when encountering turbulence. Operating the airplane at Maneuvering speed is the safest speed for flight in turbulence. Turbulent Air Penetration and Maneuvering speeds are both well below the red-line limits of the maximum operating limit speed (V_{MO}/M_{MO}).

Twin Commander has issued Service Bulletin No. 220, dated February 1, 1995, which re-emphasizes the importance of reducing airspeed before descending into known turbulence or reducing airspeed immediately upon entering unexpected turbulence on the following airplanes:

Models	Serial No.
680T and 680V	1473 through 1720.
680W	1721 through 1850.
681	6001 through 6072.
690	11001 through 11079.
690A	11100 through 11344.
690B	11350 through 11566.
690C	11600 through 11735.
690D	15001 through 15042.
695	95000 through 95084.
695A	96000 through 96100.
695B	96201 through 96208.

This service bulletin also references a placard and airplane flight manual/pilot operating handbook (AFM/POH) revisions to advise airplane operators of target speeds for operation during turbulence.

After examining the circumstances and reviewing all available information related to the accidents described above including the referenced service information, the FAA has determined that AD action should be taken to prevent structural damage to the airplane caused by excessive turbulence, which could result in loss of the airplane.

Since an unsafe condition has been identified that is likely to exist or develop in other Twin Commander 680, 681, 690, and 695 series airplanes (specific models and serial numbers

presented above) of the same type design, the proposed AD would require incorporating a placard and AFM/POH revisions that warn the airplane operator of the importance of observing the Turbulent Air Penetration and Maneuvering speeds. The following kits include the placard and AFM/POH revisions:

Kit No.	Model affected
SB220-1	680T.
SB220-2	680V.
SB220-3	680W.
SB220-4	681.
SB220-5	690.
SB220-6	690A.
SB220-7	690B.
SB220-8	690C.
SB220-9	690D.
SB220-10	695.
SB220-11	695A.
SB220-12	695B.

The FAA estimates that 566 airplanes in the U.S. registry would be affected by the proposed AD, that it would take approximately 1 workhour per airplane to accomplish the proposed action, and that the average labor rate is approximately \$60 an hour. Parts cost approximately \$38 per airplane. Based on these figures, the total cost impact of the proposed AD on U.S. operators is estimated to be \$55,468. This figure is based on the assumption that no affected airplane owner/operator has incorporated the placard and AFM/POH revisions included with the applicable SB220 kit. Twin Commander has informed the FAA that no kits have been distributed to the owners/operators of the affected airplanes.

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

For the reasons discussed above, I certify that this action (1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) if promulgated, will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A copy of the draft regulatory evaluation prepared for this action has been placed in the Rules

Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption ADDRESSES.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

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

§ 39.13 [Amended]

2. Section 39.13 is amended by adding a new AD to read as follows:

Twin Commander Aircraft Corporation:
Docket No. 95–CE–20–AD.

Applicability: The following airplane models and serial numbers, certificated in any category.

Models	Serial No.
680T and 680V	1473 through 1720.
680W	1721 through 1850.
681	6001 through 6072.
690	11001 through 11079.
690A	11100 through 11344.
690B	11350 through 11566.
690C	11600 through 11735.
690D	15001 through 15042.
695	95000 through 95084.
695A	96000 through 96100.
695B	96201 through 96208.

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 use the authority provided in paragraph (c) of this AD to request approval from the FAA. This approval may address either no action, if the current configuration eliminates the unsafe condition, or different actions necessary to address the unsafe condition described in this AD. Such a request should include an assessment of the effect of the changed

configuration on the unsafe condition addressed by this AD. In no case does the presence of any modification, alteration, or repair remove any airplane from the applicability of this AD.

Compliance: Required within the next 50 hours time-in-service after the effective date of this AD, unless already accomplished.

To prevent structural damage to the airplane caused by excessive turbulence, which could result in loss of the airplane, accomplish the following:

(a) Install the placard (to the windshield centerpost) and incorporate the airplane flight manual/pilot operating handbook (AFM/POH) revisions that are included with the kits presented below. The placard and AFM/POH revisions provide warnings to the airplane operator of the importance of observing the Turbulent Air Penetration and Maneuvering speeds:

Kit No.	Model affected
SB220–1	680T.
SB220–2	680V.
SB220–3	680W.
SB220–4	681.
SB220–5	690.
SB220–6	690A.
SB220–7	690B.
SB220–8	690C.
SB220–9	690D.
SB220–10	695.
SB220–11	695A.
SB220–12	695B.

Note 2: Twin Commander Service Bulletin No. 220, dated February 1, 1995, relates to the subject of this AD, and references the SB220 service kits specified above.

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

(c) An alternative method of compliance or adjustment of the compliance time that provides an equivalent level of safety may be approved by the Manager, Seattle Aircraft Certification Office (ACO), FAA, Northwest Mountain Region, 1601 Lind Avenue SW., Renton, Washington 98055–4056. The request shall be forwarded through an appropriate FAA 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.

(d) All persons affected by this directive may obtain copies of the document referred to herein upon request to the Twin Commander Aircraft Corporation, 19010 59th Drive, NE., Arlington, Washington 98223; or may examine this document at the FAA, Central Region, Office of the Assistant Chief Counsel, Room 1558, 601 E. 12th Street, Kansas City, Missouri 64106.

Issued in Kansas City, Missouri, on April 26, 1995.

Henry A. Armstrong,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 95–10711 Filed 5–1–95; 8:45 am]

BILLING CODE 4910–13–U

14 CFR Part 71

[Airspace Docket No. 95–AGL–1]

Proposed Modification of Class D Airspace and Removal of Class E Airspace, Rockford, IL

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: This notice proposes to modify the Class D airspace area and remove the Class E2 airspace area at Greater Rockford Airport, Rockford, IL. The Rockford Air Traffic Control Tower (ATCT) is a continuous (24 Hour a day) operation. The intent of this proposal is to amend the Class D airspace area's effective hours to coincide with the associated control tower's hours of operation, by changing the Class D airspace from part-time to full-time. The Class E2 airspace was previously needed to clarify when two-way radio communication with the ATCT was required and to provide adequate Class E airspace for instrument approach procedures when the control tower is closed. The airspace is no longer needed since the ATCT is now a continuous operation; therefore, the intent is to remove the part-time Class E2 airspace.

DATES: Comments must be received on or before June 15, 1995.

ADDRESSES: Send comments on the proposal in triplicate to: Federal Aviation Administration, Office of the Assistant Chief Counsel, AGL–7, Rules Docket No. 95–AGL–1, 2300 East Devon Avenue, Des Plaines, Illinois 60018.

The official docket may be examined in the Office of the Assistant Chief Counsel, Federal Aviation Administration, 2300 East Devon Avenue, Des Plaines, Illinois. An informal docket may also be examined during normal business hours at the Air Traffic Division, System Management Branch, Federal Aviation Administration, 2300 East Devon Avenue, Des Plaines, Illinois.

FOR FURTHER INFORMATION CONTACT:

Angeline Perri, Air Traffic Division, System Management Branch, AGL–530, Federal Aviation Administration, 2300 East Devon Avenue, Des Plaines, Illinois 60018, telephone (708) 294–7571.

SUPPLEMENTARY INFORMATION:**Comments Invited**

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal.

Communications should identify the airspace docket number and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: "Comments to Airspace Docket No. 95-AGL-1." The postcard will be date/time stamped and returned to the commenter. All communications received on or before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of comments received. All comments submitted will be available for examination in the Rules Docket, FAA, Great Lakes Region, Office of the Assistant Chief Counsel, 2300 East Devon Avenue, Des Plaines, Illinois, both before and after the closing date for comments. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

Any person may obtain a copy of the Notice of Proposed Rulemaking (NPRM) by submitting a request to the Federal Aviation Administration, Office of Public Affairs, Attention: Public Inquiry Center, APA-230, 800 Independence Avenue, S.W., Washington, DC 20591, or by calling (202) 267-3484. Communications must identify the notice number of this NPRM. Persons interested in being placed on a mailing list for future NPRMs should also request a copy of Advisory Circular No. 11-2A, which describes the application procedures.

The Proposal

The FAA is considering an amendment to part 71 of the Federal Aviation Regulations (14 CFR part 71) to modify the Class D airspace area and remove the Class E2 airspace area at

Greater Rockford Airport, Rockford, IL. The Rockford ATCT is a continuous (24 hour a day) operation. The intent of this proposal is to amend the Class D airspace area's effective hours to coincide with the associated control tower's hours of operation, by changing the Class D airspace from part-time to full-time. The Class E2 airspace was previously needed to clarify when two-way radio communication with the ATCT was required and to provide adequate Class airspace for instrument approach procedures when the control tower is closed. The airspace is no longer needed since the ATCT is now a continuous operation; therefore, the intent is to remove the part-time Class E2 airspace. Aeronautical maps and charts would reflect the defined area which would enable pilots to circumnavigate the area or otherwise comply with IFR procedures. Class D and E airspace designations are published in Paragraphs 5000 and 6002, respectively, of FAA Order 7400.9B dated July 18, 1994, and effective September 16, 1994, which is incorporated by reference in 14 CFR 71.1. The Class D and E airspace designations listed in this document would be published subsequently in the Order.

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore, this proposed regulation—(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) does not warrant preparation of a Regulatory Evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this proposed rule will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration proposes to amend part 71 of the Federal Aviation Regulations (14 CFR part 71) as follows:

PART 71—[Amended]

1. The authority citation for part 71 continues to read as follows:

Authority: 49 U.S.C. 1348(a), 1354(a), 1510; E.O. 10854, 24 FR 9565, 3 CFR, 1959-1963 Comp., p. 389; 49 U.S.C. 106(g); 14 CFR 11.69.

§71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9B, Airspace Designations and Reporting Points, dated July 18, 1994, and effective September 16, 1994, is amended as follows:

Paragraph 5000 General

* * * * *

AGL IL D Rockford, IL [Revised]

Rockford, Greater Rockford Airport, IL
(Lat. 42°11'46"N, long. 89°05'38"W)
Greater Rockford ILS Localizer
(Lat. 42°12'36"N, long. 89°05'17"W)
GILMY LOM

(Lat. 42°06'52"N, long. 89°05'55"W)

That airspace extending upward from the surface to and including 3,200 feet MSL within a 4.4-mile radius of the Greater Rockford Airport and within 1.8 miles each side of the Greater Rockford Runway 36 ILS localizer course, extending south from the 4.4-mile radius to the GILMY LOM.

* * * * *

Paragraph 6002 Class E Airspace Areas Designated as a Surface Area for an Airport

* * * * *

AGL IL E2 Rockford, IL [Removed]

* * * * *

Issued in Des Plaines, Illinois on April 17, 1995.

Roger Wall,

Manager, Air Traffic Division.

[FR Doc. 95-10774 Filed 5-1-95; 8:45 am]

BILLING CODE 4910-13-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration****21 CFR Part 173**

[Docket No. 90F-0344]

Secondary Direct Food Additives Permitted in Food for Human Consumption; Polymaleic Acid and its Sodium Salt

AGENCY: Food and Drug Administration, HHS.

ACTION: Tentative final rule.

SUMMARY: The Food and Drug Administration (FDA) is announcing its tentative decision to amend the food additive regulations to increase the

permitted use level of polymaleic acid and its sodium salt to control mineral scale during the production of beet and cane sugar juice and liquor. FDA is also announcing its tentative decision to amend the specifications for the additives and to revise the analytical method for measuring those specifications. This action is in response to a petition filed by Ciba-Geigy, Inc.

DATES: Written comments by July 17, 1995.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Vincent E. Zenger, Center for Food Safety and Applied Nutrition (HFS-206), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3105.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of November 28, 1990 (55 FR 49426), FDA announced that a food additive petition (FAP 0A4226) had been filed by Ciba-Geigy Inc., proposing that § 173.45 *Polymaleic acid and its sodium salt* (21 CFR 173.45) be amended to provide for the safe use of polymaleic acid and its sodium salt to control mineral scale during the production of beet and cane sugar juice and liquor at higher levels than the maximum currently permitted under the regulation.

The petition also contained information on a new manufacturing process for polymaleic acid and its sodium salt which results in a lower weight-average molecular weight for the additives and number-average molecular weight than those currently permitted. The molecular weight determinations were based on an improved analytical method.

FDA has evaluated data in the petition (FAP 0A4226) and other relevant material. The agency concludes that the proposed increase in the food additive use level is safe, and that the regulations should be amended as set forth below. The agency tentatively concludes that the molecular weight specifications for the additives should be amended to allow for the use of products manufactured by the new technique, and that the molecular weight determinations of the additives are to be based on the improved analytical method entitled "Determinations of Molecular Weight Distribution of Poly(Maleic)Acid" submitted by Ciba-Geigy, Inc., and dated March 17, 1992, which is incorporated by reference in amended § 173.45(a). This replaces the previous method with

the same title but different date that was incorporated by reference in the current § 173.45(a).

In the filing notice for the petition, the agency gave notice of the intent to increase the permitted use levels of polymaleic acid and its sodium salt but did not anticipate amending the allowed molecular weight range for the additives or the method for determining the molecular weight. The amended specifications are not intended to place new restrictions on the currently approved products, but to allow use of products manufactured by a new method and to take into account an improved method of molecular weight determination. Therefore, because the agency did not give notice of this change, it is publishing this document as a tentative final rule to allow interested parties an opportunity to comment on the amended product specifications.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above. As provided in 21 CFR 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 173

Food additives, Incorporation by reference.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director, Center for Food Safety and Applied Nutrition, it is proposed that 21 CFR part 173 is amended as follows:

PART 173—SECONDARY DIRECT FOOD ADDITIVES PERMITTED IN FOOD FOR HUMAN CONSUMPTION

1. The authority citation for 21 CFR part 173 continues to read as follows:

Authority: Secs. 201, 402, 409 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348).

2. Section 173.45 is amended by revising paragraphs (a) and (c) to read as follows:

§ 173.45 Polymaleic acid and its sodium salt.

* * * * *

(a) The additives have a weight-average molecular weight in the range of 540 to 850 and a number-average molecular weight in the range of 520 to 650, calculated as the acid. Molecular weights shall be determined by a method entitled "Determination of Molecular Weight Distribution of Poly(Maleic) Acid", dated March 17, 1992, produced by Ciba-Geigy, Seven Skyline Rd., Hathorne, NY 10532-2188, which is incorporated by reference. Copies are available from the Division of Product Policy, Center for Food Safety and Applied Nutrition (HFS-205), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

* * * * *

(c) The additives are to be used so that the amount of either or both additives does not exceed 4 parts per million (calculated as the acid) by weight of the beet or cane sugar juice or liquor process stream.

Dated: April 19, 1995.

Fred R. Shank,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 95-10646 Filed 5-1-95; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[PS-013-88]

RIN 1545-AL57

Certain Publicly Traded Partnerships Treated as Corporations

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking and notice of public hearing.

SUMMARY: This document contains proposed regulations relating to the classification of certain publicly traded partnerships as corporations. These proposed regulations would provide guidance needed by taxpayers to comply with changes to the law made

by the Omnibus Budget Reconciliation Act of 1987. The regulations would affect the classification of certain partnerships for federal tax purposes.

DATES: Written comments must be received by July 31, 1995. Requests to speak (with outlines of oral comments) at a public hearing scheduled for July 31, 1995, at 10 a.m. must be received by July 31, 1995.

ADDRESSES: Send submissions to: CC:DOM:CORP:T:R (PS-013-88), room 5228, Internal Revenue Service, POB 7604, Ben Franklin Station, Washington, DC 20044. In the alternative, submissions may be hand delivered between the hours of 8 a.m. and 5 p.m. to: CC:DOM:CORP:T:R (PS-013-88), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue NW, Washington, DC. The public hearing has been scheduled to be held in the Auditorium, Internal Revenue Building, 1111 Constitution Avenue NW, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Concerning the regulations, Christopher T. Kelley, (202) 622-3080; concerning submissions and the hearing, Michael Slaughter, (202) 622-7190 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Introduction

This document proposes to add § 1.7704-1 to the Income Tax Regulations (26 CFR part 1) relating to the definition of a publicly traded partnership under section 7704(b) of the Internal Revenue Code (Code).

Background

Section 7704 was added to the Code by section 10211(a) of the Omnibus Budget Reconciliation Act of 1987 (Pub. L. 100-203), as amended by sections 2004(f)(1)-(5) of the Technical and Miscellaneous Revenue Act of 1988 (Pub. L. 100-647). Section 7704(a) provides that a publicly traded partnership is treated as a corporation for federal tax purposes unless the partnership meets the 90 percent qualifying income test of section 7704(c) or qualifies as an existing partnership. The term *existing partnership* is defined in § 1.7704-2. Under section 7704(b), a partnership is a publicly traded partnership if interests in the partnership are traded on an established securities market or are readily tradable on a secondary market or the substantial equivalent thereof. Section 7704 applies to all domestic and foreign entities treated as partnerships under section 7701, including limited liability companies and other entities treated as partnerships for federal tax purposes.

No regulations have been issued regarding the circumstances under which interests in a partnership are treated as publicly traded under section 7704(b). Notice 8875, 1988-2 C.B. 386, however, provides guidance on the definition of a publicly traded partnership. Notice 88-75 provides that interests in a partnership are not treated as readily tradable on a secondary market or the substantial equivalent thereof for purposes of section 7704(b)(2) if the interests are: (1) issued in certain private placements; (2) transferred pursuant to transfers not involving trading; (3) traded in amounts that meet the requirements of a 5 percent or 2 percent safe harbor; (4) transferred through a matching service that meets certain requirements; or (5) transferred pursuant to a qualifying redemption or repurchase agreement. Notice 88-75 does not address when partnership interests are treated as traded on an established securities market for purposes of section 7704(b)(1).

Explanation of Provisions

Definitions

The proposed regulations define the terms *established securities market*, *secondary market*, and the *substantial equivalent of a secondary market* for purposes of section 7704(b). These definitions reflect congressional intent as articulated in the legislative history to section 7704. See H.R. Conf. Rep. No. 495, 100th Cong., 1st Sess. 947-50 (1987) (Conference Report).

Under the proposed regulations, an *established securities market* for purposes of section 7704(b)(1) includes: (1) A national securities exchange registered under the Securities Exchange Act of 1934; (2) a national securities exchange exempt from registration because of the limited volume of transactions; (3) a foreign securities exchange; (4) a regional or local exchange; and (5) an interdealer quotation system that regularly disseminates firm buy or sell quotations by identified brokers or dealers by electronic means or otherwise.

Under the proposed regulations, interests in a partnership that are not traded on an *established securities market* are readily tradable on a *secondary market* or the *substantial equivalent of a secondary market* for purposes of section 7704(b)(2) if the partners are readily able to buy, sell, or exchange their partnership interests in a manner that is comparable, economically, to trading on an *established securities market*. The proposed regulations further provide

that interests in a partnership are readily tradable on a *secondary market* if: (1) Interests in the partnership are regularly quoted by any person, such as a broker or dealer, making a market in the interest, or (2) any person regularly makes available to the public (including customers or subscribers) bid or offer quotes with respect to interests in the partnership and stands ready to effect buy or sell transactions at the quoted prices for itself or on behalf of others. This provision clarifies that a secondary market exists whenever interests in the partnership are subject to firm-quote trading.

The proposed regulations also provide that, if there is no secondary market, interests in a partnership are readily tradable on the *substantial equivalent of a secondary market* if: (1) The holder of an interest in the partnership has a readily available, regular, and ongoing opportunity to sell or exchange the interest through a public means of obtaining or providing information of offers to buy, sell, or exchange interests, or (2) prospective buyers and sellers have the opportunity to buy, sell, or exchange interests in a time frame and with the regularity and continuity that the existence of a secondary market would provide.

The proposed regulations define an interest in a partnership for purposes of section 7704(b) as any interest in the capital or profits of the partnership (including any right to partnership distributions) and any financial instrument or contract the value of which is determined in whole or in part by reference to the partnership (including the amount of partnership distributions, the value of partnership assets, or the results of partnership operations). This definition is intended to prevent the avoidance of section 7704(b) through the creation and transfer of interests other than traditional partnership interests, such as the creation and transfer of derivative partnership interests. The proposed regulations also provide several exceptions to the definition of an interest in the partnership. Under these exceptions, an interest in the partnership does not include non-convertible debt or an interest in a partnership or a corporation that holds an interest in a lower-tier partnership. For example, an interest in a regulated investment company that holds an interest in a partnership is not treated as an interest in the partnership.

The proposed regulations also define a transfer of an interest in a partnership to include a transfer in any form, including a redemption by the partnership or the entering into of a

financial instrument or contract described above. This provision applies only for purposes of determining when a transaction is treated as a transfer for purposes of section 7704(b) and does not apply in determining any other federal tax consequences of a transaction, including whether the transaction is a sale or exchange or whether the transferee is a partner of the partnership for any purpose other than section 7704(b).

The proposed regulations also provide that a transfer of an interest in a partnership is taken into account for purposes of section 7704(b) only if: (1) The partnership redeems the interest; (2) the transferee is admitted as a partner; or (3) the partnership otherwise recognizes any rights of the transferee, such as a right of the transferee to partnership distributions (directly or indirectly) or the right of the transferee to acquire an interest in the capital or profits of the partnership. For example, if a partner enters into a financial contract providing for a payment by the partner in an amount calculated by reference to the amount of partnership distributions, the financial contract is treated as an interest in the partnership and the entering into the contract is treated as a transfer of an interest for purposes of section 7704. The transfer is not taken into account, however, unless the partnership admits the transferee as a partner or otherwise recognizes the rights of the transferee to partnership distributions by, for example, making distributions directly to the transferee or to a third party on behalf of the transferee. This provision is intended to limit transfers for purposes of section 7704(b) to transfers that the partnership is aware of and has recognized, thereby preventing a partnership from becoming publicly traded without the knowledge or participation of the partnership.

Transfers That Do Not Create Public Trading

As discussed above, guidance issued in Notice 88-75 provided certain exclusions for purposes of section 7704(b)(2). The proposed regulations generally adopt these exclusions with certain modifications. The modifications are necessary to more appropriately implement congressional intent and to ensure that any partnership in which interests are subject to firm-quote trading is treated as a publicly traded partnership under section 7704. As in Notice 88-75, none of these exclusions apply in determining whether interests in a partnership are traded on an established securities market.

The proposed regulations adopt the exclusion in section II.A of Notice 88-75 for partnership interests issued in certain private placements with four modifications. First, the proposed regulations provide that the exclusion applies only for purposes of determining whether interests in a partnership are readily tradable on the substantial equivalent of a secondary market. Unlike Notice 88-75, this exclusion does not apply for purposes of determining whether the interests are readily tradable on a secondary market. As a result, a private placement partnership is treated as a publicly traded partnership if the interests in the partnership are readily tradable on a secondary market. This modification was made to ensure that, consistent with the purpose of section 7704(b), all partnerships, including private placement partnerships, are treated as publicly traded if interests in the partnership are subject to firm-quote trading.

Secondly, the proposed regulations provide that the private placement exclusion does not apply if the partnership has more than 50 partners at any time during its taxable year and the sum of the percentage interests in partnership capital or profits transferred during the taxable year of the partnership (other than in private transfers described in paragraph (d) of this section) exceeds 10 percent of the total interests in partnership capital or profits. This modification was made because transfers in excess of 10 percent indicate the existence of the type of market that section 7704(b) intended to treat as public trading. This modification does not apply to partnerships with 50 or fewer partners because such partnerships are unlikely to develop any public trading.

Thirdly, as in Notice 88-75, the private placement exclusion applies only if the partnership does not have more than 500 partners or the initial offering price of each unit of partnership interest is at least \$20,000. The proposed regulations clarify that a partnership satisfies the 500 partner requirement only if the partnership does not have more than 500 partners at any time during the taxable year of the partnership. Finally, the proposed regulations provide that the indirect ownership rule for determining the number of partners in a partnership does not apply to persons owning interests in a partnership through a regulated investment company (as defined in section 851) or a real estate investment trust (as defined in section 865).

The proposed regulations adopt, with two additions, the exclusion contained in section II.B of Notice 88-75 for transfers not involving trading (private transfers). Under the proposed regulations, private transfers include all of the transfers described in section II.B of Notice 88-75 plus: (1) distributions from an individual retirement account, and (2) transfers by one or more partners of interests representing more than 50 percent of the total interests in partnership capital and profits in one transaction or a series of related transactions. The proposed regulations also provide that a block transfer means the transfer by a partner in one or more transactions during any 30 calendar day period of partnership interests representing in the aggregate more than 2 percent of the total interests in partnership capital or profits, rather than 5 percent as in Notice 88-75.

In lieu of the 5 percent and 2 percent safe harbors contained in section II.C of Notice 88-75, the proposed regulations provide a more limited *de minimis* trading exclusion. The percentage safe harbors in Notice 88-75 applied in determining whether interests in a partnership were readily tradable on a secondary market or the substantial equivalent thereof. The Conference Report, however, gives no indication that a *de minimis* level of trading on a secondary market should be permitted, and the IRS and Treasury do not believe that a broad-based *de minimis* rule that allows firm-quote trading on a secondary market is appropriate. Furthermore, the percentage safe harbors contained in Notice 88-75 apparently have encouraged the type of firm-quote trading that Congress intended to prohibit by enacting section 7704.

Accordingly, the proposed regulations provide that interests in a partnership are not readily tradable on a substantial equivalent of a secondary market if the sum of the percentage interests in partnership capital or profits transferred during the taxable year of the partnership does not exceed 2 percent of the total interests in partnership capital or profits. All transfers of an interest in a partnership (including redemptions) are taken into account for purposes of this 2 percent rule, except for: (1) Private transfers; (2) transfers pursuant to redemption and repurchase agreements meeting certain requirements as specified in the regulations; and (3) transfers pursuant to a qualified matching service, discussed below. The 2 percent rule differs from the percentage safe harbors in Notice 88-75 because the 2 percent rule applies only for purposes of determining

whether interests in a partnership are readily tradable on the substantial equivalent of a secondary market. As a result, the 2 percent rule does not apply in determining whether interests are readily tradable on a secondary market and thus does not apply to partnerships with interests subject to firm quote trading.

The proposed regulations contain a qualified matching service exclusion similar to the matching service exclusion contained in section II.D of Notice 88-75. The proposed regulations, however, contain certain modifications designed to prevent a qualified matching service from operating as a secondary market or the substantial equivalent thereof. For example, the matching service can display only nonfirm quotes or nonbinding indications of interest and cannot provide firm quotes or two-sided quotes. The selling partner cannot enter into a binding agreement to sell an interest until the 15th calendar day after the date information regarding the offering of an interest for sale is made available to potential buyers, and closing of the sale cannot occur prior to the 30th calendar day after the first day that the seller can enter into a binding agreement to sell the interest. The matching service must obtain written representations from any subscribers that the subscribers and their customers will not act as market makers for any partnership interest listed on the matching service and that the subscriber, acting on its own account or on behalf of the same investor, will not enter offers for interests in the same partnership more than once in any 15 calendar day period.

As in Notice 88-75, this matching service exclusion does not apply if more than 10 percent of the total percentage interests in partnership capital or profits is transferred during the taxable year. For purposes of this 10 percent limitation, all transfers (other than private transfers) are considered, including transfers that do not take place on the matching service and transfers that are eligible for another exclusion under the proposed regulations. For example, if 1 percent of the total partnership interests in capital or profits is transferred on a nonqualified matching service, the amount of interests that can be transferred pursuant to a qualified matching service and still qualify for the matching service exclusion is reduced to 9 percent.

The proposed regulations clarify that certain activities will not prevent a matching service from qualifying for the exclusion. Under the proposed

regulations, a qualifying matching service may provide: (1) Prior pricing information, including information regarding resales of interests and actual prices paid for interests; (2) a description of the business of the partnership; and (3) financial and reporting information from the partnership's financial statements and reports. The operator of the matching service may also assist with the transfer documentation necessary to transfer the partnership interest. The operator may receive and deliver funds for completed transactions, and its fee may be a flat fee for use of the service, a fee based on completed transactions, or any combination thereof. While these activities may allow the operator of the matching service to assist in the completion of the transfer, the activities should not, by themselves, result in the type of activity that would cause the matching service to be a secondary market or the substantial equivalent thereof under section 7704(b)(2).

The proposed regulations adopt the exclusions for redemption and repurchase agreements contained in section II.E of Notice 88-75 with no significant modifications.

The IRS and Treasury request comments on the proposed regulations. In particular, comments are requested concerning: (1) Whether transitional relief is necessary for partnerships that qualified for an exclusion contained in Notice 88-75, but do not qualify for an exclusion contained in the proposed regulations and, if so, what type of relief would be appropriate; (2) whether further modifications to the private placement exclusion are necessary in light of developments in the securities laws since the issuance of Notice 88-75, including the issuance of Rule 144A (17 CFR 230.144A) and Regulation S (17 CFR 230.901); and (3) which members in a limited liability company or other entity that is treated as a partnership for federal tax purposes should be treated as general partners for purposes of determining the percentage interests in partnership capital or profits transferred during the taxable year of the partnership under paragraph (j)(1) of the proposed regulations.

Proposed Effective Date

These regulations are proposed to apply for taxable years of a partnership beginning on or after the date the final regulations are published in the **Federal Register**. The provisions of Notice 88-75 regarding the definition of readily tradable on a secondary market or the substantial equivalent thereof for purposes of section 7704(b) will

continue to apply until these regulations are effective.

Special Analyses

It has been determined that this notice of proposed rulemaking is not a significant regulatory action as defined in EO 12866. Therefore, a regulatory assessment is not required. It also has been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) and the Regulatory Flexibility Act (5 U.S.C. chapter 6) do not apply to these regulations and, therefore, a Regulatory Flexibility Analysis is not required. Pursuant to section 7805(f) of the Internal Revenue Code, this notice of proposed rulemaking will be submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business.

Comments and Public Hearing

Before these proposed regulations are adopted as final regulations, consideration will be given to any written comments (a signed original and eight (8) copies) that are submitted timely to the IRS. All comments will be available for public inspection and copying.

A public hearing has been scheduled for July 31, 1995, at 10 a.m. in the Auditorium, Internal Revenue Building, 1111 Constitution Avenue NW, Washington, DC. Because of access restrictions, visitors will not be admitted beyond the Internal Revenue Building lobby more than 15 minutes before the hearing starts.

The rules of 26 CFR 601.601(a)(3) apply to the hearing.

Persons that wish to present oral comments at the hearing must submit written comments and an outline of the topics to be discussed (a signed original and eight (8) copies) by July 31, 1995.

A period of 10 minutes will be allotted for each person for making comments.

An agenda showing the scheduling of the speakers will be prepared after the deadline for receiving outlines has passed. Copies of the agenda will be available free of charge at the hearing.

Drafting Information: The principal author of these regulations is Christopher T. Kelley, Office of Chief Counsel (Passthroughs and Special Industries). However, other personnel from the IRS and Treasury Department participated in their development.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Proposed Amendments to the Regulations

Accordingly, 26 CFR part 1 is proposed to be amended as follows:

PART 1—INCOME TAXES

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

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

Par. 2. Section 1.7704-1 is added to read as follows:

§ 1.7704-1 Publicly traded partnerships.

(a) *In general*—(1) *Publicly traded partnership.* A domestic or foreign partnership is a publicly traded partnership for purposes of section 7704(b) and this section if—

(i) Interests in the partnership are traded on an established securities market; or

(ii) Interests in the partnership are readily tradable on a secondary market or the substantial equivalent thereof.

(2) *Partnership interest*—(i) *In general.* For purposes of section 7704(b) and this section, an interest in a partnership includes—

(A) Any interest in the capital or profits of the partnership (including the right to partnership distributions); and

(B) Any financial instrument or contract the value of which is determined in whole or in part by reference to the partnership (including the amount of partnership distributions, the value of partnership assets, or the results of partnership operations).

(ii) *Exception for non-convertible debt.* For purposes of section 7704(b) and this section, an interest in a partnership does not include any financial instrument or contract that—

(A) Is treated as debt for federal tax purposes; and

(B) Is not convertible into or exchangeable for an interest in the capital or profits of the partnership and does not provide for a payment of equivalent value.

(iii) *Exception for tiered entities.* For purposes of section 7704(b) and this section, an interest in a partnership or a corporation (including a regulated investment company as defined in section 851 or a real estate investment trust as defined in section 856) that holds an interest in a partnership (lower-tier partnership) is not considered an interest in the lower-tier partnership.

(3) *Definition of transfer.* For purposes of section 7704(b) and this section, a transfer of an interest in a partnership means a transfer in any form, including a redemption by the partnership or the

entering into of a financial instrument or contract described in paragraph (a)(2)(i)(B) of this section.

(4) *Transfers taken into account.* For purposes of section 7704(b) and this section, a transfer of an interest in a partnership is taken into account only if—

(i) The transferee is admitted as a partner;

(ii) The partnership otherwise recognizes any rights of the transferee, such as a right of the transferee to partnership distributions (directly or indirectly) or the right of the transferee to acquire an interest in the capital or profits of the partnership; or

(iii) The partnership redeems or repurchases the interest.

(b) *Established securities market.* For purposes of section 7704(b) and this section, an established securities market includes—

(1) A national securities exchange registered under section 6 of the Securities Exchange Act of 1934 (15 U.S.C. 78f);

(2) A national securities exchange exempt from registration under section 6 of the Securities Exchange Act of 1934 (15 U.S.C. 78f) because of the limited volume of transactions;

(3) A foreign securities exchange that, under the law of the jurisdiction where it is organized, satisfies regulatory requirements that are analogous to the regulatory requirements under the Securities Exchange Act of 1934 described in paragraph (b)(1) or (2) of this section (such as the London International Financial Futures Exchange; the Marche a Terme International de France; the International Stock Exchange of the United Kingdom and the Republic of Ireland, Limited; the Frankfurt Stock Exchange; and the Tokyo Stock Exchange);

(4) A regional or local exchange; and

(5) An interdealer quotation system that regularly disseminates firm buy or sell quotations by identified brokers or dealers by electronic means or otherwise.

(c) *Readily tradable on a secondary market or the substantial equivalent thereof*—(1) *In general.* For purposes of section 7704(b) and this section, interests in a partnership that are not traded on an established securities market (within the meaning of section 7704(b) and paragraph (b) of this section) are readily tradable on a secondary market or the substantial equivalent thereof if the partners are readily able to buy, sell, or exchange their partnership interests in a manner that is comparable, economically, to

trading on an established securities market.

(2) *Secondary market.* For purposes of paragraph (c)(1) of this section, interests in a partnership are readily tradable on a secondary market if—(i) Interests in the partnership are regularly quoted by any person, such as a broker or dealer, making a market in the interests; or

(ii) Any person regularly makes available to the public (including customers or subscribers) bid or offer quotes with respect to interests in the partnership and stands ready to effect buy or sell transactions at the quoted prices for itself or on behalf of others.

(3) *Substantial equivalent of a secondary market.* For purposes of paragraph (c)(1) of this section, interests that are not readily tradable on a secondary market are readily tradable on the substantial equivalent of a secondary market if—

(i) The holder of an interest in the partnership has a readily available, regular, and ongoing opportunity to sell or exchange the interest through a public means of obtaining or providing information of offers to buy, sell, or exchange interests in the partnership; or

(ii) Prospective buyers and sellers have the opportunity to buy, sell, or exchange interests in the partnership in a time frame and with the regularity and continuity that the existence of a secondary market would provide.

(d) *Transfers not involving trading*—(1) *In general.* For purposes of section 7704(b) and this section, the following transfers (*private transfers*) are disregarded in determining whether interests in a partnership are readily tradable on a secondary market or the substantial equivalent thereof—

(i) Transfers in which the basis of the partnership interest in the hands of the transferee is determined, in whole or in part, by reference to its basis in the hands of the transferor or is determined under section 732;

(ii) Transfers at death;

(iii) Transfers between members of a family (as defined in section 267(c)(4));

(iv) Transfers involving the issuance of interests by (or on behalf of) the partnership in exchange for cash, property, or services;

(v) Transfers involving distributions from a retirement plan qualified under section 401(a) or an individual retirement account;

(vi) Block transfers (as defined in paragraph (d)(2) of this section);

(vii) Transfers pursuant to a right under a redemption or repurchase agreement (as defined in paragraph (d)(3) of this section) that is exercisable only—

(A) Upon the death, disability, or mental incompetence of the partner; or

(B) Upon the retirement or termination of the performance of services of an individual who actively participated in the management of, or performed services on a full-time basis for, the partnership;

(viii) Transfers pursuant to a closed end redemption plan (as defined in paragraph (d)(4) of this section); and

(ix) Transfers by one or more partners of interests representing more than 50 percent of the total interests in partnership capital and profits in one transaction or a series of related transactions.

(2) *Block transfers.* For purposes of paragraph (d)(1)(vi) of this section, a block transfer means the transfer by a partner in one or more transactions during any 30 calendar day period of partnership interests representing in the aggregate more than 2 percent of the total interests in partnership capital or profits.

(3) *Redemption or repurchase agreement.* For purposes of section 7704(b) and this section, a redemption or repurchase agreement means a plan of redemption or repurchase maintained by a partnership whereby the partners may tender their partnership interests for purchase by the partnership, another partner, or a person related to another partner (within the meaning of section 267(b) or section 707(b)(1)).

(4) *Closed end redemption plan.* For purposes of paragraph (d)(1)(viii) of this section, a redemption or repurchase agreement (as defined in paragraph (d)(3) of this section) is a closed end redemption plan if—

(i) The partnership does not issue any interest after the initial offering (other than the issuance of additional interests prior to August 5, 1988); and

(ii) No partner or person related to any partner (within the meaning of section 267(b) or 707(b)(1)) provides contemporaneous opportunities to acquire interests in similar or related partnerships which represent substantially identical investments.

(e) *Redemption and repurchase agreements.* For purposes of section 7704(b) and this section, the transfer of an interest in a partnership pursuant to a redemption or repurchase agreement (as defined in paragraph (d)(3) of this section) that is not described in paragraph (d)(1) (vii) or (viii) of this section is disregarded in determining whether interests in the partnership are readily tradable on a secondary market or the substantial equivalent thereof only if—

(1) The redemption or repurchase agreement requires receipt of written

notification from the transferor partner by the partnership or a partner (or an agent thereof) at least 60 calendar days before the redemption or repurchase date of such partner's intention to exercise the redemption or repurchase right;

(2) Either—

(i) The redemption or repurchase agreement requires that the redemption or repurchase price not be established until at least 60 calendar days after receipt of such notification by the partnership or the partner; or

(ii) The redemption or repurchase price is established not more than 4 times during the partnership's taxable year; and

(3) The sum of the percentage interests in partnership capital or profits transferred during the taxable year of the partnership (other than in private transfers described in paragraph (d) of this section) does not exceed 10 percent of the total interests in partnership capital or profits.

(f) *Qualified matching services—(1) In general.* For purposes of section 7704(b) and this section, the transfer of an interest in a partnership through a qualified matching service is disregarded in determining whether interests in the partnership are readily tradable on a secondary market or the substantial equivalent thereof.

(2) *Requirements.* A matching service is a qualified matching service only if—

(i) The matching service consists of a computerized or printed listing system that lists customers' bid and/or ask prices in order to match partners who want to sell their interests in a partnership (the selling partner) with persons who want to buy those interests;

(ii) Matching occurs either by matching the list of interested buyers with the list of interested sellers or through a bid and ask process that allows interested buyers to bid on the listed interest;

(iii) The selling partner cannot enter into a binding agreement to sell the interest until the 15th calendar day after the date information regarding the offering of the interest for sale is made available to potential buyers and such time period is established by contemporaneous records maintained by the operator at a central location;

(iv) The closing of the sale effected by virtue of the matching service does not occur prior to the 30th calendar day after the first day that the selling partner can enter into a binding agreement to sell the interest (as specified in paragraph (f)(2)(iii) of this section) and such time period is established by

contemporaneous records maintained by the operator at a central location;

(v) The matching service displays only quotes that do not commit any person to buy or sell a partnership interest (nonfirm price quotes) or quotes that express interest in a partnership interest without an accompanying price (nonbinding indications of interest) and does not display quotes at which any person is committed to buy or sell a partnership interest (firm quotes) or two-sided quotes;

(vi) The operator of the matching service (or any person related to the operator within the meaning of section 267(b) or section 707(b)(1)) does not quote prices at which the operator (or a related person) stands ready to buy or sell partnership interests for itself or on behalf of others, make such quotes available to the public (or customers or subscribers), or buy or sell interests for itself or on behalf of others;

(vii) The matching service obtains written representations from any subscribers to the service that—

(A) The subscriber and its customers will not create or facilitate a secondary market (within the meaning of paragraph (c)(2) of this section) for any partnership interest listed on the matching service; and

(B) The subscriber, acting for its own account or on behalf of the same investor, will not enter offers for interests in the same partnership more than once in any 15 calendar day period;

(viii) The selling partner's information is removed from the matching service within 120 calendar days after the date information regarding the offering of the interest for sale is made available to potential buyers and, following any removal (other than removal by reason of a sale of any part of such interest) of the selling partner's information from the matching service, no interest in the partnership is entered into the matching service by the selling partner for at least 60 calendar days; and

(ix) The sum of the percentage interests in partnership capital or profits transferred during the taxable year of the partnership (other than in private transfers described in paragraph (d) of this section) does not exceed 10 percent of the total interests in partnership capital or profits.

(3) *Closing.* For purposes of paragraph (f)(2)(iv) of this section, the closing of a sale occurs no later than the earlier of—

(i) The passage of title to the partnership interest;

(ii) The payment of the purchase price; or

(iii) The date, if any, that the operator of the matching service (or any person

related to the operator within the meaning of section 267(b) or section 707(b)(1) loans, advances, or otherwise arranged for funds to be available to the seller in anticipation of the payment of the purchase price.

(4) *Optional features.* A qualified matching service may be sponsored or operated by a partner of the partnership (either formally or informally), the underwriter that handled the issuance of the partnership interests, or an unrelated third party. In addition, a qualified matching service may offer the following features—

(i) The matching service may provide prior pricing information, including information regarding resales of interests and actual prices paid for interests; a description of the business of the partnership; financial and reporting information from the partnership's financial statements and reports; and information regarding material events involving the partnership, including special distributions, capital distributions, and refinancings or sales of significant portions of partnership assets;

(ii) The operator may assist with the transfer documentation necessary to transfer the partnership interest;

(iii) The operator may receive and deliver funds for completed transactions; and

(iv) The operator's fee may consist of a flat fee for use of the service, a fee based on completed transactions, or any combination thereof.

(g) *Private placements—(1) In general.* For purposes of section 7704(b) and this section, interests in a partnership are not readily tradable on the substantial equivalent of a secondary market if—

(i) All interests in the partnership were issued in a transaction (or transactions) that was not required to be registered under the Securities Act of 1933;

(ii) Either—

(A) The partnership does not have more than 500 partners at any time during the taxable year of the partnership; or

(B) The initial offering price of each unit of partnership interest is at least \$20,000 and the partnership agreement provides that no unit of partnership interest may be subdivided for resale into units smaller than a unit the initial offering price of which would have been at least \$20,000; and

(iii) If the partnership has more than 50 partners at any time during the taxable year of the partnership, the sum of the percentage interests in partnership capital or profits transferred during the taxable year of the partnership (other than in private

transfers described in paragraph (d) of this section) does not exceed 10 percent of the total interests in partnership capital or profits.

(2) *Number of partners.* For purposes of determining the number of partners under paragraph (g)(1) of this section—

(i) Each person indirectly owning an interest in the partnership through another partnership, a grantor trust, or an S corporation (but not through a regulated investment company, as defined in section 851, or a real estate investment trust, as defined in section 865) is treated as a partner; and

(ii) Partnerships are aggregated when they jointly operate one or more businesses, or the operations of the partnerships are interrelated, and a principal purpose for the use of multiple partnerships is to permit any of the partnerships to qualify for the rule provided under this paragraph (g).

(h) *Lack of actual trading—(1) General rule.* For purposes of section 7704(b) and this section, interests in a partnership are not readily tradable on the substantial equivalent of a secondary market if the sum of the percentage interests in partnership capital or profits transferred during the taxable year of the partnership (other than in transfers described in paragraph (d), (e), or (f) of this section) does not exceed 2 percent of the total interests in partnership capital or profits.

(2) *Examples.* The following examples illustrate the rules of this paragraph (h).

Example 1. Calculation of percentage interest transferred. (i) ABC, a calendar year limited partnership formed in 1995, has 9,000 units of limited partnership interests outstanding at all times during 1996, representing in the aggregate 95 percent of the total interests in capital and profits of ABC.

(ii) During 1996, the following transactions occur with respect to the units of ABC's limited partnership interests—

(A) 800 units are sold through the use of a qualified matching service that meets the requirements of paragraph (f) of this section;

(B) 50 units are sold through the use of a matching service that does not meet the requirements of paragraph (f) of this section; and

(C) 500 units are transferred as a result of private transfers described in paragraph (d) of this section.

(iii) The private transfers of 500 units and the sale of 800 units through a qualified matching service are disregarded under paragraph (h)(1) of this section for purposes of applying the 2 percent rule. As a result, the total percentage interests in partnership capital and profits transferred for purposes of the 2 percent rule is .528 percent, determined by—

(A) Dividing the number of units sold through a matching service that did not meet the requirements of paragraph (f) of this section (50) by the total number of

outstanding limited partnership units (9,000); and

(B) Multiplying the result by the percentage of total interests represented by limited partnership units (95 percent) $(50/9,000) \times .95 = .528$ percent).

Example 2. Application of the 2 percent rule. (i) ABC operates a service consisting of computerized video display screens on which subscribers view and publish quotes that do not commit any person to buy or sell a partnership interest and quotes that express interest in a partnership interest without an accompanying price. The ABC service does not provide two-sided quotes or quotes at which any person (including the operator of the service) is committed to buy or sell a partnership interest. Subscribers are limited to broker-dealers registered with the National Association of Securities Dealers.

(ii) The ABC service is not an established securities market for purposes of section 7704(b)(1) and this section because the service does not satisfy any of the definitions of an established securities market in paragraph (b) of this section. The ABC service also is not a secondary market because the service does not provide two-sided quotes or quotes at which any person (including the operator of the service) is committed to buy or sell a partnership interest. Therefore, partnerships whose interests are listed and transferred on the ABC service are not publicly traded for purposes of section 7704(b) and this section as a result of such listing or transfers if the sum of the percentage interests in partnership capital or profits transferred during the taxable year of the partnership (other than in transfers described in paragraph (d), (e), or (f)) does not exceed 2 percent of the total interests in partnership capital or profits. In addition, assuming the ABC service complies with the necessary requirements, the service may qualify as a matching service described in paragraph (f) of this section.

Example 3. Effect of firm quotes. Assume the same facts as in *Example 2*, except that, in addition to operating the matching service, ABC regularly quotes prices at which it stands ready to buy interests in certain partnerships listed on the service. As a result of the regular quotes, interests in the quoted partnerships are readily tradable on a secondary market under paragraph (c)(2) of this section. The quoted partnerships are therefore publicly traded partnerships for purposes of section 7704 and this section, regardless of whether the sum of the percentage interests in partnership capital or profits transferred during the taxable year of the partnership exceeds 2 percent of the total interests in partnership capital or profits.

(i) [Reserved].

(j) *Percentage interests in partnership capital or profits—(1) Interests considered—(i) General rule.* Except as otherwise provided in this paragraph (j), for purposes of this section, the total interests in partnership capital or profits are determined by reference to all outstanding interests in the partnership.

(ii) *Exceptions—(A) General partner with greater than 10 percent interest.* If

the general partners and any person related to the general partners (within the meaning of section 267(b) or section 707(b)(1)) own, in the aggregate, more than 10 percent of the outstanding interests in partnership capital or profits at any one time during the taxable year of the partnership, the total interests in partnership capital or profits are determined without reference to the interests owned by such persons.

(B) *Derivative interests.* Any partnership interests described in paragraph (a)(2)(ii) of this section are taken into account for purposes of determining the total interest in partnership capital or profits only as and to the extent that the transfer of the interest is taken into account under paragraph (a)(4) of this section.

(2) *Monthly determination.* For purposes of this section, except in the case of block transfers (as defined in paragraph (d)(2) of this section), the percentage interests in partnership capital or profits represented by partnership interests that are transferred during a taxable year of the partnership is equal to the sum of the percentage interests transferred for each calendar month during the taxable year of the partnership in which a transfer of a partnership interest occurs (other than a private transfer as described in paragraph (d) of this section). The percentage interests in capital or profits of interests transferred during a calendar month is determined by reference to the partnership interests outstanding during that month.

(3) *Monthly conventions.* For purposes of paragraph (j)(2) of this section, a partnership may use any reasonable convention in determining the interests outstanding for a month, provided the convention is consistently used by the partnership from month to month during a taxable year and from year to year. Reasonable conventions include, but are not limited to, a determination by reference to the interests outstanding at the beginning of the month, on the 15th day of the month, or at the end of the month.

(4) *Block transfers.* For purposes of paragraph (d)(2) of this section (defining block transfers), the partnership must determine the percentage interests in capital or profits for each transfer of an interest during the 30 calendar day period by reference to the partnership interests outstanding immediately prior to such transfer.

(5) *Example.* The following example illustrates the rules of this paragraph (j).

Example. Conventions. (i) ABC limited partnership, a calendar year partnership formed in 1995, has 1,000 units of limited partnership interests outstanding on January

1, 1996, representing in the aggregate 95 percent of the total interests in capital and profits of ABC. The remaining 5 percent is held by the general partner.

(ii) The following transfers take place during 1996—

(A) On January 15, 10 units of limited partnership interests are sold in a transaction that is not a private transfer;

(B) On July 10, 1,000 additional units of limited partnership interests are issued by the partnership (the general partner's percentage interest is unchanged); and

(C) On July 20, 15 units of limited partnership interests are sold in a transaction that is not a private transfer.

(iii) For purposes of determining the sum of the percentage interests in partnership capital or profits transferred, ABC chooses to use the end of the month convention. The percentage interests in partnership capital and profits transferred during January is .95 percent, determined by dividing the number of transferred units (10) by the total number of limited partnership units (1,000) and multiplying the result by the percentage of total interests represented by limited partnership units $[(10/1,000) \times .95]$. The percentage interests in partnership capital and profits transferred during July is .7125 percent $[(15/2,000) \times .95]$. ABC is not required to make determinations for the other months during the year because no transfers of partnership interests occurred during such months. ABC may qualify for the 2 percent rule for its 1996 taxable year because less than 2 percent $(.95 \text{ percent} + .7125 \text{ percent} = 1.6625 \text{ percent})$ of its total interests in partnership capital and profits was transferred during that year.

(iv) If ABC had chosen to use the beginning of the month convention, the interests in capital or profits sold during July would have been 1.425 percent $[(15/1,000) \times .95]$ and ABC would not have satisfied the 2 percent rule for its 1996 taxable year because 2.375 percent $(.95 + 1.425)$ of ABC's interests in partnership capital and profits was transferred during that year.

(k) *Effective date.* This section applies for taxable years of a partnership beginning on or after the date final regulations are published in the **Federal Register**.

Margaret Milner Richardson,

Commissioner of Internal Revenue.

[FR Doc. 95-10765 Filed 5-1-95; 8:45 am]

BILLING CODE 4830-01-U

26 CFR Part 1

[FI-21-95]

RIN 1545-AT46

Definition of Personal Property for Purposes of the Straddle Rules

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking and notice of public hearing.

SUMMARY: This document contains proposed regulations relating to the definition of personal property for purposes of the straddle rules. This action is necessary to reflect changes in the law made by the Tax Reform Act of 1984. The regulations provide guidance to persons who enter into straddle transactions.

DATES: Written comments must be received by July 31, 1995. Requests to appear and outlines of topics to be discussed at the public hearing scheduled for August 30, 1995, must be submitted by August 9, 1995.

ADDRESSES: Send submissions to: CC:DOM:CORP:T:R (FI-21-95), room 5228, Internal Revenue Service, POB 7604, Ben Franklin Station, Washington, DC 20044. In the alternative, submissions may be hand delivered between the hours of 8 a.m. and 5 p.m. to: CC:DOM:CORP:T:R (FI-21-95), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue, NW., Washington, DC. A public hearing has been scheduled for Wednesday, August 30, 1995, at 10 a.m. in the Auditorium, Internal Revenue Building, 1111 Constitution Avenue, NW., Washington, DC.

FOR FURTHER INFORMATION CONTACT: Concerning the regulations, Robert B. Williams, (202) 622-3960; concerning submissions and the hearing, Michael Slaughter, (202) 622-7190 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Background

Section 1092(d) of the Internal Revenue Code provides definitions and special rules relating to straddles. Under section 1092(d)(3)(B)(i)(II), an ownership interest in stock, which generally is not treated as personal property subject to the straddle rules, may be personal property if it is part of a straddle at least one of the offsetting positions of which is, under regulations, a position with respect to substantially similar or related property (other than stock). On March 20, 1995, the IRS published final regulations (§ 1.1092(d)-2) under section 1092(d)(3)(B). Those regulations generally apply the rules of § 1.246-5 to determine whether an offsetting position is a position with respect to substantially similar or related property (other than stock) within the meaning of section 1092(d)(3)(B)(i)(II).

Explanation of Provisions

The proposed regulations clarify the definition of the term "personal property" under section 1092(d)(1) as it applies to stock. The proposed

regulations provide that personal property includes any stock of a type that is actively traded and that is part of a straddle at least one of the offsetting positions of which is a position with respect to substantially similar or related property (other than stock). For this purpose, a position with respect to substantially similar or related property (other than stock) does not include direct ownership of stock or a short sale of stock but includes any other position with respect to substantially similar or related property. These proposed regulations thus clarify that, for example, stock and an equity swap with respect to property that is substantially similar or related to that stock can constitute a straddle for purposes of section 1092.

The proposed regulations also address the scope of section 1092(d)(3)(B)(i), which provides that stock that is offset by an option with respect to that stock or substantially identical stock or by a position with respect to substantially similar or related property (other than stock) is treated as personal property under section 1092(d)(3)(B). Although this provision does not contain an explicit active trading requirement, the legislative history of the Tax Reform Act of 1984 indicates that Congress contemplated that the stock would be treated as personal property under this test only if it is of a type that is actively traded. H.R. Conf. Rep. No. 861, 98th Cong., 2d Sess. 907 (1984). The regulations, therefore, include this requirement. In contrast, the regulations clarify that, for purposes of section 1092(d)(3)(B)(ii), if a corporation is formed or availed of to take positions in personal property that offset positions taken by any shareholder, stock of the corporation may be treated as personal property under section 1092(d)(3)(B) even if it is not actively traded.

The proposed regulations generally are effective for positions established on or after May 1, 1995. The IRS believes, however, that the regulations merely clarify the rule that applied once § 1.1092(d)-2 was promulgated. There is no implication that the results reached under these proposed regulations would not also be reached for positions established on or after March 17, 1995, and before May 1, 1995.

Special Analyses

It has been determined that this notice of proposed rulemaking is not a significant regulatory action as defined in EO 12866. Therefore, a regulatory assessment is not required. It also has been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) and the Regulatory

Flexibility Act (5 U.S.C. chapter 6) do not apply to these regulations, and, therefore, a Regulatory Flexibility Analysis is not required. Pursuant to section 7805(f) of the Internal Revenue Code, this notice of proposed rulemaking will be submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business.

Comments and Public Hearing

Before these proposed regulations are adopted as final regulations, consideration will be given to any written comments (a signed original and eight (8) copies) that are submitted timely to the IRS. All comments will be available for public inspection and copying.

A public hearing has been scheduled for Wednesday, August 30, 1995, at 10 a.m. The public hearing will be held in the IRS Auditorium, 7th Floor, 1111 Constitution Avenue, NW., Washington DC 20224. Because of access restrictions, visitors will not be admitted beyond the Internal Revenue Building lobby more than 15 minutes before the hearing starts.

The rules of 26 CFR 601.601(a)(3) apply to the hearing.

Persons that wish to present oral comments at the hearing must submit written comments by July 31, 1995 and submit an outline of the topics to be discussed and the time to be devoted to each topic (signed original and eight (8) copies) by August 9, 1995.

A period of 10 minutes will be allotted to each person for making comments.

An agenda showing the scheduling of the speakers will be prepared after the deadline for receiving outlines has passed. Copies of the agenda will be available free of charge at the hearing.

Drafting Information: The principal author of these regulations is Robert B. Williams, Office of Assistant Chief Counsel (Financial Institutions and Products). However, other personnel from the IRS and Treasury Department participated in their development.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Proposed Amendments to the Regulations

Accordingly, 26 CFR part 1 is proposed to be amended as follows:

PART 1—INCOME TAXES

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

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

Par. 2. Section 1.1092(d)-2 is revised to read as follows:

§ 1.1092(d)-2 Personal property.

(a) *Special rules for stock.* As defined by section 1092(d)(1), *personal property* includes—

(1) Any stock if the stock is of a type that is actively traded and the stock is part of a straddle at least one of the offsetting positions of which is—

(i) An option with respect to that stock or substantially identical stock or securities; or

(ii) Under paragraphs (b) and (c) of this section, a position with respect to substantially similar or related property (other than stock); and

(2) Any stock, whether or not of a type that is actively traded, of a corporation formed or availed of to take positions in personal property as defined by section 1092(d)(1) that offset positions taken, directly or indirectly, by any shareholder.

(b) *Substantially similar or related property.* For purposes of section 1092(d)(3)(B)(i)(II) and this section, the term substantially similar or related property is defined in § 1.246-5 (other than § 1.246-5(b)(3)). The rule in § 1.246-5(c)(6) does not narrow the related party rule in section 1092(d)(4).

(c) *Position with respect to substantially similar or related property (other than stock).* For purposes of section 1092(d)(3)(B)(i)(II) and this section, a position with respect to substantially similar or related property (other than stock) does not include direct ownership of stock or a short sale of stock but includes any other position with respect to substantially similar or related property.

(d) *Example.* The following example illustrates the application of this section.

(1) *Facts*—(i) *The stock.* A acquired 10,000 shares of actively traded X stock during 1990. On September 29, 1995, those shares had a fair market value of \$1,000,000.

(ii) *The swap.* On September 29, 1995, A entered into an “equity swap” contract with unrelated counterparty C, for a term of three years. Under the terms of that contract, on the last business day of each calendar quarter, A must pay to C an amount equal to the appreciation, if any, during the quarter on 10,000 shares of X stock. A also must pay to C an amount equal to the dividends, if any, that were paid during the quarter on 10,000 shares of X stock. On the last business day of each calendar quarter, A is to receive from C an amount equal to the depreciation, if any, during the quarter on 10,000 shares of X stock. A also is to receive from C an amount equal to the 3-month London Interbank Offered Rate (LIBOR), as determined at the close of the prior quarter, multiplied by the value of the X stock on that date.

(2) *Holdings*—(i) *The two legs as offsetting positions.* Because holding the equity swap

substantially diminishes A's risk of loss from holding the X stock, the X stock and the equity swap are offsetting positions within the meaning of section 1092(c). The remaining question is whether these are positions with respect to personal property.

(ii) *The swap leg as a position with respect to personal property.* The equity swap contract is a position with respect to personal property as defined by section 1092(d)(1). Although section 1092(d)(3)(A) generally excludes stock from the definition of personal property, this exclusion does not apply to interests in stock. Therefore, stock can be personal property when testing whether an interest in the stock, other than a direct interest in, or a short sale of, the stock, is a position with respect to personal property. Because the equity swap contract is an interest in actively traded stock, the equity swap contract is a position with respect to personal property.

(iii) *The stock leg as personal property.* As described below, ownership of the X stock is also a position with respect to personal property.

(A) *The rule of section 1092(d)(3)(B)(i)(II).* Under section 1092(d)(3)(B)(i)(II) and paragraph (a)(1)(ii) of this section, stock is not excluded from the definition of personal property if it is part of a straddle at least one of the offsetting positions of which is a position with respect to substantially similar or related property (other than stock).

(B) *The swap as a position with respect to substantially similar or related property (other than stock) for purposes of section 1092(d)(3)(B)(i)(II).* Under paragraph (b) of this section, the equity swap contract is a position with respect to property that is substantially similar or related to the X stock because A is entitled to payments under the equity swap contract that are attributable to the decline in the value of the X stock. See § 1.246-5(c)(7). Under section 1092(d)(3)(B)(i)(II) and paragraph (c) of this section, the equity swap contract is a position with respect to substantially similar or related property (other than stock) because it is not direct ownership of stock or a short sale of stock.

(C) *The stock as part of a straddle for purposes of the test of section 1092(d)(3)(B)(i)(II).* In determining whether the X stock is part of a straddle for purposes of the test of section 1092(d)(3)(B)(i) and paragraph (a)(1) of this section, section 1092(d)(3)(C) treats the X stock as personal property. Because the stock is treated as personal property for this purpose, because the equity swap contract is a position with respect to personal property (see paragraph (d)(2)(ii) of this section), and because the X stock and the equity swap contract are offsetting positions (see paragraph (d)(2)(i) of this section), the straddle test in section 1092(d)(3)(B)(i) and paragraph (a)(1) of this section is satisfied. Accordingly, under section 1092(d)(3)(B), the stock is personal property for all purposes of section 1092.

(iv) *The two legs as a straddle.* Because ownership of the X stock and the equity swap contract are offsetting positions with respect to personal property, the X stock and the equity swap contract are a straddle to A within the meaning of section 1092(c)(1).

(e) *Effective dates*—(1) *In general.* Except as provided in paragraph (e)(2) of this section, this section applies to positions established on or after May 1, 1995.

(2) *Special rules for substantially similar or related property*—(i) *In general.* Paragraph (b) of this section applies to positions established on or after March 17, 1995.

(ii) *Special rule for certain straddles.* Paragraph (b) of this section applies to positions established after March 1, 1984, if the taxpayer substantially diminished its risk of loss by holding substantially similar or related property involving the following types of transactions—

(A) Holding offsetting positions consisting of stock and a convertible debenture of the same corporation where the price movements of the two positions are related; or

(B) Holding a short position in a stock index regulated futures contract (or alternatively an option on such a regulated futures contract or an option on the stock index) and stock in an investment company whose principal holdings mimic the performance of the stocks included in the stock index (or alternatively a portfolio of stocks whose performance mimics the performance of the stocks included in the stock index).

Margaret Milner Richardson,

Commissioner of Internal Revenue.

[FR Doc. 95-10755 Filed 5-1-95; 8:45 am]

BILLING CODE 4830-01-U

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 934

North Dakota Regulatory Program

AGENCY: Office of Surface Mining Reclamation and Enforcement (OSM), Interior.

ACTION: Proposed rule; public comment period and opportunity for public hearing on proposed amendment.

SUMMARY: OSM is announcing receipt of a proposed amendment to the North Dakota regulatory program (hereinafter, the "North Dakota program") under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). The proposed amendment consists of revisions to and additions of statutory provisions pertaining to the North Dakota program's Small Operator Assistance Program and individual civil penalties. The amendment is intended to revise the North Dakota program to be

consistent with the corresponding Federal regulations and SMCRA.

DATES: Written comments must be received by 4:00 p.m., m.d.t., June 1, 1995. If requested, a public hearing on the proposed amendment will be held on May 30, 1995. Requests to present oral testimony at the hearing must be received by 4:00 p.m., m.d.t., on May 17, 1995.

ADDRESSES: Written comments should be mailed or hand delivered to Guy Padgett at the address listed below.

Copies of the North Dakota program, the proposed amendment, and all written comments received in response to this document will be available for public review at the addresses listed below during normal business hours, Monday through Friday, excluding holidays. Each requester may receive one free copy of the proposed amendment by contacting OSM's Casper Field Office.

Guy Padgett, Director, Casper Field Office, Office of Surface Mining Reclamation and Enforcement, 100 E. "B" Street, Room 2128, Casper, WY 82601-1918, Telephone: (307) 261-5776
North Dakota Public Service Commission, Reclamation Division, Capitol Building, Bismarck, ND 58505-0165, Telephone: (701) 224-4092

FOR FURTHER INFORMATION CONTACT: Guy Padgett, Telephone: (307) 261-5776.

SUPPLEMENTARY INFORMATION:

I. Background on the North Dakota Program

On December 15, 1980, the Secretary of the Interior conditionally approved the North Dakota program. General background information on the North Dakota program, including the Secretary's findings, the disposition of comments, and the conditions of approval of the North Dakota program can be found in the December 15, 1980, **Federal Register** (45 FR 82214). Subsequent actions concerning the North Dakota program and program amendments can be found at 30 CFR 934.12, 934.13, 934.15, 934.16, and 934.30.

II. Proposed Amendment

By letter dated April 12, 1995, North Dakota submitted a proposed amendment to its program pursuant to SMCRA (30 U.S.C. 1201 *et seq.*) (Amendment number XXII, Administrative Record No. ND-W-01). North Dakota submitted the proposed amendment in response to the required program amendment at 30 CFR 934.16(y) and in response to an

inconsistency with SMCRA that was identified in a July 22, 1994, rulemaking action (59 FR 37426). The provisions of the North Dakota Century Code (NDCC) that North Dakota proposes to revise or add are: NDCC 38–14.1–37(4) [SOAP, reimbursement of costs], and NDCC 38–12.1–08 [coal exploration, civil and criminal penalties].

Specifically, North Dakota proposes to revise NDCC 38–14.1–37(4) to require an operator who has received SOAP assistance under subsection 3 of the provision (training in the preparation of permit applications and compliance with the regulatory program) to reimburse the commission for the cost of the services under certain circumstances. North Dakota also proposes to revise NDCC 38–12.1–08(2) to allow the assessment of individual civil penalties only for willful specified violations. Finally, North Dakota proposes to add at NDCC 38–12.1–08(3) a new provision that any corporation or person who controls the activity of a corporation who violates NDCC Chapter 38–12.1 or any permit condition or rule implementing that chapter is subject to a civil penalty not to exceed five thousand dollars per day of such violation.

III. Public Comment Procedures

In accordance with the provisions of 30 CFR 732.17(h), OSM is seeking comments on whether the proposed amendment satisfies the applicable program approval criteria of 30 CFR 732.15. If the amendment is deemed adequate, it will become part of the North Dakota program.

1. Written Comments

Written comments should be specific, pertain only to the issues proposed in this rulemaking, and include explanations in support of the commenter's recommendations. Comments received after the time indicated under **DATES** or at locations other than the Casper Field Office will not necessarily be considered in the final rulemaking or included in the administrative record.

2. Public Hearing

Persons wishing to testify at the public hearing should contact the person listed under **FOR FURTHER INFORMATION CONTACT** by 4:00 p.m., m.d.t., in May 17, 1995. Any disabled individual who has need for a special accommodation to attend a public hearing should contact the individual listed under **FOR FURTHER INFORMATION CONTACT**. The location and time of the hearing will be arranged with those persons requesting the hearing. If no one

requests an opportunity to testify at the public hearing, the hearing will not be held.

Filing of a written statement at the time of the hearing is requested as it will greatly assist the transcriber. Submission of written statements in advance of the hearing will allow OSM officials to prepare adequate responses and appropriate questions.

The public hearing will continue on the specified date until all persons scheduled to testify have been heard. Persons in the audience who have not been scheduled to testify, and who wish to do so, will be heard following those who have been scheduled. The hearing will end after all persons scheduled to testify and persons present in the audience who wish to testify have been heard.

3. Public Meeting

If only one person requests an opportunity to testify at a hearing, a public meeting, rather than a public hearing, may be held. Persons wishing to meet with OSM representatives to discuss the proposed amendment may request a meeting by contacting the person listed under **FOR FURTHER INFORMATION CONTACT**. All such meetings will be open to the public and, if possible, notices of meetings will be posted at the locations listed under **ADDRESSES**. A written summary of each meeting will be made a part of the administrative record.

IV. Procedural Determinations

1. Executive Order 12866

This rule is exempted from review by the Office of Management and Budget (OMB) under Executive Order 12866 (Regulatory Planning and Review).

2. Executive Order 12778

The Department of the Interior has conducted the reviews required by section 2 of Executive Order 12778 (Civil Service Reform) and has determined that this rule meets the applicable standards of subsections (a) and (b) of that section. However, these standards are not applicable to the actual language of State regulatory programs and program amendments since each such program is drafted promulgated by a specific State, not by OSM. Under sections 503 and 505 of SMCRA (30 U.S.C. 1253 and 1255) and the Federal regulations at 30 CFR 730.11, 732.15, and 732.17(h)(10), decisions on proposed State regulatory programs and program amendments

submitted by the States must be based solely on a determination of whether the submittal is consistent with SMCRA and its implementing Federal regulations and whether the other requirements of 30 CFR Parts 730, 731, and 732 have been met.

3. National Environmental Policy Act

No environmental impact statement is required for this rule since section 702(d) of SMCRA (30 U.S.C. 1292(d)) provides that agency decisions on proposed State regulatory program provisions do not constitute major Federal actions within the meaning of section 102(2)(C) of the National Environmental Policy Act of 1969 (42 U.S.C. 4332(2)(C)).

4. Paperwork Reduction Act

This rule does not contain information collection requirements that require approval by OMB under the Paperwork Reduction Act (44 U.S.C. 3507 *et seq.*).

5. Regulatory Flexibility Act

The Department of the Interior has determined 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.*). The State submittal that is the subject of this rule is based upon counterpart Federal regulations for which an economic analysis was prepared and certification made that such regulations would not have a significant economic effect upon a substantial number of small entities. Accordingly, this rule will ensure that existing requirements previously promulgated by OSM will be implemented by the State. In making the determination as to whether this rule would have a significant economic impact, the Department relied upon the data and assumptions for the counterpart Federal regulations.

List of Subjects in 30 CFR Part 934

Intergovernmental relations, Surface mining, Underground mining.

Dated: April 26, 1995.

Peter A. Rutledge,

Acting Assistant Director, Western Support Center.

[FR Doc. 95–10776 Filed 5–1–95; 8:45 am]

BILLING CODE 4310–05–M

DEPARTMENT OF DEFENSE**DEPARTMENT OF TRANSPORTATION****Coast Guard****DEPARTMENT OF VETERANS AFFAIRS****38 CFR Part 21****RIN 2900-AF74****Reservists Education; Commencing Date of Award of Educational Assistance**

AGENCY: Department of Defense, Department of Transportation (Coast Guard), and Department of Veterans Affairs.

ACTION: Proposed rule.

SUMMARY: This document proposes to amend the Educational Assistance Regulations pertaining to the commencing dates of awards of educational assistance for members of the Selected Reserve. It is proposed to change these regulations to provide that all commencing dates for awards or increased awards of educational assistance be on or reasonably close to the date of the first day of class. The intended effect of the amendments is to make uniform the regulations governing the dates of commencement of awards of educational assistance under the Montgomery GI Bill—Selected Reserve both for reservists pursuing a college degree and for those enrolled in courses not leading to a college degree.

DATES: Comments must be received on or before July 3, 1995.

ADDRESSES: Mail written comments to: Director, Office of Regulations Management (02D), Department of Veterans Affairs, 810 Vermont Avenue, NW, Washington, DC 20420, or hand deliver written comments to: Office of Regulations Management, Room 1176, 801 Eye Street, NW, Washington DC 20001. Comments should indicate that they are in response to "RIN 2900-AF74." All written comments received will be available for public inspection in the Office of Regulations Management, Room 1176, 801 Eye Street, NW, Washington, DC 20001, between the hours of 8:00 a.m. and 4:30 p.m., Monday through Friday (except holidays).

FOR FURTHER INFORMATION CONTACT: June C. Schaeffer, Assistant Director for Policy and Program Administration, Education Service, Veterans Benefits Administration, (202) 273-7187.

SUPPLEMENTARY INFORMATION: In accordance with statutory authorities,

VA has established an educational assistance program for certain members of the Selected Reserve of the Ready Reserve for the purpose of encouraging membership in the Selected Reserve. The regulations established for this program are set forth at 38 CFR Subpart L, referred to below as the "Educational Assistance Regulations."

The Educational Assistance Regulations set forth criteria for determining the commencing date of an award or increased award of educational assistance. The current regulations provide that, with respect to reservists enrolled in a resident course or subject leading to a college degree, the commencing date generally is the date of registration or reporting, whichever is first. It is proposed to change these regulations, as set forth in the text portion of this document, to provide that all commencing dates for awards or increased awards of educational assistance be on or reasonably close to the date of the first day of class. It is also proposed to impose such requirements for all other reservists pursuing educational programs; i.e., those taking a course offered by independent study or correspondence. This proposal is consistent with the recommendation of the Commission to Assess Veterans' Education Policy and will help ensure that educational assistance is paid only for times close to or during the period of pursuit of the reservists' program of education.

The Secretary of Veterans Affairs, the Secretary of Defense and the Commandant of the Coast Guard have certified that this proposed rule, if promulgated, will not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act, 5 U.S.C. 601-612. The proposed rule would not directly affect any small entities. Only VA beneficiaries could be directly affected. Therefore, pursuant to 5 U.S.C. 605(b), the amended regulation is exempt from the initial and final regulatory flexibility analyses requirements of sections 603 and 604.

This proposed rule has been reviewed by the Office of Management and Budget pursuant to Executive Order 12866.

There is no Catalog of Federal Domestic Assistance number for the program affected by this proposed rule.

List of Subjects in 38 CFR Part 21

Civil rights, Claims, Education, Grant programs—education, Loan programs—education, Reporting and recordkeeping requirements, Schools, Veterans, Vocational education, Vocational rehabilitation.

Approved: April 11, 1995.

Jesse Brown,

Secretary of Veterans Affairs.

Approved: April 21, 1995.

Wayne W. Spruell,

Acting Deputy Assistant Secretary, Reserve Affairs (Manpower and Personnel), Department of Defense.

Approved: April 24, 1995.

R.M. Larrabee,

Chief, Office of Readiness and Reserve, Coast Guard, Department of Transportation.

For the reasons set out in the preamble, 38 CFR part 21, subpart L is amended as set forth below.

PART 21—VOCATIONAL REHABILITATION AND EDUCATION**Subpart L—Educational Assistance for Members of the Selected Reserve**

1. The authority citation for part 21, subpart L is revised to read as follows:

Authority: 10 U.S.C. ch. 1606; 38 U.S.C. 501(a).

2. In § 21.7631, paragraphs (b) and (c) and their authority citations are revised to read as follows:

§ 21.7631 Commencing dates.

* * * * *

(b) *Certification by school—the course or subject leads to a standard college degree.* (1) When a student enrolls in a course offered by independent study, the commencing date of the award or increased award of educational assistance will be the date the student began pursuit of the course according to the regularly established practices of the educational institution.

(2) When a student enrolls in a resident course or subject, the commencing date of the award will be the date of reporting provided that—

(i) The published standards of the school require the student to register before reporting,

(ii) The published standards of the school require the student to report no more than 14 days before the first scheduled date of classes for the term, quarter or semester for which the student has registered, and

(iii) The first scheduled class for the course or subject in which the student is enrolled begins during the calendar week when, according to the school's academic calendar, classes are generally scheduled to commence for the term.

(3) When a student enrolls in a resident course or subject whose first scheduled class begins after the calendar week when, according to the school's academic calendar, classes are scheduled to commence for the term, quarter, or semester, the commencing

date of the award or increased award of educational assistance allowance will be the actual date of the first class scheduled for the particular course or subject.

(4) When a student enrolls in a resident course or subject and neither the provisions of paragraph (b)(2) nor (b)(3) of this section apply to the enrollment, the commencing date of the award or increased award of educational assistance will be the first scheduled date of classes for the term, quarter or semester in which the student is enrolled.

(Authority: 10 U.S.C. 16136(b))

(c) *Certification by educational institution or training establishment—course does not lead to a standard college degree.* (1) When a reservist enrolls in a course which does not lead to a standard college degree and which is offered in residence, the commencing date of the award of educational assistance will be as stated in paragraph (b) of this section.

(2) When a reservist enrolls in a course which is offered by correspondence, the commencing date of the award of educational assistance shall be the later of—

(i) The date the first lesson was sent, or

(ii) The date of affirmance.

(3) When a reservist enrolls in a program of apprenticeship or other on-job training, the commencing date of the award of educational assistance shall be the first date of employment in the training position.

(Authority: 10 U.S.C. 16136(b))

* * * * *

[FR Doc. 95-10690 Filed 5-1-95; 8:45 am]

BILLING CODE 8320-01-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[AZ 42-1-6916b; FRL-5186-8]

Approval and Promulgation of State Implementation Plans; Arizona State Implementation Plan Revision, Pinal County Air Quality Control District; and Section 112(l) Approval of Pinal County Air Quality Control District Program for the Issuance of Permits Containing Voluntarily Accepted Federally Enforceable Conditions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The EPA is proposing to approve revisions to the Arizona State

Implementation Plan. The revisions concern synthetic minor permit rules from the Pinal County Air Quality Control District (Pinal or District). The intended effect of approving these synthetic minor regulations is to allow facilities to voluntarily accept federally enforceable limits on their potential emissions. This approval action will incorporate these rules into the federally approved SIP. In order to extend the federal enforceability of conditions in permits to hazardous air pollutants (HAP), EPA is also proposing to approve Pinal's synthetic minor regulations pursuant to section 112 of the Act.

In the final rules section of this **Federal Register**, EPA is approving the state's SIP revision and section 112(l) submittal as a direct final rule without prior proposal because the Agency views this as a noncontroversial amendment and anticipates no adverse comments. A detailed rationale for this approval is set forth in the direct final rule. If no adverse comments are received in response to this proposed 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. The EPA will not institute a second comment period on this document. Any parties interested in commenting on this action should do so at this time.

DATES: Comments on this proposed rule must be received in writing by June 1, 1995.

ADDRESSES: Written comments on this action should be addressed to: Regina Spindler, Operating Permits Section (A-5-2), Air and Toxics Division, U.S. Environmental Protection Agency, Region IX, 75 Hawthorne Street, San Francisco, CA 94105-3901.

Copies of the rules and EPA's Technical Support Document for the synthetic minor program are available for public inspection at EPA's Region IX office during normal business hours. Copies of the submitted rules are also available for inspection at the following locations:

Pinal County Air Quality Control District, 457 South Central Avenue, Florence, Arizona 85232
Arizona Department of Environmental Quality, 3033 North Central Avenue, Phoenix, Arizona 85012

FOR FURTHER INFORMATION CONTACT: Regina Spindler, Operating Permits Section (A-5-2), Air and Toxics Division, U.S. Environmental Protection Agency, Region IX, 75 Hawthorne

Street, San Francisco, CA 94105-3901, Telephone: (415) 744-1251.

SUPPLEMENTARY INFORMATION: This document concerns Pinal County Air Quality Control District Code of Regulations Chapter 1, Article 3, section 1-3-140, Definitions, subsections 5, 15, 21, 32, 33, 35, 50, 51, 58, 59, 103, and 123; Chapter 3, Article 1, section 3-1-081, Permit conditions, subsection (A)(8)(a); Chapter 3, Article 1, section 3-1-084, Voluntarily Accepted Federally Enforceable Emissions Limitations; Applicability; Reopening; Effective Date; and Chapter 3, Article 1, section 3-1-107, Public notice and participation, submitted to EPA on August 15, 1994 by the Arizona Department of Environmental Quality for approval into the SIP and on October 25, 1994 by the Pinal County Air Quality Control District for approval under section 112(l) of the Clean Air Act. For further information, please see the information provided in the direct final action which is located in the rules section of this **Federal Register**.

Dated: March 27, 1995.

Felicia Marcus,

Regional Administrator.

[FR Doc. 95-10699 Filed 5-1-95; 8:45 am]

BILLING CODE 6560-50-W

40 CFR Part 52

[MS-20-1-6562b; FRL-5174-1]

Approval and Promulgation of Implementation Plans Mississippi: Approval of Revisions to Construction and Operation Permit Regulations for Minor Sources

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA proposes to approve the State Implementation Plan (SIP) revision submitted by the State of Mississippi for the purpose of establishing a Federally enforceable state operating permit (FESOP) program. In order to extend the Federal enforceability of Mississippi's FESOP to hazardous air pollutants (HAP), EPA is also proposing approval of Mississippi's FESOP regulations pursuant to section 112 of the Clean Air Act as amended in 1990 (CAA). In the Final Rules Section of this **Federal Register**, EPA is approving the State's SIP revision as a direct final rule without prior proposal because the Agency views this as a noncontroversial revision amendment and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If no

adverse comments are received in response to that direct final rule, no further activity is contemplated in relation to this proposed rule. If EPA receives adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. EPA will not institute a second comment period on this document. Any parties interested in commenting on this notice should do so at this time.

DATES: To be considered, comments must be received by June 1, 1995.

ADDRESSES: Written comments should be addressed to: Carla Pierce, Title V Regional Program Manager, Air Programs Branch, Air, Pesticides & Toxics Management Division, Region 4 Environmental Protection Agency, 345 Courtland Street, NE, Atlanta, Georgia 30365.

Copies of the material submitted by Mississippi may be examined during normal business hours at the following locations:

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

Environmental Protection Agency, Region 4 Air Programs Branch, 345 Courtland Street, NE., Atlanta, Georgia 30365

Mississippi Department of Environmental Quality, Bureau of Air Quality Control, Air Quality Division, Post Office Box 10385, Jackson, Mississippi 39285

FOR FURTHER INFORMATION CONTACT:

Carla Pierce, Title V Program Development Team, Air Programs Branch, Air, Pesticides & Toxics Management Division, Region 4 Environmental Protection Agency, 345 Courtland Street, N.E., Atlanta, Georgia 30365. The telephone number is 404/347-2864.

SUPPLEMENTARY INFORMATION: For additional information see the direct final rule which is published in the rules section of this **Federal Register**.

Dated: March 1, 1995.

Patrick M. Tobin,

Acting Regional Administrator.

[FR Doc. 95-10701 Filed 5-1-95; 8:45 am]

BILLING CODE 6560-50-P

40 CFR Part 52

[MN29-1-6203b; FRL-5174-8]

Approval and Promulgation of Implementation Plans; Minnesota

AGENCY: United States Environmental Protection Agency (USEPA).

ACTION: Proposed rule.

SUMMARY: USEPA proposes to approve updated air permitting regulations that Minnesota submitted on November 23, 1993. USEPA further proposes to authorize Minnesota to issue federally enforceable State operating permits (FESOPs) under these regulations, and submit properly noticed permits as SIP revision requests. In addition, USEPA proposes to find that the updated regulations continue to satisfy new source review permitting requirements.

In the final rules section of this **Federal Register**, the USEPA is approving Minnesota's updated permitting regulations as a direct final rule without prior proposal, because USEPA views the action 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 that direct final rule, no further activity is contemplated in relation to the proposal of that action. If USEPA receives adverse public 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. USEPA 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 on this action must be received by June 1, 1995.

ADDRESSES: Written comments should be addressed to: William L. MacDowell, Chief, Regulation Development Section, Air Enforcement Branch (AE-17J), United States Environmental Protection Agency, 77 West Jackson Boulevard, Chicago, Illinois 60604.

FOR FURTHER INFORMATION CONTACT: John Summerhays, Air Enforcement Branch, Regulation Development Section (AE-17J), United States Environmental Protection, Region 5, Chicago, Illinois 60604, (312) 886-6067.

SUPPLEMENTARY INFORMATION: Supplementary information is provided in the rules section of this **Federal Register**.

Authority: 42 U.S.C. 7401-7671q.

Dated: March 8, 1995.

David A. Ullrich,

Acting Regional Administrator.

[FR Doc. 95-10703 Filed 5-1-95; 8:45 am]

BILLING CODE 6560-50-P

40 CFR Part 52

[KY-86-1-6932b; FRL-5189-7]

Approval and Promulgation of Implementation Plans; State: Kentucky; Approval of Revisions to State Implementation Plan Regarding Emission Statements

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is approving the State Implementation Plan (SIP) revision submitted by the Commonwealth of Kentucky through the Natural Resources and Environmental Protection Cabinet (Cabinet) for the purpose of implementing an emission statement program. In the final rules section of this **Federal Register**, the EPA is approving the State's SIP revision as a direct final rule without prior proposal because the Agency views this as a noncontroversial revision amendment and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If no adverse comments are received in response to that direct final rule, no further activity is contemplated in relation to this proposed rule. If EPA receives adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. The EPA will not institute a second comment period on this document. Any parties interested in commenting on this document should do so at this time.

DATES: To be considered, comments must be received by June 1, 1995.

ADDRESSES: Written comments on this action should be addressed to Scott Southwick at the EPA Regional Office listed below.

Copies of the documents relative to this action are available for public inspection during normal business hours at the following locations. The interested persons wanting to examine these documents should make an appointment with the appropriate office at least 24 hours before the visiting day.

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

Environmental Protection Agency,
Region IV Air Programs Branch, 345
Courtland Street, NE., Atlanta,
Georgia 30365
Division for Air Quality, Department for
Environmental Protection, Natural
Resources and Environmental
Protection Cabinet, 316 St. Clair Mall,
Frankfort, Kentucky 40601

FOR FURTHER INFORMATION CONTACT:
Scott Southwick, Regulatory Planning
and Development Section, Air Programs
Branch, Air, Pesticides & Toxics
Management Division, Region IV
Environmental Protection Agency, 345
Courtland Street, NE., Atlanta, Georgia
30365. The telephone number is 404/
347-3555, X4207. Reference file KY-
86-1-6932b.

SUPPLEMENTARY INFORMATION: For
additional information see the direct
final rule which is published in the
rules section of this **Federal Register**.

Dated: April 3, 1995.

Patrick M. Tobin,

Acting Regional Administrator.

[FR Doc. 95-10697 Filed 5-1-95; 8:45 am]

BILLING CODE 6560-50-P

40 CFR Part 52

[VA20-1-5996b; FRL-5179-1]

Approval and Promulgation of Air Quality Implementation Plans for the Commonwealth of Virginia—Emission Statement Program

AGENCY: Environmental Protection
Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA proposes to approve the
State Implementation Plan (SIP)
revision submitted by the
Commonwealth of Virginia for the
purpose of establishing an emission
statement program for stationary sources
of volatile organic compounds (VOCs)
and/or nitrogen oxides (NO_x). In the
Final Rules section of this **Federal
Register**, EPA is approving the State's
SIP revision as a direct final rule
without prior proposal because the
Agency views this as a noncontroversial
SIP revision and anticipates no adverse
comments. A detailed rationale for the
approval is set forth in the direct final
rule. If no adverse comments are
received in response to this proposed
rule, no further activity is contemplated
in relation to this proposed rule. If EPA
receives adverse comments, the direct
final rule will be withdrawn and all
public comments received will be
addressed in a subsequent final rule
based on this proposed rule. EPA will
not institute a second comment period

on this action. Any parties interested in
commenting on this action should do so
at this time.

DATES: Comments must be received in
writing by June 1, 1995.

ADDRESSES: Written comments on this
action should be addressed to Thomas
J. Maslany, Director, Air, Radiation, and
Toxics Division (3AT00), U.S.
Environmental Protection Agency,
Region III, 841 Chestnut Building,
Philadelphia, Pennsylvania 19107.
Copies of the documents relevant to this
action are available for public
inspection during normal business
hours at the Air, Radiation, and Toxics
Division, U.S. Environmental Protection
Agency, Region III, 841 Chestnut
Building, Philadelphia, Pennsylvania
19107; and the Virginia Department of
Environmental Quality, 629 East Main
Street, Richmond, Virginia 23219.

FOR FURTHER INFORMATION CONTACT: Enid
A. Gerena (3AT14), U.S. Environmental
Protection Agency, Air, Radiation, and
Toxics Division, 841 Chestnut Building,
Philadelphia, Pennsylvania 19107, (215)
597-8239.

SUPPLEMENTARY INFORMATION: See the
information provided in the Direct Final
action of the same title which is located
in the Rules and Regulations Section of
this **Federal Register**.

List of Subjects in 40 CFR Part 52

Environmental protection, Air
pollution control, Hydrocarbons,
Incorporation by reference,
Intergovernmental relations, Oxides of
nitrogen, Ozone, Reporting and
recordkeeping requirements, and SIP
requirements.

Authority: 42 U.S.C. 7401-7671q.

Dated: January 25, 1995.

Peter H. Kostmayer,

Regional Administrator, Region III.

[FR Doc. 95-10705 Filed 5-1-95; 8:45 am]

BILLING CODE 6560-50-P

40 CFR Part 52

[DC23-1-6790b; FRL-5181-3]

Approval and Promulgation of Air Quality Implementation Plans; District of Columbia; GSA Central And West Heating Plants

AGENCY: Environmental Protection
Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA proposes to approve the
State implementation plan (SIP)
revision submitted on October 24, 1994
by the District of Columbia consisting of
a permit-to-operate issued by the

District to General Services
Administration for its Central and West
Heating Plants. In the Final Rules
section of this **Federal Register**, EPA is
approving the District of Columbia's SIP
revision as a direct final rule without
prior proposal because the Agency
views this as a noncontroversial SIP
revision and anticipates no adverse
comments. A detailed rationale for the
approval is set forth in the direct final
rule and the associated Technical
Support Document. If no adverse
comments are received in response to
this proposed 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 June 1, 1995.

ADDRESSES: Written comments on this
action should be addressed to Marcia L.
Spink, Associate Director, Air Programs
(3AT00), U.S. Environmental Protection
Agency, Region III, 841 Chestnut
Building, Philadelphia, Pennsylvania
19107. Copies of the documents relevant
to this action are available for public
inspection during normal business
hours at the Air, Radiation, and Toxics
Division, U.S. Environmental Protection
Agency, Region III, 841 Chestnut
Building, Philadelphia, Pennsylvania
19107; and the District of Columbia
Department of Consumer and
Regulatory Affairs, 2100s Martin Luther
King Ave, SE., Washington, DC 20020.

FOR FURTHER INFORMATION CONTACT:
David J. Campbell, Technical
Assessment Section (3AT22), U.S.
Environmental Protection Agency,
Region III, 841 Chestnut Building,
Philadelphia, Pennsylvania 19107,
phone: (215) 597-9781.

SUPPLEMENTARY INFORMATION: See the
information provided in the direct final
action of the same title which is located
in the Rules and Regulations Section of
this **Federal Register**.

List of Subjects in 40 CFR Part 52

Environmental protection, Air
pollution control, Carbon monoxide,
Nitrogen dioxide, Particulate matter,
Reporting and recordkeeping
requirements, Sulfur oxides.

Dated: March 21, 1995.

Stanley L. Laskowski,

Acting Regional Administrator, Region III.

[FR Doc. 95-10707 Filed 5-1-95; 8:45 am]

BILLING CODE 6560-50-P

40 CFR Parts 52 and 81

[OH50-1-6077b; FRL-5183-6]

Approval And Promulgation Of Implementation Plans And Designation Of Areas For Air Quality Planning Purposes: State Of Ohio

AGENCY: United States Environmental Protection Agency (USEPA).

ACTION: Proposed rule.

SUMMARY: The USEPA proposes to approve the redesignation request and maintenance plan for Toledo, Ohio as a revision to Ohio's State Implementation Plan (SIP) for ozone. In the final rules section of this **Federal Register**, the USEPA is approving the State's redesignation request and maintenance plan as a direct final rule without prior proposal because USEPA views this as a noncontroversial revision amendment and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If no adverse comments are received in response to that direct final rule, no further activity is contemplated in relation to this proposed rule. If USEPA 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 the proposed rule. USEPA will not institute a second comment period on this notice. Any parties interested in commenting on this notice should do so at this time.

DATES: Comments on this action must be received by June 1, 1995.

ADDRESSES: Written comments should be mailed to:

William MacDowell, Chief, Regulation Development Section, Air Enforcement Branch (AE-17J), United States Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois, 60604
Copies of the State submittal and USEPA's analysis of it are available for inspection at:

Regulation Development Section, Air Enforcement Branch (AE-17J), United States Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois, 60604

FOR FURTHER INFORMATION CONTACT: Angela Lee, (312) 353-5142, Regulation Development Section, Air Enforcement Branch (AE-17J), United States

Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604.

SUPPLEMENTARY INFORMATION: For additional information see the direct final rule published in the final rules section of this **Federal Register**.

Dated: March 14, 1995.

Valdas V. Adamkus,

Regional Administrator.

[FR Doc. 95-10694 Filed 5-1-95; 8:45 am]

BILLING CODE 6560-50-M

40 CFR Part 82

[FRL-5199-5]

Reconsideration of the Significant New Alternatives Policy Rule

AGENCY: United States Environmental Protection Agency.

ACTION: Proposed stay.

SUMMARY: On December 8, 1994 EPA announced a 3-month administrative stay (59 FR 63255) based on EPA's decision to reconsider the Significant New Alternative Policy (SNAP) rule as it applies to substitutes manufactured solely for export (59 FR 13044, March 18, 1994). This action stays the effectiveness of the SNAP rule as it applies to substances produced solely for export, including the applicable compliance dates, until EPA takes final action reconsidering the SNAP rule. At that time, EPA will also take final action, as appropriate, establishing the effective date of the rule for such substances.

DATES: Comments on this proposal must be received by June 1, 1995 at the address below. A public hearing, if requested, will be held in Washington, D.C. Requests for a hearing should be submitted to Robert Waugh by June 1, 1995 at the address below. If a hearing is requested, EPA will publish notice of such hearing in the **Federal Register**.

ADDRESSES: Written comments on this proposed action should be addressed to Robert Waugh, Substitutes Analysis and Review Branch, Stratospheric Protection Division, Office of Air and Radiation, (6205-J) 401 M Street, SW, Washington, DC 20460. Comments should be strictly limited to the subject matter of this proposal, the scope of which is discussed below.

DOCKET: Pursuant to section 307(d)(1) of the CAA, 42 U.S.C. 7607(d)(1), this action is a public docket for this action, A-91-42, which is available for public inspection and copying between 8 a.m. and 4 p.m., Monday through Friday, at the following address. A reasonable fee

may be charged for copying. U.S. Environmental Protection Agency, Docket No. A-91-42, Air Docket (6102), Room M1500, Waterside Mall, 401 M Street SW., Washington, DC 20460 (202) 245-3639.

FOR FURTHER INFORMATION CONTACT:

Robert Waugh at (202) 233-9152 or Fax (202) 233-9577.

SUPPLEMENTARY INFORMATION:

I. Background

On December 8, 1994, EPA announced that, pursuant to CAA section 307(d)(7)(B), 42 U.S.C. 7607(d)(7)(B), it was convening a proceeding for reconsideration of the SNAP rule as it applies to substances manufactured for export (59 FR 63255). In that notice, USEPA also announced a 3-month administrative stay of the SNAP rule as it applies to substitutes produced solely for export. However, USEPA will be unable to complete reconsideration (including any appropriate regulatory revision) of the rule within the 3-month period expressly provided by CAA section 307(d)(7)(B). Therefore, EPA is proposing to temporarily extend the stay of the SNAP rule as it applies to substitute use for export until EPA completes its reconsideration and final rulemaking action. If USEPA takes final action to impose this stay, the stay would extend until the effective date of USEPA's final action following reconsideration of the SNAP rule.

II. Authority for Stay and Reconsideration

This notice proposes, pursuant to CAA section 110(c), 301(a)(1) and 307(d)(1)(B), 42 U.S.C. 7410(c), 7601(a)(1) and 7607(d)(1)(B), to temporarily stay the elements of the rule that apply to substitutes manufactured solely for export, as well as applicable compliance dates beyond the three months expressly provided in section 307(d)(7)(B). This stay is only effective if and as long as it is necessary to complete reconsideration (including any appropriate regulatory action) of the referenced elements of the rule. Pursuant to the rulemaking procedures set forth in CAA section 307(d), 42 U.S.C. 7607(d), USEPA hereby requests public comment on this proposed temporary extension of the three-month stay.

III. Administrative Requirements

It has been determined that this notice is not a "significant regulatory action" under the terms of Executive Order 12866 (58 FR 51735; October 4, 1993)

and is therefore not subject to OMB review.

List of Subjects in 40 CFR Part 82

Environmental protection, Air pollution control.

Dated: April 24, 1995.

Carol M. Browner,
Administrator.

40 CFR part 82 is amended as follows:

PART 82—PROTECTION OF STRATOSPHERIC OZONE

1. The authority citation of part 82 continues to read as follows:

Authority: 42 U.S.C. 7414, 7601, 7671–7671q.

2. Section 82.174 is amended by adding paragraph (e) to read as follows:

§ 82.174 Prohibitions.

* * * * *

(e) *Rules Stayed for Reconsideration.* Notwithstanding any other provision of this subpart, the effectiveness of subpart G is stayed from May 2, 1995 to until the effective date of USEPA's final action following reconsideration of the SNAP rule only as applied to use of substitutes for export.

[FR Doc. 95–10624 Filed 5–1–95; 8:45 am]

BILLING CODE 6560–50–P

40 CFR Part 300

[FRL–5200–3]

National Priorities List for Uncontrolled Hazardous Waste Sites

AGENCY: Environmental Protection Agency.

ACTION: Proposed rule; withdrawal.

SUMMARY: The Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (“CERCLA” or “the Act”), as amended, requires that the National Oil and Hazardous Substances Pollution Contingency Plan (“NCP”) include a list of national priorities among the known releases or threatened releases of hazardous substances, pollutants, or contaminants throughout the United States. The National Priorities List (“NPL”) which is appendix B to 40 CFR part 300 constitutes this list.

In this document, the Environmental Protection Agency (EPA) is withdrawing its proposal to list the Texas Eastern Kosciusko Compressor Station site on the NPL. Because of the unique circumstances surrounding this site, NPL listing has been deemed unnecessary. The rationale supporting this action are explained further in the

Supplementary Information section below.

DATES: This withdrawal is effective May 2, 1995.

FOR FURTHER INFORMATION CONTACT: June Wiaz, Hazardous Site Evaluation Division, (703) 603–8864, Office of Emergency and Remedial Response (5204G), U.S. Environmental Protection Agency, 401 M Street, SW., Washington, DC, 20460, or the Superfund Hotline, phone (800) 424–9346, or (703) 412–9810 in the Washington DC, metropolitan area.

SUPPLEMENTARY INFORMATION: In this document, EPA is withdrawing its proposal to list Texas Eastern's Kosciusko, Mississippi, Compressor Station Site on the National Priorities List (NPL). EPA proposed to add the Kosciusko site to the NPL on August 23, 1994 (59 FR 43314).

Texas Eastern's comments on the proposal and other information submitted to the Agency have led EPA to withdraw it. EPA's reasons for withdrawal are multi-faceted. First, this is a site unique among those on the NPL or proposed for NPL listing. The Kosciusko site is just one of 89 along the company's pipeline (which extends from the Gulf of Mexico to New York). Second, Texas Eastern currently is addressing all of the affected sites under a federally enforceable Consent Decree negotiated with the United States pursuant to the Toxic Substances Control Act (TSCA). Texas Eastern is expected to spend approximately \$750 million over the next 10 years complying with the Consent Decree.

Under the Consent Decree, dated June 1988 and amended March 1995, there is an agreed-upon schedule of characterization for the 89 sites. Texas Eastern maintains that it was their expectation, when they entered into the consent agreement, that it would shield them from inclusion on the NPL and action under CERCLA. The Agency accepts that Texas Eastern has acted in good faith to carry out the provisions of that agreement.

Texas Eastern has nominated the Kosciusko site as one of 10 of its pipeline sites scheduled for remediation in 1996. This represents an accelerated schedule for the Kosciusko site which will be fully characterized during 1995. EPA and Texas Eastern have negotiated modifications to the Consent Decree requiring that the company address all significant off-site contamination attributable to the Kosciusko Compressor Station. Texas Eastern's efforts at characterizing the site include a five-year fish study. The study which has been going on for more than two

years, will help determine the nature and extent of the PCB contamination. This characterization of downstream effects will be useful in remedy selection.

Allowing the Consent Decree process to govern cleanup of the Kosciusko site stems from a desire to avoid a fragmented approach to Texas Eastern's 89 sites. The alternative—trying to address all sites under various Federal statutes with different requirements and cleanup levels—would result in inconsistent cleanups and a much slower process. In negotiating the Consent Decree, the United States and Texas Eastern sought to develop an orderly process by which response work would proceed. Listing the site on the NPL arguably violates this process.

For these reasons EPA, at this time, elects to withdraw its proposal to list the Kosciusko compressor station site on the NPL. However, should conditions change (i.e. insufficient progress toward cleanup) such that placing the site on the NPL would effect a more thorough and timely cleanup, EPA reserves the right to re-propose the site.

List of Subjects in 40 CFR Part 300

Air pollution control, Chemicals, Environmental protection, Hazardous materials, Hazardous substances, Incorporation by reference, Intergovernmental relations, Natural resources, Occupational safety and health, Oil pollution, Reporting and recordkeeping requirements, Superfund, Waste treatment and disposal, Water pollution control, Water supply.

Dated: April 24, 1995.

Elliott P. Laws,

Assistant Administrator, Office of Solid Waste and Emergency Response.

[FR Doc. 95–10751 Filed 5–1–95; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 625

[Docket No. 950421111–5111–01; I.D. 022895B]

Summer Flounder Fishery; Dealer Reporting Requirements

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Proposed rule; request for comments.

SUMMARY: NMFS proposes to amend the regulations implementing the Fishery Management Plan for the Summer Flounder Fishery (FMP), to reduce reporting requirements for federally permitted dealers, to make it easier for them to comply with remaining reporting requirements, and to improve monitoring of the commercial summer flounder quota.

DATES: Comments must be received on or before June 1, 1995.

ADDRESSES: Comments on the proposed rule or on the proposed Interactive Voice Response system should be sent to Jon Rittgers, Acting Regional Director, National Marine Fisheries Service, Northeast Regional Office, 1 Blackburn Drive, Gloucester, MA 01930. Mark the outside of the envelope "Comments on Summer Flounder, Dealer Reporting." Comments on the proposed Interactive Voice Response system should also be sent to the Office of Information and Regulatory Affairs, Attention: NOAA Desk Officer, Office of Management and Budget, Washington, D.C. 20503.

FOR FURTHER INFORMATION CONTACT: Hannah Goodale, 508-281-9101, or Regina Spallone, 508-281-9221.

SUPPLEMENTARY INFORMATION: The FMP was developed jointly by the Atlantic States Marine Fisheries Commission and the Mid-Atlantic Fishery Management Council in consultation with the New England and South Atlantic Fishery Management Councils. The management unit for the FMP is summer flounder (*Paralichthys dentatus*) in U.S. waters of the Atlantic Ocean from the southern border of North Carolina northward to the U.S.-Canadian border. Implementing regulations for the FMP are found at 50 CFR part 625.

The summer flounder fishery is managed under a quota system. The quota is divided among the coastal states based upon set percentages. Landings must be monitored weekly in order to determine when a state's quota has been reached.

Since 1993, federally permitted summer flounder dealers have been required to report weekly all fish purchases. While several of the species of fish purchased by these dealers are under quota management systems (summer flounder, squid, mackerel, butterfish), only the summer flounder quota requires weekly monitoring at this time. The quotas for the remaining species purchased by these dealers can be adequately monitored through monthly reports. NMFS believes that reporting purchases of all species on a weekly basis is unnecessary and burdensome. Therefore, NMFS proposes

to revise the weekly reporting requirement to make it pertain to summer flounder purchases only. The comprehensive reporting of all fish purchases would be required monthly rather than weekly. This proposed change would reduce the burden associated with the reporting requirement, and, as a secondary benefit, would allow more accurate price information to be collected, since such information is often unavailable to dealers on a weekly basis.

NMFS further proposes to require that the weekly summer flounder purchase report be made via an Interactive Voice Response (IVR) system, rather than by a written report. Dealers would be provided with a toll-free number to call to report weekly purchases of summer flounder using either a touch-tone system or voice mail. An IVR system would make it easier for dealers to comply with the weekly reporting requirement and would be a more efficient method of collecting the data required for weekly monitoring of the commercial summer flounder quota.

NMFS proposes to require dealers to report the following information weekly through the IVR system: Dealer permit number, pounds of summer flounder purchased, week in which summer flounder was purchased, and state(s) of landing for summer flounder purchased. If no summer flounder were purchased during the week, the dealer would be required to make a report so stating through the IVR system. This proposed requirement is less burdensome than the current weekly report. It confines the requirement to summer flounder, and, rather than requiring the purchases to be reported by vessel, it allows dealers to report their weekly summer flounder purchases by state.

Dealers would continue to report the following information monthly on forms supplied by or approved by the Director, Northeast Region, NMFS (Regional Director): Dealer name and mailing address; dealer number; name and permit number, or name and hull number (U.S. Coast Guard Documentation Number or state registration number, as appropriate) of vessels from which fish are landed or received; dates of purchases; pounds by species (by market category if applicable); price by species (by market category if applicable) or total value by species (by market category if applicable); port landed; signature of dealer or other authorized individual; and any other information deemed necessary by the Regional Director. If no fish were purchased during the month, the dealer would be required to make a report so stating on the required form.

Dealers would still have the option of submitting the required information electronically if authorized in writing by the Regional Director.

NMFS also proposes to modify three requirements pertaining to federally permitted dealers. Dealers are currently required to report the Federal permit number of the vessels from which fish are purchased. However, many of the species purchased by dealers are not subject to Federal management and are caught by vessels that hold no Federal permits. This requirement would be modified to indicate that dealers must report either the Federal permit number or the hull number (U.S. Coast Guard Documentation Number or state registration number, as appropriate) of the vessels from which fish are purchased.

The existing monthly dealer report form specifies market categories for many species. NMFS proposes to modify the regulations to clarify that dealers must report species purchased by market category, when applicable.

Dealers are currently required to report price per pound for species purchased. Many dealers have said that it is easier to report the total value of a species purchase rather than the price per pound. NMFS proposes to amend the regulations to make either manner of reporting acceptable.

NMFS also proposes to add a paragraph to the regulations concerning the collection of biological data (fish lengths) and samples (scales and/or otoliths for ageing), which are necessary to characterize the composition of landed catch. While most dealers have historically allowed access to their premises for the collection of these data, NMFS proposes to revise the regulations to make it explicit that federally permitted dealers must allow such access.

In addition, to protect against the unauthorized submission of reports, NMFS proposes to require that all monthly report forms be signed by the dealer or other authorized individual.

Classification

This proposed rule has been determined to be not significant for purposes of E.O. 12866.

This rule is subject to the Paperwork Reduction Act and clarifies or modifies requirements previously approved under OMB Control #0648-0229 (2 minutes per response). The requirement to use an Interactive Voice Response system for weekly reporting has been submitted to OMB for approval. This requirement and the other modifications to existing reporting requirements are expected to slightly reduce or not affect

the burden on respondents. The rule also restates a requirement for mandatory reporting of employment data in the Annual Processed Products Report. This requirement is estimated to take 2 minutes per response and has been approved by OMB under control number 0648-0018. Any comments on the proposed Interactive Voice Response system should be sent to the address specified in ADDRESSES.

List of Subjects in 50 CFR Part 625

Fisheries, Reporting and recordkeeping requirements.

Dated: April 26, 1995.

Gary Matlock,

Program Management Officer, National Marine Fisheries Service.

For the reasons set out in the preamble, 50 CFR part 625 is proposed to be amended as follows:

PART 625—SUMMER FLOUNDER FISHERY

1. The authority citation for part 625 continues to read as follows:

Authority: 16 U.S.C. 1801 *et seq.*

2. In § 625.2, the definition for “reporting month” is added, in alphabetical order, to read as follows:

§ 625.2 Definitions.

* * * * *

Reporting month means the calendar month.

* * * * *

3. Section 625.6 is amended by redesignating paragraphs (a)(2) through (a)(6) as paragraphs (a)(3) through (a)(7); by revising paragraph (a)(1), and newly redesignated paragraphs (a)(3), (a)(6), and (a)(7); and by adding new paragraphs (a)(2) and (a)(8) to read as follows:

§ 625.6 Recordkeeping and reporting requirements.

(a) *Dealers*—(1) *Weekly report.* Dealers must submit the following information, and any other information required by the Regional Director, on a weekly basis to the Regional Director, or an official designee, via an Interactive Voice Response (IVR) system established by the Regional Director: Dealer number, pounds of summer flounder purchased, week in which summer flounder was purchased, and state(s) of landing for summer flounder purchased. Even if no summer flounder are purchased during the week, a report so stating must be submitted through the IVR system.

(2) *Monthly reports.* Dealers must send by mail to the Regional Director, or an official designee, on a monthly basis

on forms supplied by or approved by the Regional Director, a report of all fish purchases. If authorized in writing by the Regional Director, dealers may submit reports electronically or through other media. The following information, and any other information required by the Regional Director, must be provided in the report: Name and mailing address of dealer; dealer number; name and permit number, or name and hull number (U.S. Coast Guard Documentation Number or state registration number, as appropriate) of the vessels from which fish were landed or received; dates of purchases; pounds by species (by market category if applicable); price by species (by market category if applicable) or value by species (by market category if applicable); and port landed. Even if no fish were purchased during the month, a report so stating must be submitted on the required form. All monthly report forms must be signed by the dealer or the dealer's authorized representative.

(3) *Annual report.* All persons required to submit reports under paragraph (a)(1) of this section are required to complete the “Employment Data” section of the Annual Processed Products Reports; completion of other sections on that form is voluntary. Required data are the number of employees handling fishery products by month. Reports for a given calendar year must be submitted to: NMFS Statistics, One Blackburn Drive, Gloucester, MA 01930-2298, and must be postmarked by February 10th of the following year.

* * * * *

(6) *Submitting reports.* Weekly reports must be made by noon each Tuesday for the previous reporting week. Monthly reports must be made within 10 days after the end of each reporting month. If monthly reports are mailed, such reports will be considered made in a timely manner if postmarked within 10 days after the end of the reporting month. Dealers will be sent, shortly after receipt of a dealer permit, forms and instructions, including a chart identifying reporting weeks, the telephone number and instructions for the IVR system for submission of weekly reports, and the address to which to submit monthly reports. If no fish are purchased during a required reporting period, a report so stating must be submitted.

(7) *At-sea activities.* All federally permitted summer flounder dealers purchasing, receiving, or processing any fish at sea for landing at any port of the United States must submit information identical to that required by paragraphs (a)(1), (2) and (3) of this section and

provide those reports to the Regional Director or designee on the same frequency basis.

(8) *Additional data and sampling.* Dealers are required to allow access to their premises and to make available to an official designee of the Regional Director any fish purchased from vessels for the collection of biological data. Such data include, but are not limited to, length measurements of fish and the collection of age structures such as otoliths or scales.

* * * * *

[FR Doc. 95-10739 Filed 5-1-95; 8:45 am]

BILLING CODE 3510-22-F

National Oceanic and Atmospheric Administration

50 CFR Part 640

[Docket No. 950424112-5112-01; I.D. 032095B]

RIN 0648-AF37

Spiny Lobster Fishery of the Gulf of Mexico and South Atlantic; Amendment 4

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Proposed rule.

SUMMARY: NMFS issues this proposed rule to implement Amendment 4 to the Fishery Management Plan for the Spiny Lobster Fishery of the Gulf of Mexico and South Atlantic (FMP). Amendment 4 would allow the harvest of spiny lobster year-round and establish a daily bag or possession limit of two spiny lobster per person in the exclusive economic zone (EEZ) off the southern Atlantic states, other than Florida (i.e., EEZ off North Carolina, South Carolina, and Georgia).

DATES: Written comments must be received on or before June 12, 1995.

ADDRESSES: Comments on the proposed rule must be sent to the Southeast Regional Office, NMFS, 9721 Executive Center Drive N., St. Petersburg, FL 33702.

Requests for copies of Amendment 4, which includes a regulatory impact review and an environmental assessment, and the FMP, should be sent to the Gulf of Mexico Fishery Management Council, 5401 W. Kennedy Boulevard, Suite 331, Tampa, FL 33609-2486, FAX 813-225-7015, or to the South Atlantic Fishery Management Council, Southpark Building, One Southpark Circle, Suite 306, Charleston, SC 29407-4699, FAX 803-769-4520.

FOR FURTHER INFORMATION CONTACT:

Georgia Cranmore, 813-570-5305.

SUPPLEMENTARY INFORMATION: The FMP was prepared by the Gulf of Mexico Fishery Management Council (Gulf Council) and the South Atlantic Fishery Management Council (South Atlantic Council) and is implemented through regulations at 50 CFR part 640 under the authority of the Magnuson Fishery Conservation and Management Act (Magnuson Act).

Amendment 4

The FMP currently provides for a commercial and recreational fishing season throughout the Gulf of Mexico and South Atlantic of August 6 through March 31, except for a 2-day special recreational season in July. During the August 6 through March 31 season, there are no bag or possession limits in the commercial fishery and recreational fishermen are limited to six spiny lobster per person per day. In the EEZ off the southern Atlantic states, other than Florida, Amendment 4 would (1) allow the take of spiny lobster year-round, and (2) establish a daily bag or possession limit of two spiny lobster per person in both the recreational and commercial fisheries. The purpose of Amendment 4 is to allow fishermen in the EEZ north of Florida to harvest the resource during the warm-weather months when the season currently is closed.

Commercial and recreational landings of spiny lobster outside Florida are negligible. According to the NMFS Accumulated Landings Database, no landings from spiny lobster traps have been reported from North Carolina or South Carolina since 1990. Since 1990, only 78.0 lb (35.4 kg) were reported landed from traps in Georgia. Commercial spiny lobster divers in North Carolina took an estimated 288.0 lb (130.6 kg) in 1992 and, in 1993, the only reported harvest by commercial divers north of Florida was 1,334 lb (605 kg) landed in South Carolina.

According to NMFS' 1991 Marine Recreational Fisheries Statistics Survey, no spiny lobster recreational trips were reported in South Carolina and Georgia during a survey of southeastern states other than Florida. However, another study conducted by NMFS in 1993 attempted specifically to characterize the directed and incidental take of spiny lobster by sport divers in offshore waters of the southeastern states. This study involved a telephone survey of dive shops and clubs and indicated that a small number of spiny lobster were harvested by recreational divers in North Carolina, South Carolina, and Georgia.

According to testimony of North Carolina recreational fishermen before the South Atlantic Council, the fishery takes place about 30 nautical miles (55.6 km) offshore in at least 100 ft (30.5 m) of water. A typical dive trip at these depths lasts about 30 minutes. Lobsters harvested ranged from 2 to 16 lb (0.9 to 7.3 kg). Divers believe that the spawning season off North Carolina does not begin until July, due to the colder water temperatures. They reported seeing egg-bearing lobsters as late as September and early October. Amendment 4 would not change the current prohibition on taking egg-bearing female lobsters.

The Gulf Council and the South Atlantic Council (Councils) have concluded that a year-round daily harvest limit of two spiny lobster per person north of Florida will allow recreational fishermen to catch spiny lobster during the months when the weather is favorable. There is scientific debate regarding the biological status and population dynamics of spiny lobsters in waters north of Florida, including the issue of recruitment and the fate of larvae from the adult population in this area. However, based on the best available scientific information, the Councils believe that allowing a limited year-round harvest in the subject area will have no adverse biological impacts on the lobster resource.

The Councils have concluded that the proposed action is consistent with the FMP's objective to protect long-run yields and prevent depletion of lobster stocks, because lowering the daily recreational limit from six to two and establishing a commercial harvest limit would prevent significant increases in fishing mortality. If Amendment 4 is implemented, the South Atlantic Council would monitor the level of spiny lobster harvests north of Florida and lower the daily limit, if necessary.

Additional background and rationale for the measures discussed above are contained in Amendment 4, the availability of which was announced in the **Federal Register** on March 27, 1995, (60 FR 15743).

Additional Measures Proposed by NMFS

Pursuant to the FMP's framework procedure for implementing specified gear and harvest restrictions, certain portions of Florida's management scheme were incorporated by reference into these Federal regulations on November 30, 1992 (57 FR 56516) and October 21, 1994 (59 FR 53118). A full description of the Florida measures was contained in the preamble to the proposed rule incorporating those

measures (57 FR 32956, July 24, 1992). At the time these State statutes and regulations were incorporated, specific reference to the incorporation was not mentioned in the regulatory text. To ensure that the incorporation by reference meets procedural specifications for the Office of the Federal Register, NMFS adds appropriate language to sections 640.4(a)(1), 640.6(a), 640.20(c), and 640.22(b)(3), with references to the State statutes and regulations as recodified in 1994.

NMFS proposes a technical amendment to section 640.22 to correct and conform current regulations to the original FMP, which prohibited the use by divers, not by hook-and-line fishermen, of gear containing hooks. (See section 12.4.1, *Measures Proposed for Adoption*, Fishery Management Plan for the Spiny Lobster Fishery of the Gulf of Mexico and South Atlantic, March 1982, pages 12-20). Gear such as spears, and spear-like devices with a hook on the end, were originally prohibited because divers using such gear were unable to accurately gauge the size of lobsters prior to mortally puncturing them. Such lobsters frequently turn out to be undersized. However, the language of the prohibition in the current regulations precludes harvest or retention of a spiny lobster taken unintentionally in a hook-and-line fishery for other species.

The technical amendment will allow fishermen using hook-and-line gear to retain lobsters incidentally harvested with such gear. According to the administrative record, the occurrence of spiny lobster harvest by hook-and-line fishermen is quite rare and occurs primarily aboard headboats operating north of Florida. The record further shows that lobsters harvested in that area are much larger than the current minimum size limit. Therefore, allowing retention of spiny lobsters harvested by hook-and-line fishermen should not increase the mortality of undersized lobsters. However, to enhance enforceability of the intended prohibition, that is, the prohibition on intentional hooking of spiny lobsters with prohibited gear, a spiny lobster that is taken by hook and line could not be retained aboard a vessel that has prohibited gear aboard.

Classification

Section 304(a)(1)(D) of the Magnuson Act requires NMFS to publish regulations proposed by a council within 15 days of receipt of an amendment and regulations. At this time, NMFS has not determined that Amendment 4 is consistent with the

national standards, other provisions of the Magnuson Act, and other applicable laws. NMFS, in making that determination, will take into account the data, views, and comments received during the comment period.

This proposed rule has been determined to be not significant for purposes of E.O. 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. The year-round daily harvest limit of two spiny lobster north of Florida would not: (1) Reduce annual gross revenues in excess of 5 percent, (2) significantly increase compliance or production costs of participants, (3) require capital investment to comply with the rule, or (4) require a current participant to cease business. All entities involved are small entities. As a result, a regulatory flexibility analysis was not prepared.

List of Subjects in 50 CFR Part 640

Fisheries, Fishing, Incorporation by reference, Reporting and recordkeeping requirements.

Dated: April 26, 1995.

Gary Matlock,

Program Management Officer, National Marine Fisheries Service.

For the reasons set out in the preamble, 50 CFR part 640 is proposed to be amended as follows:

PART 640—SPINY LOBSTER FISHERY OF THE GULF OF MEXICO AND SOUTH ATLANTIC

1. The authority citation for part 640 continues to read as follows:

Authority: 16 U.S.C. 1801 *et seq.*

2. In § 640.2, definitions for “Off the Gulf states, other than Florida” and “Off the southern Atlantic states, other than Florida” are added, in alphabetical order, to read as follows:

§ 640.2 Definitions.

* * * * *

Off the Gulf states, other than Florida means the area from the coast to the outer limit of the EEZ between the Texas/Mexico border to the Alabama/Florida boundary (87°31'06" W. long.).

Off the southern Atlantic states, other than Florida means the area from the coast to the outer limit of the EEZ between the Virginia/North Carolina boundary (36°34'55" N. lat.) to the Georgia/Florida boundary (30°42'45.6" N. lat.).

* * * * *

3. In § 640.4, paragraph (a)(1) is revised to read as follows:

§ 640.4 Permits and fees.

(a) * * *

(1) *Licenses, certificates, and permits.*

(i) *EEZ off Florida and spiny lobster landed in Florida.* For a person to sell, trade, or barter, or attempt to sell, trade, or barter, a spiny lobster harvested or possessed in the EEZ off Florida, or harvested in the EEZ other than off Florida, and landed from a fishing vessel in Florida, or for a person to be exempt from the daily bag and possession limit specified in § 640.23(b)(1) for such spiny lobster, such person must have the licenses and certificates specified to be a “commercial harvester,” as defined in Rule 46–24.002(2), Florida Administrative Code, in effect as of June 1, 1994. This incorporation by reference has been submitted to the Director of the Office of the Federal Register for approval in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from the Florida Marine Fisheries Commission, 2540 Executive Center Circle West, Suite 106, Tallahassee, FL 32301; telephone: 904–487–0554. Copies may be inspected at the Office of the Regional Director; the Office of Fisheries Conservation and Management, NMFS, 1315 East-West Highway, Silver Spring, MD 20910; or the Office of the Federal Register, 800 North Capitol Street, NW, Suite 700, Washington, DC.

(ii) *EEZ other than off Florida.* For a person to sell, trade, or barter, or attempt to sell, trade, or barter, a spiny lobster harvested in the EEZ other than off Florida or for a person to be exempt from the daily bag and possession limit specified in § 640.23(b)(1) for such spiny lobster, a Federal vessel permit must be issued to the harvesting vessel and must be on board. However, see paragraph (a)(1)(i) of this section for the licenses and certificates required for a person to possess or land spiny lobster harvested in the EEZ other than off Florida and subsequently possessed in the EEZ off Florida or landed from a fishing vessel in Florida.

* * * * *

4. In § 640.6, in paragraph (c), the word “Secretary” is revised to read “Assistant Administrator” and paragraph (a) is revised to read as follows:

§ 640.6 Vessel and gear identification.

(a) *EEZ off Florida.* (1) An owner or operator of a vessel that is used to harvest spiny lobsters by traps in the EEZ off Florida must comply with the vessel and gear identification

requirements applicable to the harvesting of spiny lobsters by traps in Florida’s waters in Sections 370.14 and 370.142, Florida Statutes, in effect as of July 1, 1994, and in Rule 46–24.006(3), (4), and (5), Florida Administrative Code, in effect as of June 1, 1994.

(2) An owner or operator of a vessel that is used to harvest spiny lobsters by diving in the EEZ off Florida must comply with the vessel identification requirements applicable to the harvesting of spiny lobsters by diving in Florida’s waters in Rule 46–24.006(6), Florida Administrative Code, in effect as of June 1, 1994.

(3) The incorporation by reference in paragraphs (a)(1) and (a)(2) of this section of Sections 370.14 and 370.142, Florida Statutes, and Rule 46–24.006(3), (4), (5), and (6), Florida Administrative Code, has been submitted to the Director of the Office of the Federal Register for approval in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from the Florida Marine Fisheries Commission, 2540 Executive Center Circle West, Suite 106, Tallahassee, FL 32301; telephone: 904–487–0554. Copies may be inspected at the Office of the Regional Director; the Office of Fisheries Conservation and Management, NMFS, 1315 East-West Highway, Silver Spring, MD 20910; or the Office of the Federal Register, 800 North Capitol Street, NW, Suite 700, Washington, DC.

* * * * *

§ 640.7 [Amended]

5. In § 640.7, in paragraph (e), the reference to “§ 640.20 (c)(1) and (c)(2)” is revised to read “§ 640.20(b)(3)(i) and (b)(3)(ii)”; in paragraph (f), the reference to “§ 640.20(d)” is revised to read “§ 640.20(b)(4)”; in paragraph (p), the reference to “§ 640.23(a) or (b)” is revised to read “§ 640.23(a), (b)(1), or (b)(2)” and the reference to “§ 640.23(c) and (d)” is revised to read “§ 640.23(b)(3) and (b)(4)”; in paragraph (q), the reference to “§ 640.23(d)” is revised to read “§ 640.23(b)(4)”; in paragraph (r), the reference to “§ 640.23(g)” is revised to read “§ 640.23(d)”; and in paragraph (s), the reference to “§ 640.23(h)” is revised to read “§ 640.23(e)”.

6. Section 640.20 is revised to read as follows:

§ 640.20 Seasons.

(a) *EEZ off the southern Atlantic states, other than Florida.* In the EEZ off the southern Atlantic states, other than Florida, there are no seasonal restrictions on the harvest of spiny lobster or on the possession of traps.

(b) *EEZ off Florida and off the Gulf states, other than Florida.*

(1) *Commercial and recreational fishing season.* The commercial and recreational fishing season for spiny lobster in the EEZ off Florida and the EEZ off the Gulf states, other than Florida, begins on August 6 and ends on March 31.

(2) *Special recreational fishing seasons.*

(i) *EEZ off Florida.* There is a 2-day special recreational fishing season in the EEZ off Florida on the last Wednesday and successive Thursday of July each year during which fishing for spiny lobster is limited to diving or use of a bully net or hoop net. (See § 640.22(a) for general prohibitions on gear and methods.) In the EEZ off Monroe County, Florida, no person may harvest spiny lobster by diving at night, that is, from 1 hour after official sunset to 1 hour before official sunrise, during this 2-day special recreational fishing season.

(ii) *EEZ off the Gulf states, other than Florida.* There is a 2-day special recreational fishing season in the EEZ off the Gulf states, other than Florida, during the last Saturday and successive Sunday of July each year during which fishing for spiny lobster may be conducted by authorized gear and methods other than traps. (See § 640.22(a) for general prohibitions on gear and methods.)

(3) *Possession of traps.*

(i) In the EEZ off Florida, the rules and regulations applicable to the possession of spiny lobster traps in Florida's waters in Rule 46-24.005(3), (4), and (5), Florida Administrative Code, in effect as of June 1, 1994, apply in their entirety to the possession of spiny lobster traps in the EEZ off Florida. This incorporation by reference has been submitted to the Director of the Office of the Federal Register for approval in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from the Florida Marine Fisheries Commission, 2540 Executive Center Circle West, Suite 106, Tallahassee, FL 32301; telephone: 904-487-0554. Copies may be inspected at the Office of the Regional Director; the Office of Fisheries Conservation and Management, NMFS, 1315 East-West Highway, Silver Spring, MD 20910; or the Office of the Federal Register, 800 North Capitol Street, NW, Suite 700, Washington, DC.

(ii) In the EEZ off the Gulf states, other than Florida, a spiny lobster trap may be placed in the water prior to the commercial and recreational fishing season specified in paragraph (b)(1) of this section beginning on August 1 and

must be removed from the water after such season not later than April 5.

(iii) A spiny lobster trap, buoy, or rope in the EEZ off Florida or the EEZ off the Gulf states, other than Florida, during periods not authorized in paragraphs (b)(3)(i) and (b)(3)(ii) of this section will be considered unclaimed or abandoned property and may be disposed of in any manner considered appropriate by the Assistant Administrator or an authorized officer. An owner of such trap, buoy, or rope remains subject to appropriate civil penalties.

(4) *Possession of spiny lobsters.* A spiny lobster or part thereof in or from the EEZ off Florida or the EEZ off the Gulf states, other than Florida, may be possessed only during the periods specified in paragraphs (b)(1) and (b)(2) of this section, unless accompanied by proof of lawful harvest in the waters of a foreign nation. A spiny lobster in a trap in the water during a time such trap is authorized to be in the EEZ off Florida or the EEZ off the Gulf states, other than Florida, under paragraph (b)(3)(i) or (b)(3)(ii) of this section will not be deemed to be possessed provided such spiny lobster is returned immediately to the water unharmed when a trap is removed from the water during such time.

(c) *Primacy of seasonal restrictions in the EEZ off Florida.* The seasonal restrictions on possession of a spiny lobster or trap in the EEZ off Florida apply to all spiny lobsters and traps, including spiny lobsters that may have been lawfully harvested from or traps that may have been lawfully used in the EEZ other than off Florida.

7. In § 640.22, a sentence is added to the end of paragraph (a)(1) and paragraph (b)(3)(i) is revised to read as follows:

§ 640.22 Gear and diving restrictions.

(a) * * *

(1) * * * Hook, as used in this paragraph (a)(1), does not include a hook in a hook-and-line fishery for species other than spiny lobster; and possession of a spiny lobster that has been speared, pierced, or punctured by such hook is not considered evidence that prohibited gear was used to take the spiny lobster, provided no prohibited gear is on board the vessel.

* * * * *

(b) * * *

(3) * * *

(i) For traps in the EEZ off Florida, by the Florida Division of Law Enforcement, Department of Environmental Protection, in accordance with the procedures in Rule 46-24.006(7), Florida Administrative

Code, in effect as of June 1, 1994. This incorporation by reference has been submitted to the Director of the Office of the Federal Register for approval in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from the Florida Marine Fisheries Commission, 2540 Executive Center Circle West, Suite 106, Tallahassee, FL 32301; telephone: 904-487-0554. Copies may be inspected at the Office of the Regional Director; the Office of Fisheries Conservation and Management, NMFS, 1315 East-West Highway, Silver Spring, MD 20910; or the Office of the Federal Register, 800 North Capitol Street, NW, Suite 700, Washington, DC.

* * * * *

8. Section 640.23 is revised to read as follows:

§ 640.23 Bag/possession limits.

(a) *EEZ off the southern Atlantic states, other than Florida.* The daily bag or possession limit for spiny lobster in or from the EEZ off the southern Atlantic states, other than Florida, is two per person for commercial and recreational fishing, year-round.

(b) *EEZ off Florida and off the Gulf states, other than Florida.*

(1) *Commercial and recreational fishing season.* Except as specified in paragraphs (b)(3) and (b)(4) of this section, during the commercial and recreational fishing season specified in § 640.20(b)(1), the daily bag or possession limit of spiny lobster in or from the EEZ off Florida and off the Gulf states, other than Florida, is six per person.

(2) *Special recreational fishing seasons.* During the special recreational fishing seasons specified in § 640.20(b)(2), the daily bag or possession limit of spiny lobster—

(i) In or from the EEZ off the Gulf states, other than Florida, is six per person;

(ii) In or from the EEZ off Florida other than off Monroe County, Florida, is twelve per person; and

(iii) In or from the EEZ off Monroe County, Florida, is six per person.

(3) *Exemption from the bag/possession limit.* During the commercial and recreational fishing season specified in § 640.20(b)(1), a person is exempt from the bag and possession limit specified in paragraph (a) of this section, provided—

(i) The harvest of spiny lobsters is by diving, or by the use of a bully net, hoop net, or spiny lobster trap; and

(ii) The vessel from which the person is operating has on board the required licenses, certificates, or permits, as specified in § 640.4(a)(1).

(4) *Harvest by net or trawl.* During the commercial and recreational fishing season specified in § 640.20(b)(1), aboard a vessel with the required licenses, certificates, or permits specified in § 640.4(a)(1) that harvests spiny lobster by net or trawl or has on board a net or trawl, the possession of spiny lobster in or from the EEZ off Florida and off the Gulf states, other than Florida, may not exceed at any time 5 percent, whole weight, of the total whole weight of all fish lawfully in possession on board such vessel. If such vessel lawfully possesses a separated spiny lobster tail, the possession of spiny lobster in or from the EEZ may not exceed at any time 1.6 percent, by weight of the spiny lobster or parts thereof, of the total whole weight of all fish lawfully in possession on board such vessel. For the purposes of this paragraph (b)(4), the term “net or trawl” does not include a hand-held net, a

loading or dip net, a bully net, or a hoop net.

(5) *Diving at night.* The provisions of paragraph (b)(3) of this section notwithstanding, a person who harvests spiny lobster in the EEZ by diving at night, that is, from 1 hour after official sunset to 1 hour before official sunrise, is limited to the bag limit specified in paragraph (b)(1) of this section, whether or not a Federal vessel permit specified in § 640.4(a)(1) has been issued to and is on board the vessel from which the diver is operating.

(c) *Combination of bag/possession limits.* A person who fishes for or possesses spiny lobster in or from the EEZ under a bag or possession limit specified in paragraph (a) or (b) of this section may not combine the bag or possession limits of those paragraphs or combine such bag or possession limit with a bag or possession limit applicable to state waters.

(d) *Responsibility for bag/possession limits.* The operator of a vessel that fishes for or possesses spiny lobster in or from the EEZ is responsible for the cumulative bag or possession limit specified in paragraphs (a) and (b) of this section applicable to that vessel, based on the number of persons aboard.

(e) *Transfer at sea.* A person who fishes for or possesses spiny lobster in or from the EEZ under a bag or possession limit specified in paragraph (a) or (b) of this section may not transfer a spiny lobster at sea from a fishing vessel to any other vessel, and no person may receive at sea such spiny lobster.

§ 640.24 [Amended]

9. In § 640.24, the word “Secretary” is revised to read “Assistant Administrator”.

[FR Doc. 95–10737 Filed 4–27–95; 3:57 pm]

BILLING CODE 3510–22–F

Notices

Federal Register

Vol. 60, No. 84

Tuesday, May 2, 1995

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.

ARCHITECTURAL AND TRANSPORTATION BARRIERS COMPLIANCE BOARD

Meeting

AGENCY: Architectural and Transportation Barriers Compliance Board.

ACTION: Notice of meeting.

SUMMARY: The Architectural and Transportation Barriers Compliance Board (Access Board) has scheduled its regular business meetings to take place in Arlington, VA on Thursday and Friday, May 11–12, 1995 at the times and location noted below.

DATES: The schedule of events is as follows:

Thursday, May 11, 1995

9:00–12 Noon Vision Statement Work Group (closed meeting)
1:00–5:30 p.m. Rulemaking Priorities and Strategy Work Group (closed meeting)

Friday, May 12, 1995

9:00–10:30 p.m. Detectable Warnings Petitions Work Group (closed meeting)
10:30–12 Noon Planning and Budget Committee Meeting
1:30–3:30 p.m. Board Meeting

ADDRESSES: The meetings will be held at: Crystal Gateway Marriott, 1700 Jefferson Davis Highway, Arlington, Virginia.

FOR FURTHER INFORMATION CONTACT: For further information regarding the meetings, please contact Lawrence W. Roffee, Executive Director, (202) 272–5434 ext. 14 (voice) and (202) 272–5449 (TTY).

SUPPLEMENTARY INFORMATION: At the Board meeting, the Access Board will consider the following agenda items:

- Oath of Office by New Board Member.
- Recognition of Outgoing Board Members.

- Approval of the Minutes of the January 18, 1995 Board Meeting.
- Executive Director's Report.
- Report on Vision Statement Work Group.
- Report on Rulemaking Priorities and Strategy Work Group.
- Report on Detectable Warnings Petitions Work Group.
- Report on Fiscal Year 1995 Budget.
- Report on Reprogramming the Fiscal Year 1995 Budget.
- Report on Fiscal Year 1996 Budget.

Some meetings or items may be closed to the public as indicated above. All meetings are accessible to persons with disabilities. Sign language interpreters and an assistive listening system are available at all meetings.

Lawrence W. Roffee,

Executive Director.

[FR Doc. 95–10780 Filed 5–1–95; 8:45 am]

BILLING CODE 8150–01–M

DEPARTMENT OF COMMERCE

Bureau of the Census

Census Advisory Committee (CAC) on the American Indian and Alaska Native Populations, the CAC on the Asian and Pacific Islander Populations, the CAC on the African American Population, and the CAC on the Hispanic Population; Public Meeting

Pursuant to the Federal Advisory Committee Act (Pub. L. 92–463 as amended by Pub. L. 94–409), we are giving notice of a joint meeting followed by separate and jointly held (described below) meetings of the CAC on the American Indian and Alaska Native Populations, the CAC on the Asian and Pacific Islander Populations, the CAC on the African American Population, and the CAC on the Hispanic Population. The joint meeting will convene on May 11–12, 1995 at the Bureau of the Census in the Conference Center, Room 1630, Federal Building 3, Suitland, Maryland 20233.

Each of these Committees is composed of nine members appointed by the Secretary of Commerce. They provide an organized and continuing channel of communication between the communities they represent and the Bureau of the Census on its efforts to reduce the differential undercount in the 2000 census and on ways the census data can be disseminated to maximum

usefulness to their communities and other users.

The Committees will draw on past experience with the 1990 census process and procedures, results of evaluations and research studies, and the expertise and insight of their members to provide advice and recommendations during the research and development phase on various topics, and provide advice and recommendations during the design planning and implementation phases of the 2000 census.

The agenda for the May 11 combined meeting is: (1) Introductory remarks by the Director, Bureau of the Census; (2) reengineered 2000 census; (3) 1995 Census Test update; (4) outreach and promotion; and (5) issues on race and ethnicity.

The agendas for the four committees in their separate and jointly held meetings are as follows:

The CAC on the African American Population: (1) Outreach and promotion; (2) issues on race and ethnicity; and (3) review of responses to committee recommendations.

The CAC on the American Indian and Alaska Native Populations: (1) Outreach and promotion; (2) issues on race and ethnicity; (3) review of responses to committee recommendations; (4) plans for the 2000 census geography; (5) plans for the 1996 reservation site test; and (6) discussion of agenda items for fall meeting.

The CAC on the Asian and Pacific Islander Populations: (1) Outreach and promotion; (2) issues on race and ethnicity; and (3) review of responses to committee recommendations.

The CAC on the Hispanic Population: (1) outreach and promotion; (2) issues on race and ethnicity; and (3) review of responses to committee recommendations.

The agenda for the May 12 combined meeting is: (1) Format of advisory meeting; (2) electronic release of data and innovations in development of data products; and (3) sampling and estimation.

The agendas for the four committees in their separate and jointly held meetings are:

The CAC on the African American Population: (1) Review of plenary session topics; (2) discussion of agenda items for next meeting; and (3) development and discussion of recommendations.

The CAC on the American Indian and Alaska Native Populations: (1) Review of plenary session topics; (2) discussion of agenda items for next meeting; (3) survey of American Indian and Alaska Native government administrative records; and (4) development and discussion of recommendations.

The CAC on the Asian and Pacific Islander Populations: (1) Review of plenary session topics; (2) discussion of agenda items for next meeting; and (3) development and discussion of recommendations.

The CAC on the Hispanic Population: (1) Review of plenary session topics; (2) discussion of agenda items for next meeting; and (3) development and discussion of recommendations.

All meetings are open to the public and a brief period is set aside on May 12 for public comment and questions. Those persons with extensive questions or statements must submit them in writing to the Census Bureau official named below at least three days before the meeting.

These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should also be directed to the Census Bureau official named below.

Persons wishing additional information regarding these meetings or who wish to submit written statements may contact Ms. Diana Harley, Decennial Management Division, Bureau of the Census, Room 3587, Federal Building 3, Suitland, Maryland. (Mailing address: Washington, DC 20233-7100). Telephone: (301) 457-4047—TDD (301) 457-2540.

Dated: April 25, 1995.

Martha Farnsworth Riche,

Director, Bureau of the Census.

[FR Doc. 95-10787 Filed 5-1-95; 8:45 am]

BILLING CODE 3510-07-P

International Trade Administration

[A-588-703]

Certain Internal-Combustion Industrial Forklift Trucks From Japan; Amendment to Final Results of Antidumping Duty Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

ACTION: Notice of amendment to final results of antidumping duty administrative review.

SUMMARY: On January 28, 1992, the Department of Commerce (the

Department) published in the **Federal Register** the final results of its 1987-89 administrative review of the antidumping duty order on certain internal-combustion industrial forklift trucks from Japan. The review covered four manufacturers/exporters of this merchandise to the United States during the period November 24, 1987, through May 31, 1989. Based on the correction of a ministerial error, we are amending the final results with respect to Mitsubishi Heavy Industries, Limited (Mitsubishi).

EFFECTIVE DATE: May 2, 1995.

FOR FURTHER INFORMATION CONTACT: Davina Friedmann or Michael Rill, Office of Antidumping Compliance, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, N.W., Washington, D.C. 20230, telephone: (202) 482-4733.

SUPPLEMENTARY INFORMATION:

Background

On January 28, 1992, the Department published in the **Federal Register** the final results of its 1987-89 administrative review of the antidumping duty order (June 7, 1988, 53 FR 20882) on certain internal-combustion industrial forklift trucks from Japan (57 FR 3167). The review covered four manufacturers/exporters of this merchandise to the United States during the period November 24, 1987 through May 31, 1989.

It has come to our attention that, in those final results, the Department inadvertently made a typographical error in publishing the margin, based on the best information available (BIA), as 39.15 percent for Mitsubishi. As stated in those final results, the Department intended to assign the "All Others" rate from the investigation. That "All Others" rate was 39.45 percent. The Department is now correcting Mitsubishi's margin to 39.45 percent from the incorrect figure of 39.15 percent.

The Court of International Trade in *Mitsubishi Heavy Industries v. United States*, Slip Op. 93-182 (September 15, 1993), affirmed the Department's application of the "All Others" rate from the investigation as BIA for Mitsubishi.

Amended Final Results of Review

As a result of our correction of a ministerial error, we have determined the following percentage weighted-average margin to exist for the period November 24, 1987 through May 31, 1989:

Manufacturer/Exporter	Margin percent
Mitsubishi	39.45

The Department shall determine, and the Customs Service shall assess, antidumping duties on all appropriate entries. Individual differences between United States price and foreign market value may vary from the percentage stated above. The Department will issue appraisal instructions on each exporter directly to the Customs Service.

Furthermore, a cash deposit of 39.45 percent will be required for all shipments by Mitsubishi of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the date of publication of these amended final results of administrative review, as provided by section 751(a)(1) of the Tariff Act of 1930.

This deposit requirement shall remain in effect until publication of the final results of the next administrative review.

This notice also serves as a reminder to importers of their responsibility under 19 CFR 353.26 to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

This notice is published in accordance with section 751(f) of the Tariff Act of 1930, as amended (19 U.S.C. 1675(f)) and 19 CFR 353.28(c).

Dated: April 19, 1995.

Susan G. Esserman,

Assistant Secretary for Import Administration.

[FR Doc. 95-10781 Filed 5-1-95; 8:45 am]

BILLING CODE 3510-DS-P

A-427-030

Large Power Transformers From France; Preliminary Results of Antidumping Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

ACTION: Notice of preliminary results of the antidumping duty administrative review; large power transformers from France.

SUMMARY: The Department of Commerce (the Department) is conducting an administrative review of the antidumping duty finding on large

power transformers (LPTs) from France in response to a request by respondent, Jeumont Schneider Transformateurs (JST). This review covers shipments of this merchandise to the United States during the period June 1, 1993 through May 31, 1994.

We have preliminarily determined that sales have been made below the foreign market value (FMV). If these preliminary results are adopted in our final results, we will instruct U.S. Customs to assess antidumping duties equal to the differences between the United States price (USP) and FMV. We have preliminarily found a dumping margin of 1.50 percent for JST.

Interested parties are invited to comment on these preliminary results.

EFFECTIVE DATE: May 2, 1995.

FOR FURTHER INFORMATION CONTACT:

Donald Little, Elisabeth Urfer, or Maureen Flannery, Office of Antidumping Compliance, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, N.W., Washington D.C. 20230; telephone (202) 482-4733.

SUPPLEMENTARY INFORMATION:

Background

The Treasury Department published in the **Federal Register** an antidumping finding on LPTs from France on June 14, 1972 (37 FR 11772). On June 7, 1994, we published in the **Federal Register** (59 FR 29411) a notice of opportunity to request an administrative review of the antidumping finding on LPTs from France covering the period June 1, 1993 through May 31, 1994.

In accordance with 19 CFR 353.22(a), JST requested that we conduct an administrative review of its sales. We published a notice of initiation of this antidumping duty administrative review on July 15, 1994 (59 FR 36160). The Department is conducting this administrative review in accordance with section 751 of the Tariff Act of 1930, as amended (the Act).

Scope of Review

Imports covered by the review are shipments of LPTs; that is, all types of transformers rated 10,000 kVA (kilovolt-amperes) or above, by whatever name designated, used in the generation, transmission, distribution, and utilization of electric power. The term "transformers" includes, but is not limited to, shunt reactors, autotransformers, rectifier transformers, and power rectifier transformers. Not included are combination units, commonly known as rectiformers, if the entire integrated assembly is imported

in the same shipment and entered on the same entry and the assembly has been ordered and invoiced as a unit, without a separate price for the transformer portion of the assembly. This merchandise is currently classifiable under the Harmonized Tariff Schedule (HTS) item numbers 8504.22.00, 8504.23.00, 8504.34.33, 8504.40.00, and 8504.50.00. The HTS item numbers are provided for convenience and Customs purposes. The written description remains dispositive.

This review covers one manufacturer/exporter of transformers, JST, and the period June 1, 1993 through May 31, 1994.

Verification

We conducted verification of JST's questionnaire response in Lyons, France, from March 6 through March 10, 1995.

United States Price

For sales made by JST we based the USP on purchase price, in accordance with section 772(b) of the Act, because the subject merchandise was sold to unrelated purchasers in the United States prior to importation into the United States.

JST requested that we include in this review two purchase price sales that entered during the period of review (POR), and one purchase price sale which was sold during the POR, but which entered the United States after the POR. Due to the timing of this third shipment, we were unable to verify certain relevant data pertaining to this sale (see the proprietary memorandum to the file dated April 5, 1995). Therefore, we did not include this sale in our analysis for these preliminary results.

We calculated purchase price based on the delivered price to unrelated purchasers. We made deductions for ocean freight, foreign inland freight, U.S. inland freight, U.S. duty, ocean freight, and, where applicable, air freight.

Foreign Market Value

We preliminarily determine that there are no home market or third country sales of comparable merchandise. Therefore, in accordance with section 773(a)(2) of the Act, we used constructed value (CV) to calculate FMV for JST.

CV consists of the cost of materials, labor, fabrication, general expenses, profit, and packing. We used: (1) Actual general expenses or the statutory minimum of 10 percent of materials and fabrication, whichever was greater; (2)

actual profit or the statutory minimum of 8 percent of materials and fabrication costs and general expenses, whichever was greater; and (3) packing costs for merchandise exported to the United States. We made a circumstance-of-sale adjustment by deducting from CV home market direct selling expenses, *i.e.*, warranties and commissions, and adding to CV U.S. direct selling expenses, *i.e.*, commissions, selling expenses, and credit. No other adjustments were claimed or allowed.

Preliminary Results of the Review

We preliminarily determine that the following dumping margin exists:

Manufacturer/Exporter	Time period	Margin (percent)
Jeumont Schneider Transformateurs.	6/1/93-5/31/94	1.50

Parties to the proceeding may request disclosure within 5 days of the date of publication of this notice. Any interested party may request a hearing within 10 days of publication. Any hearing, if requested, will be held 44 days after the publication of this notice, or the first workday thereafter. Interested parties may submit case briefs within 30 days of the date of publication of this notice. Rebuttal briefs, which must be limited to issues raised in the case briefs, may be filed not later than 37 days after the date of publication. The Department will publish a notice of final results of this administrative review, which will include the results of its analysis of issues raised in any such comments.

The Department shall determine, and the Customs Service shall assess, antidumping duties on all appropriate entries. Individual differences between USP and FMV may vary from the percentage stated above. Upon completion of this review, the Department will issue appraisal instructions directly to the Customs Service.

Furthermore, the following deposit rates will be effective upon publication of the final results of these administrative reviews for all shipments of LPTs from France entered, or withdrawn from warehouse, for consumption on or after the publication date, as provided for by section 751(a)(1) of the Act: (1) The cash deposit rate for the reviewed company will be the rate established in the final results of this review; (2) for previously reviewed or investigated companies not listed above, the cash deposit rate will continue to be the company-specific rate

published for the most recent period; (3) if the exporter is not a firm covered in this review, a prior review or the original less-than-fair-value investigation, but the manufacturer is, the cash deposit rate will be the rate established for the most recent period for the manufacturer of the merchandise; and (4) for all other producers and/or exporters of this merchandise, the cash deposit rate shall be 24 percent, the rate established in the first notice of final results of administrative review published by the Department (47 FR 10268, March 10, 1982).

These deposit rates, when imposed, shall remain in effect until publication of the final results of the next administrative review.

This notice also serves as a preliminary reminder to importers of their responsibility under 19 CFR 353.26 to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

This administrative review and notice are in accordance with section 751(a)(1) of the Act (19 U.S.C. 1675(a)(1)) and 19 CFR 353.22.

Dated: April 25, 1995.

Paul L. Joffe,

Deputy Assistant Secretary for Import Administration.

[FR Doc. 95-10782 Filed 5-1-95; 8:45 am]

BILLING CODE 3510-DS-P

National Oceanic and Atmospheric Administration

[I.D. 042595C]

Endangered Species; Permits

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Issuance of modification 2 to permit 900 (P770#66), modification 1 to permit 914 (P770#67), and modification 5 to permit 795 (P503A).

SUMMARY: Notice is hereby given that NMFS has issued modifications to permits authorizing takes of listed species for the purpose of scientific research, subject to certain conditions set forth therein, to the Northwest Fisheries Science Center, NMFS (NWFSC) and the Idaho Department of Fish and Game (IDFG).

ADDRESSES: The applications and related documents are available for review in the following offices, by appointment:

Office of Protected Resources, F/PR8, NMFS, 1315 East-West Highway, Silver Spring, MD 20910-3226 (301-713-1401); and

Environmental and Technical Services Division, F/NWO3, NMFS, 525 NE Oregon Street, Portland, OR 97232-4169 (503-230-5400).

SUPPLEMENTARY INFORMATION: Notice was published on January 19, 1995 (60 FR 3844) that an application had been filed by NWFSC (P770#66) for modification 2 to permit 900 to take listed species as authorized by section 10 of the Endangered Species Act of 1973 (ESA) (16 U.S.C. 1531-1543) and the NMFS regulations governing listed fish and wildlife permits (50 CFR parts 217-222).

NWFSC requested an increase in the take of juvenile, listed, Snake River spring/summer chinook salmon (*Oncorhynchus tshawytscha*) associated with Study 3, a preliminary evaluation of the new juvenile collection, bypass, and sampling facility at McNary Dam. The increased take was requested to test an automatic system for detecting and diverting run-of-the-river fish tagged with passive integrated transponders (PIT) from the population of fish moving through the collection facility. The purpose of the automatic PIT tag detector and diversion system is to facilitate the collection of scientific information on juvenile salmonid migration while minimizing adverse impacts to the fish. Modification 2 to permit 900 was issued on April 7, 1995. The increased take is valid for 1995 only. Permit 900 expires on December 31, 1998.

Notice was published on February 9, 1995 (60 FR 7752) that an application had been filed by NWFSC (P770#67) for modification 1 to permit 914 to take listed species as authorized by the above laws and regulations.

NWFSC requested an increase in the take of juvenile, listed, naturally-produced and artificially-propagated Snake River spring/summer chinook salmon (*Oncorhynchus tshawytscha*) and juvenile, endangered, Snake River fall chinook salmon (*Oncorhynchus tshawytscha*) to assess the incidence of gas bubble disease (GBD) in selected aquatic biota of the Columbia River Basin during episodes of high spill volumes at Ice Harbor Dam on the Snake River and Bonneville Dam on the Columbia River in the Pacific Northwest. NWFSC also requested authorization to take juvenile,

endangered, Snake River sockeye salmon (*Oncorhynchus nerka*) for a new study to compare the prevalence of signs of GBD in juvenile salmonids collected from the reservoir and tailrace of Ice Harbor Dam on the Snake River and the reservoir of McNary Dam on the Columbia River with the prevalence of signs of GBD in fish examined by Fish Passage Center Smolt Monitoring Program personnel at the same two dams. Modification 1 to permit 914 was issued on April 14, 1995. The increased take is valid for 1995 only. Permit 914 expires on December 31, 1998.

Notice was published on January 19, 1995 (60 FR 3844) that an application had been filed by IDFG (P503A) for modification 5 to permit 795 to take listed species as authorized by the above laws and regulations.

Permit 795 authorizes a take of listed species associated with scientific research and enhancement activities, including a captive broodstock program, on endangered Snake River sockeye salmon (*Oncorhynchus nerka*). For modification 5, IDFG requested authorization to: (1) Release second generation progeny of anadromous sockeye salmon that returned to Redfish Lake in 1991, (2) release progeny of 1991 outmigrant sockeye females spawned in 1993 with anadromous sockeye males, (3) release broodyear 1993 progeny of anadromous sockeye females that returned to Redfish Lake in 1993, and (4) increase the annual number of outmigrant sockeye juveniles to be trapped and handled at the Redfish Lake Creek weir. Modification 5 to permit 795 was issued on April 19, 1995. Activities 1-3 are valid for 1995 only. Activity 4 is valid for the duration of the permit. Permit 795 expires on July 31, 1997.

Issuance of these modifications, as required by the ESA, was based on a finding that such modifications: (1) Were applied for in good faith, (2) will not operate to the disadvantage of the listed species that are the subject of the permits, and (3) are consistent with the purposes and policies set forth in section 2 of the ESA and the NMFS regulations governing listed species permits.

Dated: April 26, 1995.

Russell J. Bellmer,

Chief, Endangered Species Division, National Marine Fisheries Service.

[FR Doc. 95-10740 Filed 5-1-95; 8:45 am]

BILLING CODE 3510-22-F

[I.D. 042595B]

Endangered Species; Permits

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Issuance of permits 946 (P770#68), 947 (P504F), 948 (P563A), 949 (P45Q), and 950 (P45R).

SUMMARY: Notice is hereby given that NMFS has issued permits authorizing takes of listed species for the purpose of scientific research, subject to certain conditions set forth therein, to the Northwest Fisheries Science Center, NMFS (NWFSC), the Northern Wasco County People's Utility District (NWCPUD), the U.S. Army Corps of Engineers, Department of Defense (Corps), the National Biological Survey (NBS), and the Oregon Cooperative Fishery Research Unit, National Biological Survey (OCFRU).

ADDRESSES: The applications and related documents are available for review in the following offices, by appointment:

Office of Protected Resources, F/PR8, NMFS, 1315 East-West Highway, Silver Spring, MD 20910-3226 (301-713-1401); and

Environmental and Technical Services Division, F/NWO3, NMFS, 525 NE Oregon Street, Portland, OR 97232-4169 (503-230-5400).

SUPPLEMENTARY INFORMATION: Notice was published on January 19, 1995 (60 FR 3844) that an application had been filed by NWFSC (P770#68) for a permit to take listed species as authorized by section 10 of the Endangered Species Act of 1973 (ESA) (16 U.S.C. 1531-1543) and the NMFS regulations governing listed fish and wildlife permits (50 CFR parts 217-222).

NWFSC requested a take of the following listed species while conducting six studies: Adult and juvenile Snake River spring/summer chinook salmon (*Oncorhynchus tshawytscha*), juvenile Snake River fall chinook salmon (*Oncorhynchus tshawytscha*), and juvenile Snake River sockeye salmon (*Oncorhynchus nerka*). The objective of Study 1 is to compare the survival to adulthood of spring/summer chinook salmon smolts transported from either Lower Granite or Little Goose Dam on the Snake River to below Bonneville Dam on the Columbia River with the survival to adulthood of smolts migrating volitionally through six or seven dams and reservoirs under prevailing river conditions. The objective of Study 2 is to assess the migration timing and

relative survival of transported and inriver juvenile chinook salmon migrating volitionally from Bonneville Dam to the mouth of the Columbia River. The objective of Studies 3-6 is to determine the effectiveness of fish guidance devices and other bypass system components being considered for installation at four Snake and Columbia River hydroelectric dams for the purpose of improving anadromous fish passage past these dams during juvenile outmigration. Permit 946 was issued to NWFSC on April 7, 1995. Study 1 will take place during 3 of the next 5 years, Study 2 will take place for a duration of 5 years, and Studies 3-6 will take place in 1995 only.

Notice was published on January 30, 1995 (60 FR 5624) that an application had been filed by the Corps (P504F) for a permit to take listed species as authorized by the above laws and regulations.

The Corps requested authorization to capture, tag, release, recapture, and re-release juvenile, listed, artificially-propagated spring/summer chinook salmon (*Oncorhynchus tshawytscha*) as part of a turbine passage survival study at Lower Granite Dam on the Snake River in Washington. The purpose of the research is to determine the immediate and delayed (48 to 120 hour) survival rates of run-of-the-river chinook salmon smolts passing through a turbine at the dam under different locations and operating conditions. This information will be used to: (1) Develop a turbine model study, which is part of a Corps project to minimize fish turbine passage mortality; (2) refine normal dam operations to minimize adverse effects to migrating juvenile fish; and (3) provide a baseline for turbine survival estimates needed under the changing conditions of a reservoir drawdown. Permit 947 was issued to the Corps on April 13, 1995. The duration of the study will be from April 15 to June 10 in 1995 only.

Notice was published on January 30, 1995 (60 FR 5624) that an application had been filed by NWCPUD (P563A) for a permit to take listed species as authorized by the above laws and regulations.

NWCPUD requested a take of the following listed species while conducting research: Juvenile, naturally produced and artificially-propagated, Snake River spring/summer chinook salmon (*Oncorhynchus tshawytscha*), juvenile Snake River fall chinook salmon (*Oncorhynchus tshawytscha*), and juvenile Snake River sockeye salmon (*Oncorhynchus nerka*). The objective of the annual study is to assess run-of-the-river juvenile anadromous

fish condition after passage through the screened turbine intake channel at The Dalles Dam, located on the Columbia River. Continued observation of juvenile fish passing through the screened intake channel during the smolt migration provides specific information on possible unsuitable passage conditions below the water surface which are not directly observable. Permit 948 was issued to NWCPUD on April 11, 1995. The research will take place from April to September for the next 5 years.

Notice was published on February 9, 1995 (60 FR 7752) that an application had been filed by NBS (P45Q) for a permit to take listed species as authorized by the above laws and regulations.

NBS requested authorization for a lethal take of juvenile, listed, naturally-produced Snake River spring/summer chinook salmon (*Oncorhynchus tshawytscha*) as part of a study designed to compare the physiological responses of wild chinook smolts with hatchery-produced chinook smolts when subjected to the bypass and collection facility at Lower Granite Dam on the Lower Snake River in Washington. A comparison of the physiological responses of wild and hatchery-produced chinook smolts may indicate what aspects of bypass and collection for downriver transportation past hydropower projects are most stressful to wild listed fish. Permit 949 was issued to NBS on April 13, 1995. The duration of the study is April 15 to June 30 in 1995 only.

Notice was published on March 9, 1995 (60 FR 12913) that an application had been filed by OCFRU (P45R) for a permit to take listed species as authorized by the above laws and regulations.

OCFRU requested authorization to take juvenile, listed, Snake River spring/summer and fall chinook salmon (*Oncorhynchus tshawytscha*) as part of a study designed to provide information that will be used to: (1) Recommend siting of the bypass outfall to be constructed at The Dalles Dam on the Columbia River, (2) evaluate the juvenile salmonid nighttime spill pattern at The Dalles Dam, (3) assess the relationship between flow rate and juvenile salmonid outmigration velocity in The Dalles pool and elsewhere, (4) evaluate juvenile salmonid passage routes at John Day Dam on the Columbia River, (5) estimate juvenile salmonid mortality in the lower Columbia River, and (6) provide information on the vulnerability of salmonids to predation by northern squawfish (*Ptychocheilus oregonensis*). The listed fish to be used for the research will be collected with

run-of-the-river fish and anesthetized at the John Day Handling Facility at John Day Dam by NMFS personnel under the authority of permit 822. The NMFS personnel will then provide OCFRU personnel with a representative sample made up of listed and non-listed fish. Once the fish are provided to OCFRU, they will be implanted with radio telemetry transmitters (radio tags), held for 36-48 hours in tanks supplied with circulating river water to determine tag retention and delayed mortality, released near the mouth of the John Day River, and tracked electronically to determine their fate. Permit 950 was issued to OCFRU on April 19, 1995. The duration of the study is from April 15 to July 15 in 1995 only.

Issuance of these permits, as required by the ESA, was based on a finding that such permits: (1) Were applied for in good faith, (2) will not operate to the disadvantage of the listed species which are the subject of the permits, and (3) are consistent with the purposes and policies set forth in section 2 of the ESA and the NMFS regulations governing listed species permits.

Dated: April 26, 1995.

Russell J. Bellmer,

Chief, Endangered Species Division, National Marine Fisheries Service.

[FR Doc. 95-10742 Filed 5-1-95; 8:45 am]

BILLING CODE 3510-22-F

[I.D. 042595E]

Marine Mammals and Endangered Species; Permits

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Receipt of application for a scientific research permit (P771#72).

SUMMARY: Notice is hereby given that the National Marine Mammal Laboratory, has applied in due form for a permit to take the marine mammals listed below for the purpose of scientific research.

DATES: Written comments must be received on or before June 1, 1995.

ADDRESSES: The application and related documents are available for review upon written request or by appointment in the following offices:

Permits Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13130, Silver Spring, MD 20910 (301/713-2289);

Director, Alaska Region, NMFS, P.O. Box 21668, Juneau AK 99802-1668 (907/586-7221);

Written data or views, or requests for a public hearing on this request, should be submitted to the Chief, Permits Division, F/PR1, Office of Protected Resources, Silver Spring, MD 20910, within 30 days of the publication of this notice.

FOR FURTHER INFORMATION CONTACT: Gary Barone, (301/713-2289).

SUPPLEMENTARY INFORMATION: Those individuals requesting a hearing should set forth the specific reasons why a hearing on this particular request would be appropriate.

Concurrent with the publication of this notice in the **Federal Register**, the Secretary of Commerce is forwarding copies of this application to the Marine Mammal Commission and its Committee of Scientific Advisors.

The subject permit is requested under the authority of the Marine Mammal Protection Act of 1972, as amended (16 U.S.C. 1361 *et seq.*), and the Regulations Governing the Taking and Importing of Marine Mammals (50 CFR part 216).

The applicant seeks authorization to biopsy sample 120 beluga whales (*Delphinapterus leucas*) and conduct genetic and dietary analyses on the samples over a 3-year period. In addition, the applicant seeks authorization to take by harassment up to 2,000 beluga whales incidental to the sampling. Proposed taking will be by small boat. Field work will be conducted from July, 1995 through October, 1998 in Cook Inlet, Norton Sound, Bristol Bay, Kotzebue Sound, and Beaufort Sea, on the west coast of Alaska. The results of the research will provide information on the stock boundaries.

Dated: April 20, 1995.

Ann D. Terbush,

Chief, Permits & Documentation Division, National Marine Fisheries Service.

[FR Doc. 95-10741 Filed 5-1-95; 8:45 am]

BILLING CODE 3510-22-F

Technology Administration

National Medal of Technology Nomination Evaluation Committee; Determination for Closure of Meeting

The National Medal of Technology Nomination Evaluation Committee has scheduled a meeting for May 3, 1995.

The Committee was established to assist the Department in executing its responsibilities under 15 U.S.C. 3711. Under this provision, the Secretary is responsible for recommending to the President prospective recipients of the National Medal of Technology. The Committee's recommendations are made

after reviewing all nominations received in response to a public solicitation. The Committee is chartered to have from six to twelve members, of which ten are now serving. Two additional Committee members are in the process of being appointed.

The meeting will be closed to discuss the relative merits of persons and companies nominated for the Medal. Public disclosure of this information would be likely to impair the National Medal of Technology program because premature publicity about candidates under consideration for the Medal who may or may not ultimately receive the award, would be likely to discourage nominations for the Medal.

Accordingly, I find and determine, pursuant to Section 10(d) of the Federal Advisory Committee Act, 5 U.S.C. app. 2, as amended, that the May 3, 1995, meeting may be closed to the public in accordance with Section 552b(c)(9)(B) of Title 5, United States Code because revealing information about Medal candidates would be likely to significantly frustrate implementation of a proposed agency action.

Dated: April 27, 1995.

Gloria Gutierrez,

Deputy Assistant Secretary for Administration.

Dated: April 26, 1995.

Barbara S. Fredericks,

Assistant General Counsel for Administration.

[FR Doc. 95-10783 Filed 5-1-95; 8:45 am]

BILLING CODE 3510-18-M

COMMODITY FUTURES TRADING COMMISSION

New York Cotton Exchange: Proposed Amendments Relating to the Maximum Daily Price Fluctuation and the Minimum Price Fluctuation Limits for the Cotton No. 2 Futures Contract

AGENCY: Commodity Futures Trading Commission.

ACTION: Notice of Proposed Contract Rule Change.

SUMMARY: The New York Cotton Exchange ("NYCE") has submitted proposed amendments to its cotton No. 2 futures contract that will: (1) Increase to three from two cents per pound the contract's base maximum daily price fluctuation limit (base maximum limit) for all contract months listed for trading whenever the settlement price for any one contract month equals or exceeds 95 cents per pound; (2) provide that the proposed three-cent-per-pound maximum limit may be increased to

four and one-half cents per pound under specified conditions; and (3) increase to 5/100ths from 1/100th of one cent per pound the minimum price fluctuation limit for a contract month whenever prices for that contract month equal or exceed 95 cents per pound.

In accordance with Section 5a(a)(12) of the Commodity Exchange Act and acting pursuant to the authority delegated by Commission Regulation 140.96, the Acting Director of the Division of Economic Analysis ("Division") of the Commodity Futures Trading Commission ("Commission") has determined, on behalf of the Commission, that publication of the proposed amendments is in the public interest and will assist the Commission in considering the views of interested persons.

DATES: Comments must be received on or before May 9, 1995.

ADDRESSES: Interested persons should submit their views and comments to Jean A. Webb, Secretary, Commodity Futures Trading Commission, 2033 K Street NW, Washington, DC 20581. Reference should be made to the proposed amendments relating to changes in the maximum price and the minimum price fluctuation limits for the cotton No. 2 futures contract.

FOR FURTHER INFORMATION CONTACT: Frederick V. Linse, Division of Economic Analysis, Commodity Futures Trading Commission, 2033 K Street NW, Washington, DC 20581, telephone (202) 254-7303.

SUPPLEMENTARY INFORMATION: The cotton No. 2 futures contract currently specifies a base maximum limit of 2 cents per pound above or below the previous day's settlement price. The contract's existing terms also provide that, whenever the prices for 3 or more contract months increase or decrease by the base maximum limit for 3 consecutive business days, the base maximum limit is increased to 3 cents per pound for those contract months only. The current minimum price fluctuation limit is 1/100 of one cent per pound.

As noted, the proposed amendments will provide that, whenever the daily settlement price for any single futures contract month is 95 cents per pound or higher, the base maximum limit for all contract months on the next business day will be three cents per pound. The proposed amendments also will stipulate that, if three or more contract months settle at the higher three-cent-per-pound maximum limit for three consecutive business days and the price for at least one contract month is 95 cents per pound or greater, the three-

cent maximum limit will be increased to four and one-half cents per pound for all contract months. The limit will remain at this level until (1) there are no individual-month settlement prices which are 95 cents per pound or higher, and (2) the settlement prices for no more than 2 months have increased or decreased by the three-cent limit.

In addition, the proposed amendments will specify that, whenever the prices for a contract month are 95.00 cents per pound or higher, the minimum price fluctuation for that contract month shall be 5/100ths of one cent per pound, except that straddle transactions may continue to be made at prices expressed in minimum values of 1/100th of one cent per pound.

The NYCE intends to apply the proposed amendments to all existing and newly listed contract months following Commission approval.

In support of the proposal to increase the base maximum limit when futures prices are trading at or above 95 cents per pound, the Exchange stated that:

It is the view of the [NYCE's Board of Directors] that trading at * * * levels [of 95 cents per pound] is another indication of market activity warranting the ability to trade further before the market locks limit up. During discussion, it was noted that cotton futures already have the most restrictive price limits, regular limits being about two percent of current market value and expanded limits, being approximately three percent of such values.

The Commission is requesting comments on the proposals within the specified period of time in view of the cotton market's recent heightened volatility and the consequent need for timely consideration by the Commission of the proposals. In this respect, on the vast majority of the trading days during April 1995, the settlement prices for at least one of the two nearby contract months listed for this future contract have increased or decreased by the existing two-cent-per-pound base maximum limit.

Copies of the proposed amendments will be available for inspection at the Office of the Secretariat, Commodity Futures Trading Commission, 2033 K Street NW, Washington, DC 20581. Copies of the amended terms and conditions can be obtained through the Office of the Secretariat by facsimile by telephone at (202) 254-6314.

The materials submitted by the NYCE in support of the proposed amendments may be available upon request pursuant to the Freedom of Information Act (5 U.S.C. 552) and the Commission's regulations thereunder (17 CFR Part 145 (1987)). Requests for copies of such materials should be made to the FOI,

Privacy and Sunshine Act Compliance Staff of the Office of the Secretariat at the Commission's headquarters in accordance with CFR 145.7 and 145.8.

Any person interested in submitting written data, views or arguments on the proposed amendments should send such comments to Jean A. Webb, Secretary, Commodity Futures Trading Commission, 2033 K Street NW, Washington, DC 20581 by the specified date.

Issued in Washington, DC, on April 28, 1995.

Blake Imel,

Acting Director, Division of Economic Analysis.

[FR Doc. 95-10883 Filed 5-1-95; 8:45 am]

BILLING CODE 6351-01-M

DEPARTMENT OF DEFENSE

Department of the Navy

Government-Owned Inventions; Availability for Licensing

AGENCY: Department of the Navy, Department of Defense.

ACTION: Notice of availability of inventions for licensing.

SUMMARY: The inventions listed below are assigned to the United States Government as represented by the Secretary of the Navy and are made available for licensing by the Department of the Navy.

Copies of patents cited are available from the Commissioner of Patents and Trademarks, Washington, D.C. 20231, for \$3.00 each. Requests for copies of patents must include the patent number.

Copies of patent applications cited are available from the National Technical Information Service (NTIS), Springfield, Virginia 22161 for \$6.95 each (\$10.95 outside North American Continent). Requests for copies of patent applications must include the patent application serial number. Claims are deleted from the copies of patent applications sold to avoid premature disclosure.

FOR FURTHER INFORMATION CONTACT: Mr. R. J. Erickson, Staff Patent Attorney, Office of Naval Research (Code OOC), Arlington, Virginia 22217-5660, telephone (703) 696-4001.

Patent 5,158,760: 99mTC LABELED LIPOSOMES; filed 30 May 1990; patented 27 October 1992.

Patent 5,313,266: DEMODULATORS FOR OPTICAL FIBER INTERFEROMETERS WITH (3 X 3) OUTPUTS; filed 17 August 1992; patented 17 May 1994.

- Patent 5,326,425: PREPARATION OF TERTIARYBUTYLDIMETHYL-ANTIMONY AND USE THEREOF; filed 28 January 1993; patented 5 July 1994.
- Patent 5,333,198: DIGITAL INTERFACE CIRCUIT; filed 7 May 1993, patented 26 July 1994.
- Patent 5,339,066: ENERGY-MEASURING RESISTOR BANK; filed 30 March 1993; patented 16 August 1994.
- Patent 5,339,087: WAVEFRONT SIMULATOR FOR EVALUATING RF COMMUNICATION ARRAY SIGNAL PROCESSORS; filed 23 October 1993; patented 1 August 1994.
- Patent 5,339,288; UNDERWATER SOUND SOURCE WITH REMOTE CONTROLLED ACTUATOR; filed 12 July 1993, patented 16 August 1994.
- Patent 5,350,953: DIGITALLY WEIGHTED NEURON FOR ARTIFICIAL NEURAL NETWORK; filed 28 May 1993; patented 27 September 1994.
- Patent 5,351,553: HIGH RATE FLYWHEEL TENSILE TESTING APPARATUS FOR VISCOELASTIC MATERIALS; filed 3 May 1993; patented 4 October 1994.
- Patent 5,351,623: EXPLOSIVE SIMULATOR; filed 21 June 1993; patented 4 October 1994.
- Patent 5,351,889: FLOW TRIPPED INJECTOR; filed 16 October 1991; patented 4 October 1994.
- Patent 5,352,429: DYNAMIC COMPACTION PROCESSING SYSTEM; filed 14 July 1992; patented 4 October 1994.
- Patent 5,352,760: POLYMERIZATION OF OLIGOMERIC MULTIPLE AROMATIC ETHER-CONTAINING PHTHALONITRILES; filed 18 February 1993; patented 4 October 1994.
- Patent 5,352,829: SPIRO (N,N'-DINITROE-THYLENEDIAMINO) CYCLOTRIPHOSPHAZENES; filed 2 April 1993; patented 4 October 1994.
- Patent 5,353,291: LASER SYNCHROTRON SOURCE (LSS); filed 19 February 1993; patented 4 October 1994.
- Patent 5,354,420: METHOD FOR LASER-ASSISTED ETCHING OF III-V AND II-VI SEMICONDUCTOR COMPOUNDS USING CHLOROFLUOROCARBON AMBIENTS; filed 10 April 1990; patented 11 October 1994.
- Patent 5,354,654: LYOPHILIZED LIGAND-RECEPTOR COMPLEXES FOR ASSAYS AND SENSORS; filed 16 July 1993; patented 11 October 1994.
- Patent 5,355,312: INVERSE TOMOGRAPHY BY MATCHED FIELD PROCESSING; filed 24 September 1991; patented 11 October 1994.
- Patent 5,355,325: METHODS AND APPARATUS FOR CORRELATING OBJECT MEASUREMENTS WITH OBJECT MEASUREMENT ESTIMATES; filed 24 June 1992; patented 11 October 1994.
- Patent 5,355,683: CRYOGENIC TEMPERATURE CONTROL AND TENSION/COMPRESSION ATTACHMENT STAGE FOR AN ELECTRON MICROSCOPE; filed 14 December 1993; patented 18 October 1994.
- Patent 5,356,187: RECOVERY AND DEPLOYMENT DEVICE; filed 21 June 1993; patented 18 October 1994.
- Patent 5,356,872: METHOD OF MAKING HIGH TC SUPERCONDUCTING THIN FILMS WITH FULLERENES BY EVAPORATION; filed 17 March 1994; patented 18 October 1994.
- Patent 5,356,936: PROCESS FOR PRODUCING HYDROPHILIC POLYMER MEMBRANES; filed 28 September 1993; patented 18 October 1994.
- Patent 5,357,484: METHOD AND APPARATUS FOR LOCATING AN ACOUSTIC SOURCE; filed 22 October 1993; patented 18 October 1994.
- Patent 5,357,893: SNAP LOAD SUPPRESSION SYSTEM; filed 1 October 1993; patented 25 October 1994.
- Patent 5,359,256: REGULATABLE FIELD EMITTER DEVICE AND METHOD OF PRODUCTION THEREOF; filed 30 July 1992; patented 25 October 1994.
- Patent 5,359,329: JAMMER REFERENCE TARGET MEASUREMENT SYSTEM; filed 18 March 1981; patented 25 October 1994.
- Patent 5,359,411: METHOD AND APPARATUS FOR EVALUATING THE OPTICAL SPATIAL RESPONSE CHARACTERISTICS OF OBJECTS; filed 8 June 1992; patented 25 October 1994.
- Patent 5,359,574: ELECTROMAGNETICALLY ACTIVATED COMPLAINT WAVY-WALL; filed 27 August 1993; patented 25 October 1994.
- Patent 5,359,612: HIGH REPETITION RATE, MODE LOCKED, FIGURE EIGHT LASER WITH EXTRACAVITY FEEDBACK; filed 29 September 1993; patented 25 October 1994.
- Patent 5,359,663: METHOD AND SYSTEM FOR SUPPRESSING NOISE INDUCED IN A FLUID MEDIUM BY A BODY MOVING THERETHROUGH; filed 2 September 1993; patented 25 October 1994.
- Patent 5,359,917: SIMPLIFIED REUSABLE SONOBUOY LAUNCHER; filed 28 July 1993; patented 1 November 1994.
- Patent 5,359,951: ACTIVE TURBULENCE CONTROL USING MICROELECTRODES, PERMANENT MAGNETS IN MICROGROOVES; filed 11 February 1993; patented 1 November 1994.
- Patent 5,360,235: SECRET OPTICAL MARKING; filed 14 November 1969; patented 1 November 1994.
- Patent 5,360,325: GEAR PUMP WITH REDUCED FLUID-BORNE NOISE; filed 30 September 1993; patented 1 November 1994.
- Patent 5,361,049: TRANSITION FROM DOUBLE-RIDGE WAVEGUIDE TO SUSPENDED SUBSTRATE; filed 19 April 1986; patented 1 November 1994.
- Patent 5,361,073: DETERMINATION OF JAMMER RANGE AND AZIMUTH BY USE OF A COHERENT SIDE LOBE CANCELLER SYSTEM; filed 26 June 1975; patented 1 November 1994.
- Patent 5,361,074: MAINLOBE CANCELLER SYSTEM; filed 5 May 1980; patented 1 November 1994.
- Patent 5,361,130: FIBER GRATING-BASED SENSING SYSTEM WITH INTERFEROMETRIC WAVELENGTH-SHIFT DETECTION; filed 4 November 1992; patented 1 November 1994.
- Patent 5,361,702: MECHANICAL SHIELDING FOR ELECTRIC PRIMER; filed 2 April 1993; patented 8 November 1994.
- Patent 5,361,703: INERT THERMALLY ACTIVATED BURSTER; filed 26 May 1992; patented 8 November 1994.
- Patent 5,361,710: METHOD AND APPARATUS FOR THE ACTIVE CONTROL OF A COMPACT WASTE INCINERATOR; filed 7 October 1993; patented 8 November 1994.
- Patent 5,362,098: RELEASABLE UNCONSTRAINED INFLATABLE BODY PROTECTOR; filed 11 August 1993; patented 8 November 1994.
- Patent 5,362,450: LASER CONTROLLED DECOMPOSITION OF CHLOROFLUOROCARBONS; filed 21 February 1991; patented 8 November 1994.
- Patent 5,362,580: LIGHTWEIGHT BATTERY ELECTRODE AND METHOD OF MAKING IT; filed 7 July 1993; patented 8 November 1994.
- Patent 5,362,659: METHOD FOR FABRICATING VERTICAL BIPOLAR JUNCTION TRANSISTORS IN SILICON BONDED TO AN INSULATOR; filed 25 April 1994; patented 8 November 1994.
- Patent 5,363,264: VERSATILE DIGITAL RECORDING SYSTEM FOR RECORDING HIGH RESOLUTION

- VIDEO IMAGERY; filed 7 December 1992; patented 8 November 1994.
- Patent 5,363,298: CONTROLLED RISK DECOMPRESSION METER; filed 29 April 1993; patented 8 November 1994.
- Patent 5,363,346: CONFORMING TUNING COUPLER FOR FLEXENSIONAL TRANSDUCERS; filed 7 January 1993; patented 8 November 1994.
- Patent 5,363,650: HYDRAULIC CYLINDER ASSEMBLY FOR USE IN VARIABLE EXTERNAL PRESSURE ENVIRONMENTS; filed 12 October 1993; patented 15 November 1994.
- Patent 5,363,701: MATERIAL CHARACTERIZING SYSTEM; filed 14 April 1994; patented 15 November 1994.
- Patent 5,363,798: LARGE AREA SEMICONDUCTOR WAFERS; filed 29 September 1993; patented 15 November 1994.
- Patent 5,364,434: PLASMA TREATMENT OF GLASS SURFACES TO REMOVE CARBON; filed 30 September 1992; patented 15 November 1994.
- Patent 5,364,574: METHOD OF FORMING A CORROSION-RESISTANT EMI SHIELDING GASKET BETWEEN GRAPHITE AND METAL COMPONENTS; filed 2 April 1992; patented 15 November 1994.
- Patent 5,364,816: FABRICATION METHOD FOR III-V HETEROSTRUCTURE FIELD-EFFECT TRANSISTORS; filed 29 January 1993; patented 15 November 1994.
- Patent 5,364,819: ULTRAVIOLET FARADAY ROTATOR GLASS; filed 29 April 1993; patented 15 November 1994.
- Patent 5,365,072: REPOSITIONABLE SUBSTRATE FOR MICROSCOPES; filed 30 August 1993; patented 15 November 1994.
- Patent 5,365,171: REMOVING THE EFFECTS OF ACOUSTIC RINGING AND REDUCING TEMPERATURE EFFECTS IN THE DETECTION OF EXPLOSIVES BY NQR; filed 30 November 1992; patented 15 November 1994.
- Patent 5,365,234: HIGH-RESOLUTION SIDELobe-CANCELLER AUXILIARY ANTENNAS; filed 23 March 1977; patented 15 November 1994.
- Patent 5,365,239: FIBER OPTIC FEED AND PHASED ARRAY ANTENNA; filed 6 November 1991; patented 15 November 1994.
- Patent 5,365,245: HYBRID ORTHOGONAL TRANSVERSE ELECTROMAGNETIC FED REFLECTOR ANTENNA; filed 6 May 1993; patented 15 November 1994.
- Patent 5,365,334: MICRO PHOTOREFLECTANCE SEMICONDUCTOR WAFER ANALYZER; filed 21 December 1990; patented 15 November 1994.
- Patent 5,365,338: WAVELENGTH SENSOR FOR FIBER OPTIC GYROSCOPE; filed 20 May 1991; patented 15 November 1994.
- Patent 5,365,457: IN SITU DYNAMIC MATERIAL PROPERTY MEASUREMENT SYSTEM; filed 19 October 1992; patented 15 November 1994.
- Patent 5,365,472: NON-LINEAR RESISTIVE GRID KERNEL ESTIMATOR USEFUL IN SINGLE FEATURE, TWO-CLASS PATTERN CLASSIFICATION; filed 26 November 1993; patented 15 November 1994.
- Patent 5,365,477: DYNAMIC RANDOM ACCESS MEMORY DEVICE; filed 16 June 1992; patented 15 November 1994.
- Patent 5,365,490: METHOD AND SYSTEM FOR REDUCING DRAG ON A BODY MOVING THROUGH A FLUID MEDIUM; filed 2 September 1993; patented 15 November 1994.
- Patent 5,366,198: VIBRATION ISOLATION MOUNT WITH LOCKING MEANS; filed 29 March 1993; patented 22 November 1994.
- Patent 5,366,254: SMART MATERIAL JOINT BAND; filed 30 December 1993; patented 22 November 1994.
- Patent 5,366,881: POLYMERIZABLE LIPIDS FOR PREPARING VESICLES THAT CONTROLLABLY RELEASE AN ENCAPSULANT; filed 23 February 1993; patented 22 November 1994.
- Patent 5,367,175: METHOD OF MEASURING LIQUID LEVEL WITH A THERMAL INTERFACE DETECTION; filed 24 November 1993; patented 22 November 1994.
- Patent 5,367,333: PASSIVE RANGE MEASUREMENT SYSTEM; filed 27 July 1992; patented 22 November 1994.
- Patent 5,367,376: PLANAR AND LINEAR FIBER OPTIC ACOUSTIC SENSORS EMBEDDED IN AN ELASTOMER MATERIAL; filed 20 August 1992; 22 November 1994.
- Patent 5,367,496: APPARATUS FOR PRODUCING IMAGES ACOUSTICALLY; filed 29 March 1993; patented 22 November 1994.
- Patent 5,367,500: TRANSDUCER STRUCTURE; filed 30 September 1992; patented 22 November 1994.
- Patent 5,367,501: DUAL-FREQUENCY SONAR SYSTEM; filed 8 January 1993; patented 22 November 1994.
- Patent 5,367,970: CONTROLLABLE CAMBER FIN; filed 22 September 1993; patented 29 November 1994.
- Patent 5,368,344: COUPLING STUD ASSEMBLY; filed 24 September 1993; patented 29 November 1994.
- Patent 5,368,914: VIBRATION-DAMPING STRUCTURAL COMPONENT; filed 3 March 1993; patented 29 November 1994.
- Patent 5,369,007: MICROASSAY ON A CARD; filed 26 August 1992; patented 29 November 1994.
- Patent 5,369,485: FIBER OPTIC ACCELEROMETER WITH CENTRALLY SUPPORTED FLEXURAL DISK; filed 9 December 1993; patented 29 November 1993.
- Patent 5,369,625: THERMOACOUSTIC SOUND GENERATOR; filed 31 May 1991; patented 29 November 1994.
- Patent 5,369,663: SPATIAL COMBINER FOR A DIGITAL VLF/LF RECEIVER; filed 5 March 1991; patented 29 November 1994.
- Patent 5,369,992: SEAWATER MAGNETOHYDRODYNAMIC TEST APPARATUS; filed 11 February 1993; patented 6 December 1994.
- Patent 5,370,033: PRESSURE BALANCED FAST OPENING FIRING SYSTEM FOR A STORED ENERGY LAUNCHING SYSTEM; filed 30 September 1993; patented 6 December 1994.
- Patent 5,370,087: LOW VIBRATION POLYMERIC COMPOSITE ENGINE; filed 28 September 1993; patented 6 December 1994.
- Patent 5,371,257: PREPARATION OF DIISOPROPYL STIBINES AND USE THEREOF; filed 30 November 1993; patented 6 December 1994.
- Patent 5,371,479: PRE-AMPLIFIER WITH MUTLI-STAGE FEEDBACK; filed 25 March 1994; patented 6 December 1994.
- Patent 5,371,504: PHASE-CODED MONOPULSE MTI; filed 6 July 1976; patented 6 December 1994.
- Patent 5,371,542: DUAL WAVEBAND SIGNAL PROCESSING SYSTEM; filed 23 June 1992; patented 6 December 1994.
- Patent 5,371,720: OPTICAL FIBER PRESSURE SENSOR FOR LIQUID LEVEL MONITORING; filed 22 February 1994; patented 6 December 1994.
- Patent 5,371,801: ENERGY ABSORPTION APPARATUS; filed 4 January 1993; patented 6 December 1994.
- Patent 5,371,814: PASSIVE MULTI-CHANNEL FIBER OPTIC ROTARY JOINT ASSEMBLY; filed 10 November 1993; patented 6 December 1994.
- Patent 5,372,069: PYRONAL TORCH; filed 9 September 1993; patented 13 December 1994.
- Patent 5,372,634: SONIC APPARATUS FOR DEGASSING LIQUIDS; filed 1

- June 1993; patented 13 December 1994.
- Patent 5,372,930: SENSOR FOR ULTRA-LOW CONCENTRATION MOLECULAR RECOGNITION; filed 16 September 1992; patented 13 December 1994.
- Patent 5,373,297: MICROWAVE REPEATER WITH BROADBAND ACTIVE AND/OR PASSIVE ISOLATION CONTROL; filed 31 December 1990; patented 13 December 1994.
- Patent 5,373,318: APPARENT SIZE PASSIVE RANGE METHOD; filed 15 July 1993; patented 13 December 1994.
- Patent 5,373,456: EXPERT SYSTEM FOR ASSESSING ACCURACY OF MODELS OF PHYSICAL PHENOMENA AND FOR SELECTING ALTERNATE MODELS IN THE PRESENCE OF NOISE; filed 2 November 1992; patented 13 December 1994.
- Patent 5,373,773: ANTI-TORPEDO STERN DEFENSE SYSTEM; filed 6 August 1981; patented 20 December 1994.
- Patent 5,374,085: LOCKING DEVICE FOR FLUID COUPLING; filed 19 February 1993; patented 20 December 1994.
- Patent 5,374,347: TRIVALENT CHROMIUM SOLUTIONS FOR SEALING ANODIZED ALUMINUM; filed 1 October 1993; patented 20 December 1994.
- Patent 5,374,414: SELF-SUPPORTING DIAMOND FILAMENTS; filed 6 June 1991; patented 20 December 1994.
- Patent 5,374,589: PROCESS OF MAKING A BISTABLE PHOTOCONDUCTIVE COMPONENT; filed 5 April 1994; patented 20 December 1994.
- Patent 5,375,502: FAST ACTING VALVE FOR PROJECTIVE LAUNCHING SYSTEMS; filed 20 December 1993; patented 27 December 1994.
- Patent 5,376,594: LOW TEMPERATURE SYNTHESIS OF $\text{YBa}_2\text{Cu}_3\text{O}_8 - \text{X}$ AND OTHER CRYSTALLINE OXIDES; filed 2 August 1993; patented 27 December 1994.
- Patent 5,376,624: JOSEPHSON BREAK JUNCTION THIN FILM DEVICE; filed 10 October 1991; patented 27 December 1994.
- Patent 5,376,859: TRANSDUCERS WITH IMPROVED SIGNAL TRANSFER; filed 25 January 1994; patented 27 December 1994.
- Patent 5,376,938: METHOD AND APPARATUS FOR MAINTAINING LINEARITY AND FREQUENCY ACCURACY OF AN FM CHIRP WAVEFORM; filed 4 April 1994; patented 27 December 1994.
- Patent 5,377,165: COMMUNICATION SYSTEM FOR SUBMARINES; filed 5 May 1994; patented 27 December 1994.
- Patent Application 08/063,227: PROGRAMMABLE MODULAR NETWORK INTERFACE; filed 17 May 1993.
- Patent Application 08/134,762: TRIVALENT CHROMIUM SOLUTIONS FOR SEALING ANODIZED ALUMINUM; filed 1 October 1993.
- Patent Application 08/169,276: LATERAL FORCE DEVICE FOR UNDERWATER TOWED ARRAY; filed 20 December 1993.
- Patent Application 08/194,434: OWN SHIP SENSOR SYSTEM SIMULATOR; filed 10 February 1994.
- Patent Application 08/215,542: ENZYME-BASED DETECTOR FOR TRACE METALS; filed 22 March 1994.
- Patent Application 08/217,511: PITCH SENSOR SYSTEM; filed 24 March 1994.
- Patent Application 08/223,346: FAULT PROTECTION CIRCUIT FOR POWER DEVICE; filed 5 April 1994.
- Patent Application 08/227,640: SEDIMENT CLASSIFICATION SYSTEM; filed 14 April 1994.
- Patent Application 08/236,823: FIBER OPTIC COUPLER; filed 2 May 1994.
- Patent Application 08/236,856: SHOCK ISOLATION METHOD AND APPARATUS; filed 2 May 1994.
- Patent Application 08/238,036: EARLY COMMIT OPTIMISTIC COMPUTER DATABASE PROTOCOL; filed 28 April 1994.
- Patent Application 08/238,045: EARLY COMMIT LOCKING COMPUTER DATABASE PROTOCOL; filed 28 April 1994.
- Patent Application 08/246,900: FIBER OPTIC PRESSURE AND/OR VIBRATION DETECTOR; filed 18 May 1994.
- Patent Application 08/247,827: COMMUNICATION WITH REENTRY VEHICLE THROUGH MODULATED PLASMA; filed 23 May 1994.
- Patent Application 08/250,768: SILOXANES WITH STRONG HYDROGEN BOND DONATING FUNCTIONALITIES; filed 27 May 1994.
- Patent Application 08/251,146: BROADBAND THERMAL OPTICAL LIMITER FOR THE PROTECTION OF EYES AND SENSORS; filed 31 May 1994.
- Patent Application 08/251,419: ANTIFOULING AND FOUL-RELEASE COATINGS; filed 31 May 1994.
- Patent Application 08/266,758: GROWING AND RELEASING DIAMONDS; filed 23 April 1994.
- Patent Application 08/266,770: POLISHING DIAMOND SURFACE; filed 23 June 1994.
- Patent Application 08/268,597: TORPEDO TUBE AND SLIDE VALVE GRATES; filed 30 June 1994.
- Patent Application 08/268,598: SUBMARINE HULL STRUCTURE PROVIDING ACOUSTICALLY ISOLATED HULL OPENINGS; filed 30 June 1994.
- Patent Application 08/269,460: TORPEDO TUBE SLIDE VALVE; filed 30 June 1994.
- Patent Application 08/274,183: COAXIAL HYBRID WIGGLER; filed 12 July 1994.
- Patent Application 08/279,037: HYDROFOIL FORCE BALANCE; filed 20 July 1994.
- Patent Application 08/280,975: UNDERWATER VORTEX SHEDDER; filed 27 July 1994.
- Patent Application 08/286,590: STABILIZING JACKET FOR A TOWED CABLE OR ANTENNA STRUCTURE; filed 8 August 1994.
- Patent Application 08/287,023: BROADBAND PRESSURE BARRIER FOR CIRCULAR WAVEGUIDE; filed 8 August 1994.
- Patent Application 08/287,026: IMPROVED BROADBAND WAVEGUIDE PRESSURE WINDOW; filed 8 August 1994.
- Patent Application 08/287,027: FIBER-OPTIC ROTARY JOINT WITH BUNDLE COLLIMATOR ASSEMBLIES; filed 8 August 1994.
- Patent Application 08/287,028: METHOD FOR MAKING FIBER-OPTIC BUNDLE COLLIMATOR ASSEMBLY; filed 8 August 1994.
- Patent Application 08/287,029: FIBER-OPTIC BUNDLE AND COLLIMATOR ASSEMBLY; filed 8 August 1994.
- Patent Application 08/301,505: LONG ROD EXTENSION SYSTEM UTILIZING SHAPE MEMORY ALLOY; filed 7 September 1994.
- Patent Application 08/304,334: SHUTTER DOOR ASSEMBLY; filed 12 September 1994.

Dated: April 21, 1995.

M. D. Schetzle,

Lt, JAGC, USNR, Alternate Federal Register Liaison Officer.

[FR Doc. 95-10746 Filed 5-1-95; 8:45 am]

BILLING CODE 3810-AE-M

DEPARTMENT OF ENERGY**Floodplain Statement of Findings for Operable Unit 2 Removal Action No. 30 at the Fernald Environmental Management Project**

AGENCY: Department of Energy (DOE).

ACTION: Floodplain statement of findings.

SUMMARY: This is to give notice of DOE's planned actions for the Fernald Environmental Management Project (FEMP), located approximately 18 miles (29 kilometers) northwest of downtown Cincinnati, Ohio. The subject of this Floodplain Statement of Findings is Operable Unit 2 Removal Action No. 30. DOE proposes to protect human health and the environment by excavating contaminated sediments and constructing a seepage collection system to prevent leaching and infiltration of contaminated sediments into the Great Miami Aquifer. Excavation and construction activities associated with implementation of this action would involve a small portion of the floodplain along Paddys Run in Hamilton County, Ohio. In accordance with Executive Order 11988 and 10 CFR 1022, DOE prepared a floodplain assessment describing the effects, alternatives and measures designed to avoid or minimize potential harm to or within the affected floodplain. The assessment found that the proposed action would have minimal temporary or long-term impacts on the floodplain.

DATES: Written comments must be received by the DOE at the following address on or before May 17, 1995.

ADDRESSES: Mail comments and/or requests for further information, including a site map, to: Mr. Wally Quaid, Acting Associate Director, Office of Safety & Assessment, U.S. Department of Energy, Fernald Area Office, P.O. Box 538705, Cincinnati, Ohio 45253-8705, Phone: (513) 648-3137, Facsimile: (513) 648-3077.

FURTHER INFORMATION: For further information on general DOE floodplain and wetland environmental review requirements, contact: Ms. Carol Borgstrom, Director, Office of NEPA Policy and Assistance, EH-42, U.S. Department of Energy, 1000 Independence Avenue, SW, Washington, D.C. 20585, Phone: (202) 586-4600 or 1-800-472-2756.

SUPPLEMENTARY INFORMATION: This Floodplain Statement of Findings for Operable Unit 2 Removal Action No. 30 at the FEMP has been prepared in accordance with Executive Order 11988, "Floodplain Management," and 10 CFR

Part 1022, "DOE Regulations for Compliance with Floodplain/Wetland Environmental Review Requirements." A Notice of Floodplain Involvement was published in the **Federal Register** (FR) on April 13, 1995 (60 FR 18805) and a Floodplain Assessment was incorporated in the Removal Action No. 30 Work Plan. DOE is proposing to protect human health and the environment by excavating contaminated sediments (in the low area in the southeast corner of the South Field) to prevent leaching of contaminated sediments into the Great Miami Aquifer, and by constructing a seepage collection system to prevent infiltration of contaminated sediments into the Great Miami Aquifer. In order to eliminate the threat of a release to Paddy's Run, limited excavation would occur in the floodplain. Direct physical impact to the floodplain would result from the operation of heavy equipment during excavation of contaminated sediments and construction of a sump/pump station and portion of a discharge line within the floodplain. Potential indirect impacts to the 100- and 500-year floodplain, as a result of removal activities involving the Inactive Flyash Pile and South Field, include surface water runoff and sedimentation loading into the floodplain. Several alternatives were considered and evaluated in making this determination, including no-action, removal of sediment/construction of a seepage interceptor system, and sediment removal/construction of a seepage collection system (i.e., the preferred alternative). Direct and indirect impacts would occur during the implementation of any action alternative considered. However, minimal or no change in flood elevations would be expected. The proposed removal action has been designed to conform to applicable Federal and State regulations, including floodplain protection standards. Before this action begins, approval would be obtained from the Federal and State agencies having jurisdiction.

DOE has determined that there is no practicable alternative to the proposed removal action and that this action has been designed to minimize harm to the 100- and 500-year floodplain of Paddys Run. Engineering controls (e.g., silt fences, straw bales) will minimize any indirect impacts such as runoff and sediment deposition to the floodplain. Backfilling activities following the Operable Unit 2 Removal Action will eliminate any long-term adverse impacts.

Issued in Miamisburg, Ohio on April 19, 1995.

George R. Gartrell,

Acting Deputy Manager, Ohio Field Office.

[FR Doc. 95-10643 Filed 5-1-95; 8:45 am]

BILLING CODE 6450-01-M

Federal Energy Regulatory Commission

[Project Nos. 10822-000 10823-000-CT]

Summit Hydropower [Upper and Lower Collinsville Projects]; Notice of Intention To Prepare an Environmental Assessment and Conduct Public Scoping Meetings

April 26, 1995.

The Federal Energy Regulatory Commission (Commission) has received applications for two original licenses for the construction and operation of the Upper Collinsville Project No. 10822; and the Lower Collinsville Project No. 10823. The projects are located on the Farmington River in Hartford County, Connecticut.

The Commission staff has determined that licensing these projects would not constitute a major federal action significantly affecting the quality of the human environment. Therefore, the staff intends to prepare an environmental assessment (EA) on the hydroelectric projects in accordance with the National Environmental Policy Act. The staff's EA will objectively consider both site specific and cumulative environmental effects of the projects and reasonable alternatives, and will include an economic, financial and engineering analysis.

A draft EA will be issued and circulated for review by all interested parties. All comments filed on the draft EA will be analyzed by the staff and considered in a final EA. The staff's conclusions and recommendations will then be presented for the consideration of the Commission in reaching its final licensing decisions.

Scoping Meetings

The Commission staff will conduct two scoping meetings. The evening scoping meeting is primarily for public input while the day-time meeting will focus on resource agency and non-governmental organization (NGO) concerns. All interested individuals, organizations, and agencies are invited to attend and assist the staff in identifying the scope of environmental issues that should be analyzed in the EA.

To help focus discussions, a preliminary scoping document outlining

subject areas to be addressed at the meeting will be distributed by mail to interested parties on the Commission mailing list. Copies of the preliminary scoping document will also be available at the scoping meetings.

The public scoping meeting which will be conducted by staff will be held at 7:30 p.m. on May 15, 1995, at the Canton Town Hall, 3rd Floor, Canton, Connecticut. The agency meeting will be held at 9:30 a.m. on May 16, 1995, at the Connecticut Department of Environmental Protection, Holcombe Conference Room, 5th Floor, 79 Elm Street, Hartford, Connecticut.

Objectives

At the scoping meetings, the staff will: (1) Summarize the environmental issues tentatively identified for analysis in the planned EA; (2) solicit from the meeting participants all available information, especially quantifiable data, on the resources at issue, (3) encourage statements from experts and the public on issues that should be analyzed in the EA, including viewpoints in opposition to, or in support of, the staff's preliminary views, (4) determine the relative depth of analysis for issues to be addressed in the EA, and (5) identify resource issues that are not important and do not require detailed analysis.

Procedures

The meetings will be recorded by a stenographer and will become part of the formal record of the Commission proceeding on the Farmington River projects under consideration. Individuals presenting statements at the meetings will be asked to sign in before the meeting starts and to clearly identify themselves for the record.

Individuals, organizations, and agencies with environmental expertise and concerns are encouraged to attend the meetings and to assist the staff in defining and clarifying the issues to be addressed in the EA.

Participants wishing to make oral comments in the public meeting are asked to keep them to five minutes to allow everyone the opportunity to speak.

Persons choosing not to speak at the meetings, but who have views on the issues, may submit written statements for inclusion in the public record at the meeting. In addition, written scoping comments may be filed with the Secretary, Federal Energy Regulatory Commission, 825 North Capitol Street NE, Washington, DC 20426. All correspondence should clearly show one or more of the following captions on the first page: Upper Collinsville Project

No. 10822-000; and Lower Collinsville Project No. 10823-000.

All those that are formally recognized by the Commission as intervenors in the Collinsville Projects' proceedings are asked to refrain from engaging the staff in discussions of the merits of the projects outside of any announced meetings.

Further, parties are reminded of the Commission's Rules of Practice and Procedures, which require parties filing documents with the Commission, to serve a copy of the document on each person whose name is on the official service list, including agents of the applicant.

For further information, please contact Julie Bernt at (202) 219-2814.

Lois D. Cashell,

Secretary.

[FR Doc. 95-10667 Filed 5-1-95; 8:45 am]

BILLING CODE 6717-01-M

[Docket Nos. RP93-187-009, RP93-62-012, and CP88-546-007]

Equitrans, Inc.; Notice of Proposed Changes in FERC Gas Tariff

April 26, 1995.

Take notice that on April 21, 1995, Equitrans, Inc. (Equitrans) tendered for filing the proposed tariff sheets classified on Appendix A in the filing.

Equitrans states that its filing is made pursuant to the Commission's April 13, 1995, Order in the referenced dockets approving its rate case settlement without modification. Equitrans states that pro forma tariff sheets were included in the January 19, 1995, settlement filing. Equitrans states that this filing is intended to implement the Order and the settlement.

The settlement covers three time periods. Equitrans states the revised tariff sheets reduce base tariff rates for the period from July 1, 1993 through August 31, 1993 (Period 1), from September 1, 1993 through February 28, 1994 (Period 2), and from March 1, 1994 forward (Period 3). Changes in the rates that took place within the refund period due to periodic adjustments in ACA and GRI charges are indicated in the Appendix A tariff sheets.

In addition, Section IV of Appendix A contains miscellaneous tariff revisions which will become effective June 1, 1995 on a prospective basis. Equitrans states that June 1, 1995 was chosen as the effective date for these tariff sheets as Equitrans anticipates that this will be the first day of the month following the effective date of the settlement.

Any person desiring to protest this application should file a protest with

the Federal Energy Regulatory Commission, 825 North Capitol Street, N.E., Washington, D.C. 20426, in accordance with Section 385.211 of the Commission's Rules and Regulations. All such protests should be filed on or before May 3, 1995. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Copies of this filing are on file with the Commission and are available for public inspection in the Public Reference Room.

Lois D. Cashell,

Secretary.

[FR Doc. 95-10668 Filed 5-1-95; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. RP95-245-000]

Koch Gateway Pipeline Co.; Notice of Proposed Changes in FERC Gas Tariff

April 26, 1995.

Take notice that on April 21, 1995, Koch Gateway Pipeline Company (KGPC) tendered for to become part of its FERC Gas Tariff Fifth Revised Volume No. 1, the following tariff sheets, to become effective May 4, 1995:

First Revised Sheet No. 3603
First Revised Sheet No. 3605
First Revised Sheet No. 3606
First Revised Sheet No. 3607
Second Revised Sheet No. 3608
First Revised Sheet No. 3609
First Revised Sheet No. 3610
First Revised Sheet No. 3611

KGPC states that the above referenced tariff sheets reflect KGPC's compliance with the Commission's Final Rule (Order No. 577) issued March 29, 1995 at Docket No. RM95-5-000. KGPC states that these tariff sheets reflect modifications to KGPC's capacity release provisions to reflect the Commission's revision of Section 284.243(h) of its Regulations.

KGPC, pursuant to Section 154.51 of the Commission's Regulations, respectfully requests waiver of the notice requirement of Section 154.22 of said Regulations to permit the tendered tariff sheets to become effective May 4, 1995 which is the date Order No. 577 will become effective.

KGPC also states that the revised tariff sheets are being served upon all its customers, State Commissions, and other interested parties.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, N.E., Washington, D.C. 20426, in accordance with Sections

385.214 and 385.211 of the Commission's regulations. All such motions or protests should be filed on or before May 3, 1995. Protests will be considered by the Commission in determining 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.

Lois D. Cashell,

Secretary.

[FR Doc. 95-10669 Filed 5-1-95; 8:45 am]

BILLING CODE 6717-01-M

[Project No. 2620 South Carolina]

Lockhart Power Co.; Notice of Intent To File an Application for a New License

April 26, 1995.

Take notice that Lockhart Power Company, the existing licensee for the Lockhart Power Project No. 2620, filed a timely notice of intent to file an application for a new license, pursuant to 18 CFR 16.6 of the Commission's Regulations. The original license for Project No. 2620 was issued effective November 21, 1963, and expires March 31, 2000.

The project is located on the Broad River in Union, Chester, York and Cherokee Counties, South Carolina. The principal works of the Lockhart Project include a concrete gravity dam, 1,300 feet long and 16 feet high, with a 862-foot-long spillway; a 300 acre reservoir at elevation 397.35 feet m.s.l.; a canal 7,497 feet in length and averaging 250 feet in width; a 1.5 mile long by passed reach; a concrete and brick powerhouse with an installed capacity of 12,300 Kw; generator leads, 2.3 KV bus, and a 50 foot tie to a transformer in the switchyard; and appurtenant facilities.

Pursuant to 18 CFR 16.7, the licensee is required henceforth to make available certain information to the public. This information is now available from the licensee at 1 River Street, Lockhart, South Carolina 29364.

Pursuant to 18 CFR 16.8, 16.9 and 16.10, each application for a new license and any competing license applications must be filed with the Commission at least 24 months prior to the expiration of the existing license. All applications for license for this project must be filed by March 31, 1998.

Lois D. Cashell,

Secretary.

[FR Doc. 95-10670 Filed 5-1-95; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. RP95-246-000]

Mississippi Valley Gas Company Complainant v. Southern Natural Gas Company Respondent; Notice of Complaint

April 26, 1995.

Take notice that on April 24, 1995, Mississippi Valley Gas Company (Mississippi Valley) filed a complaint against Southern Natural Gas Company (Southern). Mississippi Valley states that it is one of the individual Southern customers the Commission concluded in its September and December 1993, RS92-10 Restructuring Orders to be entitled to mitigation of costs unduly shifted to them due to Southern's change to Straight Fixed Variable (SFV) rate design. Mississippi Valley further states that the relationship between winter and summer maximum daily quantity (MDQ) established in Southern's Restructuring proceeding determines the effective rate paid by Mississippi Valley, and thus the rate mitigation received by Mississippi Valley.

In accordance with the terms of its firm transportation (FT) service agreement with Southern, Mississippi Valley asserts that it reduced its winter season MDQ from 42,500 to 20,000, effective November 1, 1994, and timely requested Southern's recognition of the pro rata reduction of Mississippi Valley's summer season MDQ, thereby avoiding any change in the effective rate paid for FT service.

Mississippi Valley complains that Southern has refused to permit the requested pro rata reduction of summer season MDQ. Mississippi Valley asks the Commission to confirm by order that Mississippi Valley's summer season MDQ is reduced on a monthly average level for billing purposes in the same proportion as its winter season MDQ is reduced, that is:

November 1994-March 1995: 42,500 to 20,000 Mcf/day. April-October 1994: 16,234 to an average of 7,630 Mcf/day.

Mississippi Valley states that it has served the foregoing document to the parties on the official service list compiled by the Secretary in this proceeding.

Any person desiring to be heard or to protest said complaint should file a motion to intervene or a protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, N.E., Washington, D.C. 20426, in accordance with Rules 214 and 211 of the Commission's Rules of Practice and Procedure 18 CFR 385.214, 385.211. All such motions or protests should be filed on or before May 17, 1995. 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. Answers to this complaint shall be due on or before May 17, 1995.

Lois D. Cashell,

Secretary.

[FR Doc. 95-10671 Filed 5-1-95; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. RP95-242-000]

Natural Gas Pipeline Company of America; Notice of Proposed Changes in FERC Gas Tariff

April 26, 1995.

Take notice that on April 21, 1995, Natural Gas Pipeline Company of America (Natural) tendered for filing as part of its FERC Gas Tariff, Sixth Revised Volume No. 1, First Revised Sheet Nos. 204 through 208 to be effective May 21, 1995.

Natural states that the purpose of the filing is to establish procedures for the transition to new services on Natural's system to be effective December 1, 1995.

Natural requested waiver of the Commission's Regulations to the extent necessary to permit the tariff sheets to become effective May 21, 1995.

Natural states that copies of the filing are being mailed to Natural's jurisdictional customers and interested state regulatory agencies.

Any person desiring to be heard or to protest said filing should file a motion to intervene or a protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, N.E., Washington, D.C. 20426, in accordance with Sections 385.214 and 385.211. All such motions or protests should be filed on or before May 3, 1995. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection in the Public Reference Room.

Lois D. Cashell,

Secretary.

[FR Doc. 95-10672 Filed 5-1-95; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. RP94-343-008]

NorAm Gas Transmission Co.; Notice of Filing

April 26, 1995.

Take notice that on April 21, 1995, NorAm Gas Transmission Company (NGT) tendered for filing to become part of its FERC Gas Tariff, Fourth Revised Volume No. 1, the filing following tariff sheets, to be effective February 1, 1995:

Second Sub Original Sheet No. 9
Substitute Original Sheet No. 35
Substitute Original Sheet No. 127
Substitute Original Sheet No. 215
Sub Original Sheet No. 215A
Substitute Original Sheet No. 225
Substitute Original Sheet No. 226
Substitute Original Sheet No. 236

Pursuant to the Commission's March 30, 1995, Order Accepting Tariff Sheets, Subject to Conditions, NGT is correcting a pagination error in tariff sheets filed on March 2, 1995, and is clarifying Section 5.7(c)(ii)(3) of its General Terms and Conditions to provide that a shipper may transfer an imbalance between any two zones to the extent of the lesser opposite imbalance.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, N.E., Washington, D.C. 20426, in accordance with Rule 211 of the Commission's Rules of Practice and Procedure (18 CFR 385.211). All such protests should be filed on or before May 3, 1995. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Copies of this filing are on file with the Commission and are available for public inspection in the Public Reference Room.

Lois D. Cashell,
Secretary.

[FR Doc. 95-10673 Filed 5-1-95; 8:45 am]

BILLING CODE 6717-01-M

[Project No. 2567 Wisconsin]

Northern States Power Co.; Notice of Intent To File an Application for a New License

April 26, 1995.

Take notice that Northern States Power Company, the existing licensee for the Wisconsin Hydroelectric Project No. 2567, filed a timely notice of intent to file an application for a new license, pursuant to 18 CFR 16.6 of the Commission's Regulations. The original license for Project No. 2567 was issued effective July 1, 1950 and expires June 30, 2000.

The project is located on the Chippewa River in Chippewa County, Wisconsin. The principal works of the Wisconsin Project include a dam, 6,033 feet long and 70 feet high, with five various earth sections, a concrete spillway section containing 13 automatic gates, two concrete Ambursen type sections, and a concrete intake section; a 13-mile-long reservoir with a surface area of about 7,000 acres; a concrete and brick powerhouse with an installed capacity of 36,000 Kw; a substation and transmission line connection; and appurtenant facilities.

Pursuant to 18 CFR 16.7, the licensee is required henceforth to make available certain information to the public. This information is now available from the licensee at 100 North Barstow Street, P.O. Box 8, Eau Claire, WI 54702-0008.

Pursuant to 18 CFR 16.8, 16.9 and 16.10, each application for a new license and any competing license applications must be filed with the Commission at least 24 months prior to the expiration of the existing license. All applications for license for this project must be filed by June 30, 1998.

Lois D. Cashell,
Secretary.

[FR Doc. 95-10676 Filed 5-1-95; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. RP95-161-000]

Northern Natural Gas Co.; Notice of Technical Conference

April 26, 1995.

In the Commission's order issued March 15, 1995, the Commission held that the filing in the above captioned proceeding raises issues that should be addressed in a technical conference.

Take notice that the technical conference will be held on Wednesday, May 10, 1995, at 1:00 p.m., in a room to be designated at the offices of the Federal Energy Regulatory Commission, 810 First Street, N.E., Washington D.C. 20426. All interested parties and Staff are permitted to attend.

Lois D. Cashell,
Secretary.

[FR Doc. 95-10674 Filed 5-1-95; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. RP95-185-000]

Northern Natural Gas Co.; Notice of Technical Conference

April 26, 1995.

In the Commission's order issued March 30, 1995, the Commission held that the filing in the above captioned

proceeding raises issues that should be addressed in a technical conference.

Take notice that the technical conference will be held on Wednesday, May 10, 1995, at 10:00 a.m., in a room to be designated at the offices of the Federal Energy Regulatory Commission, 810 First Street, N.E., Washington D.C. 20426. All interested parties and Staff are permitted to attend.

Lois D. Cashell,
Secretary.

[FR Doc. 95-10675 Filed 5-1-95; 8:45 am]

BILLING CODE 6717-01-M

[Project No. 1981 Wisconsin]

Oconto Electric Cooperative; Notice of Intent To File an Application for a New License

April 26, 1995.

Take notice that Oconto Electric Cooperative, the existing licensee for the Stiles Hydroelectric Project No. 1981, filed a timely notice of intent to file an application for a new license, pursuant to 18 CFR 16.6 of the Commission's Regulations. The original license for Project No. 1981 was issued effective March 1, 1950, and expires February 28, 2000.

The project is located on the Oconto River in Oconto County, Wisconsin. The principal works of the Stiles Project include a 1,860-foot-long north embankment and a 300-foot-long south embankment, 20 to 30 feet high with a top width from 8 to 18 feet; an integral concrete masonry powerhouse and tainter gate spillway structure; a reservoir with a surface area of about 600 acres and a volume of 2,300 acre-feet at elevation 623.6 feet NGVD; an installed powerhouse capacity of 1000-kW; connections to transmission facilities; and appurtenant facilities.

Pursuant to 18 CFR 16.7, the licensee is required henceforth to make available certain information to the public. This information is not available from the licensee at 7479 REA Road, Oconto Falls, WI 54154-9573.

Pursuant to 18 CFR 16.8, 16.9 and 16.10, each application for a new license and any competing license applications must be filed with the Commission at least 24 months prior to the expiration of the existing license. All applications for license for this project must be filed by February 28, 1998.

Lois D. Cashell,
Secretary.

[FR Doc. 95-10677 Filed 5-1-95; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. RP95-248-000]**Overthrust Pipeline Co.; Notice of Tariff Filing**

April 26, 1995.

Take notice that on April 24, 1995, Overthrust Pipeline Company, tendered for filing to become part two of its FERC Gas Tariff, First Revised Volume No. 1-A, First Revised Sheet Nos. 48, 49 and 49A, to be effective May 4, 1995.

Overthrust explains that these tariff sheets revise Section 8 of the General Terms and Conditions of its tariff to conform with Order No. 577 capacity release provisions.

Overthrust states that this filing complies with Order No. 577 by revising the capacity release provisions found in Section 8 of the General Terms and Conditions of Part 1 of its tariff by (1) extending to one calendar month the exception from the advance posting and bidding requirement applicable to released capacity, (2) adding tariff language to explain that shippers under this exemption that release capacity at a rate less than the maximum rate in the tariff may not re-release that capacity to the same replacement shipper at a rate less than the maximum tariff rate until 28 days after the first release period has ended and (3) adding additional tariff language so that Overthrust's tariff will comport with Commission Regulations that address bidding for pre-arranged releases for a month or less at a rate less than the maximum rate.

Overthrust states further that a copy of this filing has been served upon its jurisdictional customers as well as the Utah and Wyoming public service commissions.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, N.E., Washington, D.C. 20426, in accordance with Rules 385.211 and 385.214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). All such motions or protests should be filed on or before May 3, 1995. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,
Secretary.

[FR Doc. 95-10678 Filed 5-1-95; 8:45 am]

BILLING CODE 6717-01-M

[Project No. 1927-008]**PacifiCorp; Notice of Staff Attendance at Project Tour**

April 26, 1995.

Staff from the Federal Energy Regulatory Commission, Office of Hydropower Licensing, Division of Project Review, will be attending a May 18, 1995, tour of the North Umpqua Hydroelectric Project. The tour will be conducted by Umpqua National Forest staff, and will begin at 9:00 am at the Umpqua National Forest Supervisor's Office in Roseburg, Oregon. Those wishing to participate in the tour should contact Jim Wieman, Umpqua National Forest, at (503) 942-5591.

Lois D. Cashell,
Secretary.

[FR Doc. 95-10679 Filed 5-1-95; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. RP95-247-000]**Questar Pipeline Co; Notice of Tariff Filing**

April 26, 1995.

Take notice that on April 24, 1995, Questar Pipeline Company, tendered for filing to become part of its FERC Gas Tariff, First Revised Volume No. 1, Second Revised Sheet Nos. 59, 60 and 60A to be effective May 4, 1995.

Questar explains that these tariff sheets revise Section 6 of the General Terms and Conditions of Part 1 of its tariff to conform with Order No. 577 capacity release provisions.

Questar states that this filing complies with Order No. 577 by revising the capacity release provisions found in Section 6 of the General Terms and Conditions of Part 1 of its tariff by (1) extending to one calendar month the exception from the advance posting and bidding requirement applicable to released capacity, (2) adding tariff language to explain that shippers under this exemption that release capacity at a rate less than the maximum rate in the tariff may not re-release that capacity to the same replacement shipper at a rate less than the maximum tariff rate until 28 days after the first release period has ended and (3) adding additional tariff language so that Questar's tariff will comport with Commission Regulations that address bidding for pre-arranged releases for one calendar month or less at a rate less than the maximum rate.

Questar states further that a copy of this filing has been served upon its jurisdictional customers as well as the Utah and Wyoming public service commissions.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, N.E., Washington, DC 20426, in accordance with Rules 385.211 and 385.214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). All such motions or protests should be filed on or before May 3, 1995. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,
Secretary.

[FR Doc. 95-10680 Filed 5-1-95; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. RP95-243-000]**Southern Natural Gas Co.; Notice of Proposed Changes to FERC Gas Tariff**

April 26, 1995.

Take notice that on April 21, 1995, Southern Natural Gas Company (Southern) tendered for filing to become part of its FERC Gas Tariff, Seventh Revised Volume No. 1, the following tariff sheets, to be effective June 1, 1995, and March 1, 1995, respectively:

Effective June 1, 1995

First Revised Sheet No. 139a
First Revised Sheet No. 140

Effective March 1, 1995

Third Revised Sheet Nos. 404-407
Third Revised Sheet No. 408
Third Revised Sheet No. 410

Southern states that the purpose of this filing is to revise the calculation of the net imbalance percentage for cashing out imbalances of downstream operators who have elected to have the variance between nominations and actual deliveries at its Delivery Point (swing) allocated to its own transportation agreements. Since the allocation of the swing to the operator's agreement increases its imbalance risk, Southern has agreed to take this factor into account in the calculation of the swing operator's net imbalance percentage, as more particularly described in the filing.

Southern has requested that these sheets become effective June 1, 1995. Southern also submits updates to its Index of Purchasers and requests any waivers of the Commission's Regulations necessary to make such revised sheets effective March 1, 1995.

Southern states that copies of the filing will be served upon its shippers and interested state commissions.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR Sections 385.211 and 385.214). All such motions and protests should be filed on or before May 3, 1995. Protests will not be considered by the Commission in determining the parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 95-10682 Filed 5-1-95; 8:45 am]

BILLING CODE 6717-01-M

[Project No. 2964, Michigan]

City of Sturgis, Michigan; Notice of Intent To File an Application for a New License

April 26, 1995.

Take notice that the City of Sturgis, Michigan, the existing licensee for the Sturgis Hydroelectric Project No. 2964, filed a timely notice of intent to file an application for a new license, pursuant to 18 CFR 16.6 of the Commission's Regulations. The original license for Project No. 2964 was issued effective April 14, 1961, and expires March 31, 2000.

The project is located on the St. Joseph River in St. Joseph County, Michigan. The principal works of the Sturgis Project include a dam with a concrete section 300 feet long and 25 feet high and an earth section 500 feet long with an average height of 12.5 feet; a reservoir with a surface area of 480 acres at elevation 825.5 feet m.s.l.; two powerhouses with a total installed capacity of 2,600 kW; a 24-kV transmission substation and a 24-kV transmission line, about 18 miles long, extending to a substation in Sturgis; and appurtenant facilities.

Pursuant to 18 CFR 16.7, the licensee is required henceforth to make available certain information to the public. This information is now available from the licensee at 130 North Nottawa, Sturgis, MI 49091.

Pursuant to 18 CFR 16.8, 16.9 and 16.10, each application for a new license and any competing license applications must be filed with the

Commission at least 24 months prior to the expiration of the existing license. All applications for license for this project must be filed by March 31, 1998.

Lois D. Cashell,

Secretary.

[FR Doc. 95-10681 Filed 5-1-95; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. RP95-244-000]

Williams Natural Gas Co.; Notice of Proposed Changes in FERC Gas Tariff

April 26, 1995.

Take notice that on April 21, 1995, Williams Natural Gas Company (WNG) tendered for filing to become part of its FERC Gas Tariff, Second Revised Volume No. 1, Second Revised Sheet No. 240. The proposed effective date of these tariff sheets is May 4, 1995.

WNG states that the purpose for the instant filing is to comply with the Commission's order in Docket No. RM95-5 issued March 29, 1995. Second Revised Sheet No. 240 includes revisions to Article 11 of WNG's FERC Gas Tariff to provide that releases for a period of one month or less will be considered short term releases, and releases for more than one month are long term releases. It also provides that long term pre-arranged releases at the maximum rate will be exempted from the advance posting and bidding requirements.

WNG states that a copy of its filing was served on all 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, 825 North Capitol Street, N.E., Washington, D.C. 20426, in accordance with Sections 385.214 and 385.211 of the Commission's Rules and Regulations. All such motions or protests should be filed on or before May 3, 1995. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection in the Public Reference Room.

Lois D. Cashell,

Secretary.

[FR Doc. 95-10683 Filed 5-1-95; 8:45 am]

BILLING CODE 6717-01-M

Office of Hearings and Appeals

Notice of Issuance of Decisions and Orders During the Week of April 3 Through April 7, 1995

During the week of April 3 through April 7, 1995 the decisions and orders summarized below were issued with respect to applications for relief filed with the Office of Hearings and Appeals of the Department of Energy. The following summary also contains a list of submissions that were dismissed by the Office of Hearings and Appeals.

Personnel Security Hearing

Albuquerque Operations Office, 4/4/95, VSO-0012

An OHA Hearing Officer issued an opinion restoring the access authorization and PSAP authorization of a Respondent. The Respondent's authorizations had been suspended when it was discovered that he had once smoked marijuana. The Hearing Officer found that the Respondent's youth was a significant factor in his decision to engage in an experimental use of marijuana. In addition, the Hearing Officer found that the Respondent had shown adequate rehabilitation and growth in his sense of responsibility since the incident.

Refund Applications

Dalco Petroleum/Farmland Industries Inc., et al., 4/3/95, RF248-8 et al.

The DOE issued a Supplemental Decision and Order concerning four Applications for Refund filed by purchasers of propane from Dalco Petroleum Inc. In an earlier Decision, the applicants were granted refunds from monies collected from Dalco pursuant to the terms of a consent order with DOE. Recently, Dalco made a supplemental payment to the DOE. *Dalco Petroleum Inc./Farmland Industries Inc.*, 16 DOE ¶ 85,057 (1987). Prior to granting supplemental refunds, DOE modified the terms by which the refund proceeding is conducted by increasing the small claims injury presumption refund ceiling from \$5,000 to \$10,000. In addition, the DOE applied a medium-range injury presumption under which applicants could receive a refund of 40% of their maximum potential refund without presenting detailed evidence of injury, subject to \$50,000 ceiling. The supplemental refunds granted in this proceeding total \$672,930 (\$639,224 principal plus \$33,706 interest). The DOE also stated its intention to make all residual funds in the Dalco settlement fund available for indirect restitution pursuant to the Petroleum Overcharge Distribution and

Restitution Act of 1986 as of September 30, 1995.

Enron Corp./Austin Hydro Gas Co., et al., 4/5/95, RF340-189, RF340-195

The DOE issued a Decision and Order concerning refund applications that Austin Hydro Gas Company, Inc. (Austin) and General Development Utilities, Inc. (GDU) submitted in the Enron Corporation (Enron) special refund proceeding. The DOE found that those firms were retailers of Enron products who qualified for refunds under the 60% mid-range presumption of injury. However, the DOE found that both firms claimed gallonage purchased outside the refund period and that GDU had inadvertently overestimated its average monthly purchases by including a disproportionate number of winter months in its estimate. Accordingly, the DOE reduced the total gallonage estimates submitted by these firms. The DOE granted Austin and GDU a total refund of \$125,396.

Texaco Inc./MAPCO, Inc., 4/5/95, RR321-152, RF321-21063

The DOE issued a Decision and Order in the Texaco Inc. special refund proceeding granting a Motion for Reconsideration filed by MAPCO, Inc. (MAPCO) and rescinding a refund granted to MAPCO previously. In the Motion, MAPCO sought a refund equal to its full allocable share based on its purchases of Texaco propane. In support of its claim of injury above the medium-range presumption level, the firm submitted information showing the status of its cumulative banked propane cost at the end of the "banking" regulation period, as well as competitive disadvantage analysis for its Texaco purchases of propane. The data submitted showed that MAPCO had accumulated sufficient banks to justify a full volumetric refund, and that the firm may have experienced a substantial competitive disadvantage as a result of its Texaco purchases. Accordingly, the

Motion was granted, and MAPCO received a total refund of \$766,274 (\$526,685 principal and \$239,589 interest). However, MAPCO had previously been granted a refund in the Texaco Inc. special refund proceeding based on the medium-range presumption of injury for its Texaco propane purchases. In its Motion MAPCO chose to abandon the medium-range presumption of injury in its efforts to show injury so as to receive its full allocable share. Therefore MAPCO's prior refund of \$50,000 plus interest was rescinded.

Refund Applications

The Office of Hearings and Appeals issued the following Decisions and Orders concerning refund applications, which are not summarized. Copies of the full texts of the Decisions and Orders are available in the Public Reference Room of the Office of Hearings and Appeals.

Atlantic Richfield Company/Bowers Oil Co., Inc. et al	RF304-13611	04/07/95
Gulf Oil Corporation/James River Corporation	RF300-21352	04/07/95
Gulf Oil Corporation/Ward School Bus Manufacturing, Inc	RF300-21387	04/07/95
Monsanto Chemical Company	RF272-98770	04/05/95
Monsanto Chemical Company	RF272-98771	
Monsanto Chemical Company	RF272-98772	
Monsanto Chemical Company	RF272-98773	
Monsanto Chemical Company	RF272-98774	
Monsanto Chemical Company	RF272-98821	
Monsanto Chemical Company	RF272-98822	
Monsanto Agrucultural Company	RC272-286	
Parker Brothers & Company, Inc	RF272-77544	04/07/95
Pay-N-Save, Inc	RF272-98812	04/05/95
Shell Oil Company/St. Regis Forest Prod. Div	RF315-8235	04/05/95
Texaco Inc./Bill Boyd's Texaco et al	RF321-20871	04/03/95
Texaco Inc./Glenview Texaco	RF321-19295	04/03/95
Greenbay Pit Stop Service	RF321-19296	
Holiday Texaco	RF321-19297	
Zion Pit Stop #2 Texaco	RF321-19298	
Ravinia Texaco	RF321-19299	
Countryside Texaco	RF321-19300	
Pit Stop #3 Texaco	RF321-19301	
Tower Texaco	RF321-19302	
North Chicago Pit Stop #4	RF321-19303	
Texaco Inc./Lewis & Son Texaco	RF321-21062	04/03/95
Texaco Inc./Monte's Texaco #1	RF321-11318	04/03/95
Charles William Newell	RF321-21061	
Texaco Inc./Stewart's Texaco et al	RF321-20395	04/05/95
Texaco Inc./the Waysider et al	RF321-9371	04/03/95

Dismissals

The following submissions were dismissed:

Name	Case No.
Bamberg Texaco	RF321-8230
Better Roads Inc	RF272-90949
Bill & Bob's Texaco	RF321-19939
Bud Lord's Arco #1	RF304-14836
Bud Lord's Arco #2	RF304-14837
Burt's Texaco	RF321-12873
Central Texaco	RF321-5976
Convenience Marketing Corp	RF321-12599
Dewey County, OK	RF272-86283
Flowers Snack of Tennessee	RF272-94440
Grant's Dairy, Inc	RF272-92810
Ho Ho Kus Texaco	RF321-20811

Name	Case No.
Huntsville Utilities	RF272-78672
Lake Region Union High School	RF272-96586
Live Oak LPG	RF304-14816
Lockheed Environmental Systems & Technologies Company	VWD-0001
Mound Bayou Public Schools	RF272-88263
Redmond Sand & Gravel Co	RF272-98122
Sam Denaro's Texaco Service	RF321-20331
Santee's Arco	RF304-14809
Southside Texaco of Monroe	RF321-8134
West Park Texaco	RF321-11379
Winn-Dixie Atlanta, Inc	RF272-77493

Copies of the full text of these decisions and orders are available in the Public Reference Room of the Office of Hearings and Appeals, Room 1E-234, Forrestal Building, 1000 Independence Avenue, S.W., Washington, D.C. 20585, Monday through Friday, between the hours of 1:00 p.m. and 5:00 p.m., except federal holidays. They are also available in Energy Management: Federal Energy Guidelines, a commercially published loose leaf reporter system.

Dated: April 21, 1995.

George B. Breznay,

Director, Office of Hearings and Appeals.

[FR Doc. 95-10756 Filed 5-1-95; 8:45 am]

BILLING CODE 6450-01-P

Notice of Issuance of Decisions and Orders During the Week of February 20 Through February 24, 1995

During the week of February 20 through February 24, 1995, the decisions and orders summarized below were issued with respect to appeals and applications for other relief filed with the Office of Hearings and Appeals of the Department of Energy. The following summary also contains a list of submissions that were dismissed by the Office of Hearings and Appeals.

Appeals

David K. Hackett, 2/24/95, VFA-0021

David K. Hackett filed an Appeal from a determination issued by the Oak Ridge Operations Office (Oak Ridge) of the Department of Energy in response to a request from Mr. Hackett under the Freedom of Information Act (FOIA). Mr. Hackett sought a copy of the transcript of the deposition taken of him in the case of *Hackett v. Martin Marietta*. In denying Hackett's request, Oak Ridge stated that it did not possess the requested document. In considering the Appeal, the Office of Hearings and Appeals found that although Oak Ridge did not possess the requested transcript, it did own that document. The OHA found that since Oak Ridge owned the deposition transcript, it should have

considered whether the document should have been released. Accordingly, the matter was remanded to Oak Ridge.

J/R/A Associates, 2/23/95, VFA-0022

J/R/A Associates filed an Appeal from a determination issued to it by the Associate Deputy Secretary for Field Management of the Department of Energy (DOE) in response to a Request for Information submitted under the Freedom of Information Act (FOIA). In considering the Appeal, the DOE found that the Office of Contractor Employee Protection (OCEP) had improperly withheld the name of corporate contractors and subcontractors named in ongoing "whistleblower" investigations. OCEP had withheld this information under Exemptions 6 and 7(C), which protect personal privacy. The DOE found that corporations do not have protectable privacy interests for the purposes of these FOIA exemptions. Accordingly, the Appeal was granted in part, denied in part and remanded with instructions to either release the requested information or to issue a new determination fully explaining its reasons for continuing to withhold the information.

Refund Applications

Atlantic Richfield Co./Coast Gas, Inc., 2/23/95 RR304-63

Coast Gas, Inc. filed a Motion for Reconsideration from the dismissal of an Application for Refund that it had filed the Atlantic Richfield Company special refund proceeding. Since Coast Gas was seeking a refund in excess of \$5,000, it was required to demonstrate that it was injured by ARCO's alleged overcharges on its sales of natural gas liquids. The firm submitted evidence that it maintained banks of unrecovered product costs in excess of its refund claim and that the firm's ARCO purchases placed it at a competitive disadvantage vis-a-vis other resellers of propane and butane in its marketing area. The firm was not however, at a competitive disadvantage with respect to its purchases of ARCO natural gasoline. Accordingly, the firm was

granted a refund of its full allocable share with respect to its propane and butane purchases, and a refund equal to its above-market volumetric share with respect to its purchases of natural gasoline. The total refund issued to the firm was \$88,339 (\$49,699 in principal and \$38,640 in interest).

Texaco Inc./Cadoret Oil Company, 2/22/95 RF321-14165

The DOE issued a Decision and Order granting an Application for Refund in the Texaco Inc. special refund proceeding. Francis Cadoret filed an Application for Refund on behalf of Cadoret Oil Co., a firm he owned with his partner, Joseph Cadoret, for its purchases of Texaco petroleum products. Francis Cadoret claimed that he alone was entitled to the entire refund since he had purchased his partners share of the business. After examining the language of the relevant partnership dissolution agreement, the DOE found that the agreement had transferred Joseph Cadorets right to a refund to Francis Cadoret. Consequently, the DOE determined that Francis Cadoret was eligible to receive a refund equal to Cadoret Oil's full allocable share. Accordingly, Francis Cadoret was granted a refund of \$1,166 (\$805 principal plus \$361 interest).

Texaco Inc./27 W. Landis Texaco, Langhorne Texaco Service Station, D'ippolito Oil Company R.A. Reiff Fuels, Inc., 2/23/95 RF321-16943, RF321-16944, RF321-16950, RF321-16951

The DOE issued a Decision and Order concerning four Applications for Refund submitted by indirect purchases of Texaco products. The DOE determined that the four applicants were affiliated through varying degrees of common ownership and considered the claims together in order to determine one combined allocable share for the four firms. Further, one of the owners of R.A. Reiff Fuels, Inc. also owns 75 percent of the shares of the corporation that supplied Texaco products to R.A. Reiff Fuels, Inc. Since that supplier has

received a refund for its direct purchases of Texaco products, R.A. Reiff Fuels, Inc.'s refund attributable to the common owner was reduced by 75 percent so that he would not receive two refunds for the same gallons of

product. The total of the refunds granted to the applicants was \$12,005 (\$8,288 principal and \$3,717 interest).

Refund Applications

The Office of Hearings and Appeals issued the following Decisions and

Orders concerning refund applications, which are not summarized. Copies of the full texts of the Decisions and Orders are available in the Public Reference Room of the Office of Hearings and Appeals.

Name	Case No.	Date
Atlantic Richfield Company/R.D.P. Corporation et al	RF304-14596	02/23/95
City of Columbus et al	RF272-83003	02/22/95
Deer Trail Truckline	RC272-277	02/23/95
Deer Trail Truckline	RR272-187	
Muckleroy Cattle Co. et al	RF272-91900	02/21/95
Prins Rental et al	RF272-90188	02/22/95
Texaco Inc./Air Comfort, Inc	RF321-21058	02/21/95
Texaco Inc./Allen Texaco et al	RF321-9086	02/22/95
Texaco Inc./Pritchard's Texaco et al	RF321-17144	02/21/95
Texaco Inc./Silva's Texaco et al	RF321-20818	02/22/95

Dismissals

The following submissions were dismissed:

Name	Case No.
Arizona Chemical	RF321-20821
Schadow Texaco	RF321-12996

Copies of the full text of these decisions and orders are available in the Public Reference Room of the Office of Hearings and Appeals, Room 1E-234, Forrestal Building, 1000 Independence Avenue, S.W., Washington, D.C. 20585, Monday through Friday, between the hours of 1:00 p.m. and 5:00 p.m., except Federal holidays. They are also available in Energy Management: Federal Energy Guidelines, a commercially published loose leaf reporter system.

Dated: April 21, 1995.

George B. Breznay,

Director, Office of Hearings and Appeals.

[FR Doc. 95-10757 Filed 5-1-95; 8:45 am]

BILLING CODE 6450-01-P

Office of Hearings and Appeals

Issuance of Decisions and Orders; Week of March 20 through March 24, 1995

During the week of March 20 through March 24, 1995 the decisions and orders summarized below were issued with respect to appeals and applications for other relief filed with the Office of Hearings and Appeals of the Department of Energy. The following summary also contains a list of submissions that were dismissed by the Office of Hearings and Appeals.

Appeals

National Security Archive, 3/24/95, LFA-0297

National Security Archive filed an Appeal from a denial by the Department of Defense of a request for information that it filed under the Freedom of Information Act (FOIA). The information had been withheld by the predecessor to the DOE's Office of Declassification as classified material under Exemptions 1 and 3 of the FOIA. After considering the matter, the DOE determined that all of previously withheld material could now be released. Accordingly, the Appeal was granted.

Richard J. Levernier, 3/21/95, VFA-0025

Richard J. Levernier filed an Appeal from a determination issued by the Manager of the Department of Energy's Rocky Flats Office (DOE/RF), in response to a request for information under the Freedom of Information Act (FOIA). Levernier sought records of telephone conversations between himself and personnel of Wackenhut Services, Inc., a DOE contractor. In his Appeal, Levernier challenged the adequacy of DOE/RF's search for records. In considering the Appeal, the DOE found that, because the DOE/RF FOIA Officer consulted each of the offices at DOE/RF that were likely to possess the records, including the offices that Levernier stated had reviewed the documents, her search was reasonably calculated to uncover the records sought by the Appellant. Accordingly, the Appeal was denied.

Robert L. Hale, 3/20/95, VFA-0026

The Department of Energy issued a Decision and Order denying a Freedom of Information Act Appeal filed by Robert L. Hale. In his Appeal, Mr. Hale contested the adequacy of the search for

responsive documents performed by the DOE's Oak Ridge Operations Office. After conducting its own inquiry into the scope of the search, the DOE concluded that the search was adequate. Mr. Hale's Appeal was therefore denied.

Personnel Security Hearings

Albuquerque Operations Office, 3/22/95, VSO-0011

A Hearing Officer issued an Opinion regarding the eligibility of an individual to maintain a level "Q" access authorization under the provisions of 10 CFR part 710. The individual was alleged to have an illness or mental condition of a nature that in the opinion of a board-certified psychiatrist causes, or may cause, a significant defect in her judgment or reliability. On February 15, 1995, an evidentiary hearing was conducted in which a DOE-sponsored psychiatrist and the individual's psychiatrist testified, along with other relevant witnesses. After carefully examining the record of the proceeding, the Hearing Officer determined that although the individual suffers from recurrent major depression, her psychiatric profile, type of depression, work record and efforts at rehabilitation indicate to him that she is not a risk to national security. Accordingly, the Hearing Officer found that the individual's access authorization should be reinstated.

Albuquerque Operations Office, 3/23/95, VSO-0013

An OHA Hearing Officer issued an opinion concerning the access authorization of an individual whose security clearance was suspended because he tested positive for marijuana use and also because he lied on a DOE form, stating that he had not used illegal drugs. The Hearing Officer found that the individual was rehabilitated from

his drug use, but had not shown rehabilitation from the falsification. Accordingly, the Hearing Officer determined that the individual's clearance should not be restored.

Refund Application

Gulf Oil Corporation/Hilltop Auto Laundry, 3/23/95, RF300-15647

Hilltop Auto Laundry filed an Application for Refund in the Gulf Oil Corporation (Gulf) special refund proceeding. Hilltop requested an above-

volumetric refund based on Gulf's alleged breach of 1972 franchise and supply agreements. The conduct cited by Hilltop was Gulf's termination of the franchise arrangement, Gulf's use of a substitute supplier, and Hilltop's receipt of less product than provided for under the 1972 contract. In considering Hilltop's Application, the DOE noted that refunds are granted based on alleged or actual regulatory violations, not alleged breaches of contractual agreements. The DOE determined that

Hilltop had not demonstrated that the conduct in question violated the regulations. Accordingly, the Application was denied.

Refund Applications

The Office of Hearings and Appeals issued the following Decisions and Orders concerning refund applications, which are not summarized. Copies of the full texts of the Decisions and Orders are available in the Public Reference Room of the Office of Hearings and Appeals.

Name	Case No.	Date
Skilo Mfg. Inc.	RC272-285	03/22/95
Texaco Inc./Dave & Jack's Texaco Service, Inc.	RF321-20885	03/22/95
Millcrest Texaco	RF321-20914.	
White's Texaco	RF321-20931.	
Texaco Inc./Lake Street Texaco et al	RF321-572	03/24/95
Texaco Inc./Six Points Texaco	RF321-15920	03/22/95
Southside Texaco	RR321-159.	
Texaco Inc./Spiros Karamalegos et al	RF321-7550	03/24/95

Dismissals

The following submissions were dismissed:

Name	Case No.
Agipcoal USA, Inc.	RF272-95020
Airport Limousine Service, Inc.	RF272-91666
American Western Corporation.	RF272-67861
Benzie County	RF272-86933
Clipper's Texaco	RF321-18913
Felix M. Rivera Rivera	RF315-9352
Gibson Texaco	RF321-18974
Hardy Gulf	RF300-21714
John Morrell & Co.	RF272-96573
Luis B. Cruz	RF315-9337
McConnell Texaco	RF321-10849
Nevada Operations Office .	VSO-0022
Rafael Torres Diaz	RF315-9342
Stanley Cain	RF321-8985
Villa Prade Auto Service ...	RF315-9347

Copies of the full text of these decisions and orders are available in the Public Reference Room of the Office of Hearings and Appeals, Room 1E-234, Forrestal Building, 1000 Independence Avenue, S.W., Washington, D.C. 20585, Monday through Friday, between the hours of 1:00 p.m. and 5:00 p.m., except Federal holidays. They are also available in Energy Management: Federal Energy Guidelines, a commercially published loose leaf reporter system.

Dated: April 21, 1995.

George B. Breznay,

Director, Office of Hearings and Appeals.

[FR Doc. 95-10758 Filed 5-1-95; 8:45 am]

BILLING CODE 6450-01-P

Issuance of Decisions and Orders During the Week of February 13 through February 17, 1995

During the week of February 13 through February 17, 1995, the decisions and orders summarized below were issued with respect to appeals and applications for other relief filed with the Office of Hearings and Appeals of the Department of Energy. The following summary also contains a list of submissions that were dismissed by the Office of Hearings and Appeals.

Appeal

Southwest Resource Development, 2/15/95, VFA-0020

Southwest Resource Development (Southwest) filed an Appeal from a partial denial by the DOE's Office of Inspector General (IG) of a Request for Information which Southwest had submitted under the Freedom of Information Act (FOIA). In considering the Appeal, the DOE found that IG properly applied Exemptions 6 and 7(C) to the information requested by Southwest. The DOE found that the information requested by Southwest might identify individuals in an IG investigation by indicating certain functions performed by them. Since the interest in the identity of the individuals did not outweigh the individuals' privacy interest, the release of identifying information would constitute an unwarranted invasion of privacy. Accordingly, the Appeal was denied.

Refund Applications

Defense Logistics Agency, 2/14/95, RF272-11

The DOE issued a Decision and Order concerning an Application for Refund filed in the Subpart V Crude Oil refund proceeding by Defense Logistics Agency (DLA), a purchasing organ for the federal government. In granting the DLA refund claim, the DOE rejected challenges to the agency's right to receive a refund in the proceeding and DLA's claimed status as a product end-user. The DOE noted that agencies of the federal government are not precluded from participation in the Crude Oil refund proceeding, and that DLA was properly classified as an end-user since its purchase of refined petroleum product ended the commercial marketing of the product which was consumed by entities of the federal government. DLA was therefore granted a refund of \$34,161,149.

Holston Defense Corp., 2/13/95, RF272-91995

The DOE issued a Decision and Order denying Holston Defense Corporation's application for refund in the crude oil special refund proceeding. The applicant purchased petroleum products for work done under contract with the U.S. Department of Defense. Since the Department of Defense reimbursed Holston for all petroleum purchases, it was ineligible to receive a refund in this proceeding. Therefore, the Application for Refund was denied.

Refund Applications

The Office of Hearings and Appeals issued the following Decisions and

Orders concerning refund applications, which are not summarized. Copies of the full texts of the Decisions and

Orders are available in the Public Reference Room of the Office of Hearings and Appeals.

Name	Case No.	Date
Atlantic Richfield Company/Carl Hatton Butane Company et al	RF304-13218	02/13/95
City of Elsa	RF272-83460	02/13/95
Clark Oil & Refining Corp./Draeger Oil Company	RF342-21	02/15/95
Co-Op Gas & Oil Co. et al	RF272-89412	02/13/95
Gulf Oil Corporation/Knowles Construction Company	RF300-21823	02/13/95
Gulf Oil Corporation/Zee Line Ferry, Inc	RF300-21537	02/15/95
Zee Line Ferry, Inc	RF300-21820	
Zee Line Ferry, Inc	RF300-21821	
Zee Line Ferry, Inc	RF300-21822	
McVey Trucking et al	RF272-93769	02/17/95
Texaco Inc./Etheridge Texaco et al	RF321-4190	02/17/95
Texaco Inc./First Texaco	RF321-1933	02/13/95
McComb's Auto Service	RF321-13641	
Stull's Garage	RF321-17646	
Texaco Inc./Hall's Texaco	RF321-19732	02/13/95
Texaco Inc./Phil's Texaco & Tire et al	RF321-4193	02/17/95
Texaco Inc./Steitz Service et al	RF321-20603	02/14/95

Dismissals

The following submissions were dismissed:

Name	Case No.
Bartholomew Texaco	RF321-20794
Calaveras Cement Company.	RR272-128
Commercial Industrial Chemicals.	RF321-20688
Covington County	RF272-85265
Joe Walsh's Texaco	RF321-20567
Marengi's Texaco	RF321-20913
Marengi's Texaco	RF321-20912
Moore McCormack Lines, Inc.	RF321-20925
Munz Northern Airlines ..	RF272-89462
Orange North Supervisory Union.	RF272-96202
Southern Berkshire Auto	RF300-21409
State Street Texaco	RF321-20921

Copies of the full text of these decisions and orders are available in the Public Reference Room of the Office of Hearings and Appeals, Room 1E-234, Forrestal Building, 1000 Independence Avenue, S.W., Washington, D.C. 20585, Monday through Friday, between the hours of 1:00 p.m. and 5:00 p.m., except Federal holidays. They are also available in Energy Management: Federal Energy Guidelines, a commercially published loose leaf reporter system.

Dated: April 21, 1995.

George B. Breznay,

Director, Office of Hearings and Appeals.
[FR Doc. 95-10759 Filed 5-1-95; 8:45 am]

BILLING CODE 6450-01-P

ENVIRONMENTAL PROTECTION AGENCY

[FRL-5201-1]

Office of Research and Development; Ambient Air Monitoring Reference and Equivalent Methods; Equivalent Method Designations

Notice is hereby given that EPA, in accordance with 40 CFR part 53, has designated 3 additional equivalent methods, for the measurement of ambient concentrations of sulfur dioxide, nitrogen dioxide, and ozone. The new equivalent methods are automated methods (analyzers) that utilize a measurement principle based on differential optical absorption spectroscopy (DOAS) and measure pollutant concentrations in the ambient air over a long, open path up to 1 kilometer in length. The new designated methods are identified as follows:

EQSA-0495-101, Opsis Model AR 500 System, open path (long path) ambient air monitoring system configured for measuring SO₂, with one detector and movable grating, operated with a measurement range of 0 to 0.5 ppm, an installed monitoring path length between 20 and 500 meters (or 20 and 1000 meters with the ER 150 option), xenon lamp type B (150 watt), fiber optic cable length between 3 to 20 meters; operating within an ambient air temperature range of -50 to +50°C, an analyzer temperature range of 20 to 30°C, a measurement (integrating) time setting between 30 and 120 seconds (0 min:30 sec. to 2 min:00 sec.), and with a complete cycle time of not more than 200 seconds (3 min, 20 sec.). Under this method designation, the Model AR 500 System consists of:

AR 500 opto-analyser,
Emitter EM 110 and receiver RE 110
(together identified as ER 110),
Optic fibre cable OF 60-S,
Power supply PS 150,
OPSIS operational software, version 7.0,
Initial on-site installation, setup, and
limited operator training.

Optional components that can be used in addition to or as alternative to corresponding components listed above are:

AR 503 opto-analyzer configured as
Model AR 500 (only the center detector active, sequential monitoring),
Emitter/receiver ER 150 (for monitoring path lengths up to 1 kilometer),
Xenon lamp type A (higher short-wavelength UV output),
Optic fibre cable OF 60-R (low-loss for short wavelengths),
Multiplexers MX 004 and MX 024,
Dataloggers DL 010 and DL 016,
Analogue and digital input/output cards AO 008, AI 016, and DI 032,
Analogue and digital isolation cards IA 008, ID 008, AO 008, and OD 008,
Window heaters HF 110 and HF 150,
Mirror heaters HM 110 and HM 150,
Auto calibration unit CU 007,
Software packages IO 80 version 1.4 (for the analogue and digital input/output adapters), DL10 and DL16 (for data loggers), ComVision, and STAT 500;
and recommended calibration and accuracy audit components (or equivalent):

Wavelength calibration lamp CA 004,
Calibration bench CB 100,
Receiver unit RE 060 (two required),
Calibration unit CA 150, with same type lamp as used in the monitoring path emitter,

Power supply PS 150 for calibration unit CA 150,
Calibration cells CC 001-X, where X represents various cell lengths from 1 to 900 mm,
Special calibration cells CC 110 or CC 150 (for mounting directly on receiver),
Light meter LM 010.

EQNA-0495-102, Opsis Model AR 500 System, open path (long path) ambient air monitoring system configured for measuring NO₂, with one detector and movable grating, operated with a measurement range of 0 to 0.5 ppm, an installed monitoring path length between 50 and 500 meters (or 50 and 1000 meters with the ER 150 option), xenon lamp type B (150 watt), fiber optic cable length between 3 to 20 meters; operating within an ambient air temperature range of -50 to +50°C, an analyzer temperature range of 20 to 30°C, a measurement (integrating) time setting between 30 and 120 seconds (0 min:30 sec. to 2 min:00 sec.), and with a complete cycle time of not more than 200 seconds (3 min, 20 sec.). Under this method designation, the Model AR 500 System consists of:

AR 500 opto-analyser,
Emitter EM 110 and receiver RE 110 (together identified as ER 110),
Optic fibre cable OF 60-S,
Power supply PS 150,
OP SIS operational software, version 7.0,
Initial on-site installation, setup, and limited operator training.

Optional components that can be used in addition to or as alternative to corresponding components listed above are:

AR 503 opto-analyzer configured as Model AR 500 (only the center detector active, sequential monitoring),
Emitter/receiver ER 150 (for monitoring path lengths up to 1 kilometer),
Xenon lamp type A (higher short-wavelength UV output),
Optic fibre cable OF 60-R (low-loss for short wavelengths),
Multiplexers MX 004 and MX 024,
Dataloggers DL 010 and DL 016,
Analogue and digital input/output cards AO 008, AI 016, and DI 032,
Analogue and digital isolation cards IA 008, ID 008, AO 008, and OD 008,
Window heaters HF 110 and HF 150,
Mirror heaters HM 110 and HM 150,
Auto calibration unit CU 007,
Software packages IO 80 version 1.4 (for the analogue and digital input/output adapters), DL10 and DL16 (for data loggers), ComVision, and STAT 500;
and recommended calibration and accuracy audit components (or equivalent);

Wavelength calibration lamp CA 004,
Calibration bench CB 100,
Receiver unit RE 060 (two required),
Calibration unit CA 150, with same type lamp as used in the monitoring path emitter,
Power supply PS 150 for calibration unit CA 150,
Calibration cells CC 001-X, where X represents various cell lengths from 1 to 900 mm,
Filter GG 400,
Special calibration cells CC 110 or CC 150 (for mounting directly on receiver),
Light meter LM 010.

EQOA-0495-103, Opsis Model AR 500 System, open path (long path) ambient air monitoring system configured for measuring O₃, with one detector and moveable grating, operated with a measurement range of 0 to 0.5 ppm, an installed monitoring path length between 20 and 500 meters (or 20 and 1000 meters with the ER 150 option), xenon lamp type B (150 watt), fiber optic cable length between 3 to 20 meters; operating within an ambient air temperature range of -50 to +50°C, an analyzer temperature range of 20 to 30°C, a measurement (integrating) time setting between 30 and 120 seconds (0 min:30 sec. to 2 min:00 sec.), and with a complete cycle time of not more than 200 seconds (3 min, 20 sec.). Under this method designation, the Model AR 500 System consists of:

AR 500 opto-analyser,
Emitter EM 110 and receiver RE 110 (together identified as ER 110),
Optic fibre cable OF 60-S,
Power supply PS 150,
OP SIS operational software, version 7.0,
Initial on-site installation, setup, and limited operator training.

Optional components that can be used in addition to or as alternative to corresponding components listed above are:

AR 503 optoanalyzer configured as Model AR 500 (only the center detector active, sequential monitoring),
Emitter/receiver ER 150 (for monitoring path lengths up to 1 kilometer),
Optic fibre cable OF 60-R (low-loss for short wavelengths),
Multiplexers MX 004 and MX 024,
Dataloggers DL 010 and DL 016,
Analogue and digital input/output adapters AO 008, AI 016, and DI 032,
Analogue and digital isolation cards IA 008, ID 008, OA 008, and OD 008,
Window heaters HF 110 and HF 150,
Mirror heaters HM 110 and HM 150,
Auto calibration unit CU 007,
Software packages IO 80 version 1.4 (for the analogue and digital input/output

adapters), DL10 and DL16 (for data loggers), ComVision, and STAT 500;
and recommended calibration and accuracy audit components (or equivalent):

Wavelength calibration lamp CA 004,
Calibration bench CB 100,
Receiver unit RE 060 (two required),
Calibration unit CA 150, with same type lamp as used in the monitoring path emitter,
Power supply PS 150 for calibration unit CA 150,
Calibration cells CC 001-X, where X represents various cell lengths from 1 to 900 mm,
Special calibration cells CC 110 or CC 150 (for mounting directly on the receiver),
Ozone generator OC 500,
Light meter LM 010.

These methods are manufactured by Opsis AB, Furulund, Sweden and are available from ABB Power Plant Controls, Division of Combustion Engineering, Inc., 2 Waterside Crossing, Windsor, CT 06095. Notices of receipt of applications for these methods appeared in the **Federal Register**, Volume 56, October 29, 1991, page 55673; Volume 56, November 20, 1991, page 58574; and Volume 57, January 29, 1992, page 3429.

A test analyzer representative of these methods has been tested by the applicant, in accordance with the test procedures specified in 40 CFR part 53. After reviewing the results of these tests and other information submitted by the applicant, EPA has determined, in accordance with part 53, that these methods should be designated as equivalent methods. The information submitted by the applicant will be kept on file at EPA's Atmospheric Research and Exposure Assessment Laboratory, Research Triangle Park, North Carolina 27711, and will be available for inspection to the extent consistent with 40 CFR part 2 (EPA's regulations implementing the Freedom of Information Act).

As designated equivalent methods, these methods are acceptable for use by States and other air monitoring agencies under the requirements of 40 CFR part 58, Ambient Air Quality Surveillance. For such purposes, each method must be used in strict accordance with the operation or instruction manual associated with the method and subject to any limitations (e.g., operating range) specified in the applicable designation (see descriptions of the methods above). Users should note that these methods are the first methods designated that use a long path (open path) measurement principle. Amendments to the ambient air monitoring regulations at 40 CFR

part 58 were proposed on August 18, 1994 (59 FR 42541) to address the application, siting, and operational quality assurance of open path analyzers, and supplemental quality assurance guidance is in preparation. Until these regulatory amendments are promulgated and the supplemental guidance for open path analyzers is available, monitoring agencies interested in using these methods should contact the U.S. EPA for interim guidance pertaining to network design, siting, and quality assurance issues. The EPA contact person for information on these issues is Ms. Lee Ann B. Byrd, Monitoring and Quality Assurance Group, Office of Air Quality Planning and Standards, telephone number (919) 541-5367.

Vendor modifications of a designated method used for purposes of part 58 are permitted only with prior approval of EPA, as provided in part 53. Provisions concerning modification of such methods by users are specified under section 2.8 of appendix C to 40 CFR part 58 (Modifications of Methods by Users).

In general, one of these designations will apply to any analyzer which is identical to the analyzer described in the designation. In some cases, similar analyzers manufactured prior to the designation may be upgraded (e.g., by minor modification or by substitution of a new operation or instruction manual) so as to be identical to the designated method and thus achieve designation status at a modest cost. The manufacturer should be consulted to determine the feasibility of such upgrading.

Part 53 requires that sellers of designated methods comply with certain conditions. These conditions are given in 40 CFR 53.9 and are summarized below:

(1) A copy of the approved operation or instruction manual must accompany the analyzer when it is delivered to the ultimate purchaser.

(2) The analyzer must not generate any unreasonable hazard to operators or to the environment.

(3) The analyzer must function within the limits of the performance specifications given in table B-1 of part 53 for at least one year after delivery when maintained and operated in accordance with the operation manual.

(4) Any analyzer offered for sale as a reference or equivalent method must bear a label or sticker indicating that it has been designated as a reference or equivalent method in accordance with part 53.

(5) If such an analyzer has two or more selectable ranges, the label or sticker must be placed in close

proximity to the range selector and indicate which range or ranges have been included in the reference or equivalent method designation.

(6) An applicant who offers analyzers for sale as reference or equivalent methods is required to maintain a list of ultimate purchasers of such analyzers and to notify them within 30 days if a reference or equivalent method designation applicable to the analyzers has been canceled or if adjustment of the analyzers is necessary under 40 CFR 53.11(b) to avoid a cancellation.

(7) An applicant who modifies an analyzer previously designated as a reference or equivalent method is not permitted to sell the analyzer (as modified) as a reference or equivalent method (although he may choose to sell it without such representation), nor to attach a label or sticker to the analyzer (as modified) under the provisions described above, until he has received notice under 40 CFR 53.14(c) that the original designation or a new designation applies to the method as modified or until he has applied for and received notice under 40 CFR 53.8(b) of a new reference or equivalent method determination for the analyzer as modified.

Aside from occasional breakdowns or malfunctions, consistent or repeated noncompliance with any of these conditions should be reported to: Director, Atmospheric Research and Exposure Assessment Laboratory, Department E (MD-77), U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711.

Designation of these equivalent methods is intended to provide assistance to the States in establishing and operating their air quality surveillance systems under part 58. Technical questions concerning the method should be directed to the distributor. Additional information concerning this action may be obtained from Frank F. McElroy, Methods Research and Development Division (MD-77), Atmospheric Research and Exposure Assessment Laboratory, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711, (919) 541-2622.

Henry L. Longest II,

Acting Assistant Administrator for Research and Development.

[FR Doc. 95-10752 Filed 5-1-95; 8:45 am]

BILLING CODE 6560-50-M

[FRL-5200-5]

**Clean Air Act Advisory Committee
Notice of Meeting**

SUMMARY: The Environmental Protection Agency (EPA) established the Clean Air Act Advisory Committee (CAAAC) on November 19, 1990 to provide independent advice and counsel to EPA on policy issues associated with the implementation of the Clean Air Act of 1990. The Advisory Committee shall be consulted on economic, environmental, technical, scientific, and enforcement policy issues.

OPEN MEETING NOTICE: Pursuant to 5 U.S.C. App. 2 § 10(a)(2), notice is hereby given that the Clean Air Act Advisory Committee will hold its next open meeting on Friday, June 2, 1995 from 8:30 a.m.-4:30 p.m. at the Sheraton at Woodbridge 515 Rt 1 South and Gill Lane, Iselin, New Jersey. Seating will be available on a first come, first served basis. The three subcommittees of the CAAAC (Permits/NSR/Toxics Integration, Economic Incentives and Regulatory Innovation and Linking Energy, Transportation and Air Quality Concerns) will be conducting meetings at the Sheraton at Woodbridge on Thursday, June 1, from 7:00 p.m.-10:00 p.m. Subcommittee meeting times may change at the discretion of the co-chairs.

The agenda will include a discussion of the open market trading rule, Employee Commuter Options (ECO), regulatory reform and a report from the OTC-LEV subcommittee.

INSPECTION OF COMMITTEE DOCUMENTS:

The committee agenda and any documents prepared for the meeting will be publicly available at the meeting. Thereafter, these documents, together with the CAAAC meeting minutes will be available for public inspection in EPA Air Docket Number A-94-34 in Room 1500 of EPA Headquarters 401 M Street, S.W., Washington, D.C.

FOR FURTHER INFORMATION concerning this meeting of the CAAAC please contact Karen Smith, Office of Air and Radiation, US EPA (202) 260-6379, FAX (202) 260-5155, or by mail at US EPA, Office of Air and Radiation (Mail Code 6101), Washington, D.C. 20460. If you would like to receive an agenda for this meeting, please leave your fax number on Ms. Smith's voice mail.

Dated: April 21, 1995.

Mary D. Nichols,

Assistant Administrator for Air and Radiation.

[FR Doc. 95-10747 Filed 5-1-95; 8:45 am]

BILLING CODE 6560-50-M

[FRL-5200-4]

Common Sense Initiative Council (CSIC)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notification of Public Advisory Open Meetings of the CSI Council, the Printing Sector Subcommittee, and the Petroleum Refining Sector Subcommittee.

SUMMARY: Pursuant to the Federal Advisory Committee Act, Public Law 92-463, notice is hereby given that the Council and the Printing and Petroleum Sector Subcommittees of the Common Sense Initiative Council (CSIC) will meet on the dates and times described below. All times noted are Eastern Time. All meetings are open to the public. Seating at meetings will be on a first-come basis. For further information concerning specific meetings, please contact the individuals listed with the Council and two Sector Subcommittee announcements below.

(1) Printing Sector Subcommittee—May 17, 1995

The Common Sense Initiative Council, Printing Sector Subcommittee (CSIC-PSS) is convening an open meeting on May 17, 1995. The meeting will begin at approximately 10:00 a.m. EST and run until about 5:30 p.m. The meeting will be held at the U.S. Environmental Protection Agency, WIC Conference Room #3, 401 M Street, S.W., Washington, D.C. 20460.

The meeting has several purposes: (1) To discuss and approve draft work plans prepared by work groups covering substantive issues that they want to address; and (2) to plan and prepare for the presentation of the Subcommittee's work plan to the CSI Council.

Seating may be limited, therefore, advance registration is recommended. Agendas will be available May 10, 1995. Any person or organization interested in attending the meeting should contact Ms. Nancy Cichowicz, Alternate Designated Federal Official, no later than May 15, 1995, at (215) 597-2030. Limited time will be provided for persons wishing to make oral comments at the meeting. Anyone wishing to submit written comments must forward at least 35 copies to Ginger Gotliffe, Designated Federal Officer, U.S. EPA, Office of Compliance (2224A), 401 M Street S.W., Washington, D.C. 20460. Comments should be received by May 15, 1995.

For further meeting information contact Ginger Gotliffe, DFO, on (202) 564-7072, or Nancy Cichowicz,

Alternate DFO, Region III, on (215) 597-2030.

(2) Petroleum Refining Sector Subcommittee—May 17 and 18, 1995

The Common Sense Initiative Council, Petroleum Refining Sector Subcommittee (CSIC-PRS) is holding an open meeting on Wednesday, May 17, 1995, from 8:00 a.m. to 5:30 p.m. and Thursday, May 18, 1995, from 8:30 a.m. to 5:00 p.m., at the Dupont Plaza Hotel, 1500 New Hampshire Avenue, N.W., Washington, D.C. 20036.

Topics to be discussed at the meeting include regulatory reform, recordkeeping and reporting, compliance and permitting, and accident prevention and non-routine actions.

Members of the public may submit written comments of any length prior to the meeting. One hour of meeting time will be set aside for oral comments. In general, each individual or group making any oral presentations will be limited to a total of three minutes. Anyone who would like further information on the meeting should contact Claudia Huntley of the CSI Program Staff, U.S. EPA, 401 M Street S.W., Washington, D.C. 20460, Mail Code 6101, Phone: (202) 260-7417.

(3) Common Sense Initiative Council—May 19, 1995

The Common Sense Initiative Council (CSIC) is convening an open meeting on Friday, May 19, 1995, from 8:30 a.m. to 5:00 p.m. at the Madison Hotel, 15th and M Streets, N.W., Washington, D.C. 20005, telephone number 1-800-424-8577.

The Council will meet to review activities and projects being undertaken by its six Sector Subcommittees: Auto Manufacturing, Computers and Electronics, Iron and Steel, Metal Finishing, Petroleum Refining, and Printing. The Council also will discuss potential cross-sector issues.

Agendas will be available May 10, 1995. Limited time will be provided for members of the public wishing to make oral comments during the meeting. In general, each individual or group making oral presentations will be limited to a total of three minutes. Seating may be limited; therefore, advance registration is recommended. Any person or organization interested in attending the meeting, or submitting written comments should contact the CSI Program Staff Office on (202) 260-7417. Written comments must be forwarded with at least 35 copies by May 15, 1995.

For further information on this meeting, please call either Prudence

Goforth, Designated Federal Officer, or Vivian Daub, Interim CSI Director at EPA Headquarters, on (202) 260-7417.

FURTHER INFORMATION AND INSPECTION OF CSIC DOCUMENTS: Documents relating to the above Council and Sector Subcommittee announcements will be publicly available at the meetings. Thereafter, these documents, together with official minutes for the meetings, will be available for public inspection in room 2417 Mall of EPA Headquarters, Common Sense Initiative Program Staff, 401 M Street, S.W., Washington, D.C. 20460, phone (202) 260-7417. CSIC information can be accessed electronically through contacting Katherine Brown at: brown.katherine@epamail.epa.gov.

Dated: April 25, 1995.

Prudence Goforth,

Designated Federal Officer.

[FR Doc. 95-10749 Filed 5-1-95; 8:45 am]

BILLING CODE 6560-50-P

[FRL-5200-6]

National Drinking Water Advisory Council; Notice of Open Meeting

Under Section (1)(a)(2) of Public Law 92-423, "The Federal Advisory Committee Act," notice is hereby given that a meeting of the National Drinking Water Advisory Council established under the Safe Drinking Water Act, as amended (Pub. L. 99-339), will be held at 9:00 a.m. on May 18, 1995 and at 8:30 a.m. on May 19, 1995, at the Harley Hotel of Cincinnati, East Room, 8020 Montgomery Road, Cincinnati, Ohio 45236. Council Subcommittees will hold their meetings on May 15 and May 16, 1995, at the EPA Laboratory, 26 West Martin Luther King, Cincinnati, Ohio.

The purpose of the meeting will be to seek Council advice and comments on EPA's recently announced "Agenda For Action," which is designed to assess and identify priorities and improve the effectiveness of drinking water safety. Issues include: improving consumer information; identifying priority contaminants for regulation; providing technical assistance for small communities and the protecting source waters; identifying flexibilities for states, including monitoring approaches; and increasing investment in community drinking water facilities.

The meeting will be open to the public. The Council encourages the hearing of outside statements and will allocate a portion of its meeting time for public participation. Oral statements will be limited to ten minutes. It is preferred that there be only one

presenter for each statement. Any outside parties interested in presenting an oral statement should petition the Council by telephone at (202) 260-2285. The petition should include the topic of the proposed statement, the petitioner's telephone number and should be received by the Council before May 11, 1995.

Any person who wishes to file a written statement can do so before or after a Council meeting. Written statements received prior to the meeting will be distributed to the members before any final discussion or vote is completed. Statements received after the meeting will become part of the permanent meeting file and will be forwarded to the Council members for their information.

Any member of the public wishing to attend the Council meeting, present an oral statement, or submit a written statement, should contact Ms. Charlene Shaw, Designated Federal Officer, National Drinking Water Advisory Council, U.S. Environmental Protection Agency, Office of Ground Water and Drinking Water (4601), 401 M Street S.W., Washington, D.C. 20460 or at (202) 260-2285.

Dated: April 21, 1995.

Cynthia C. Dougherty,

Director, Office of Ground Water and Drinking Water.

[FR Doc. 95-10748 Filed 5-1-95; 8:45 am]

BILLING CODE 6560-50-M

FEDERAL ELECTION COMMISSION

[Notice 1995-7]

Schedule of Matching Fund Submission Dates and Certification Dates for 1996 Presidential Candidates

AGENCY: Federal Election Commission.

ACTION: Schedule of Matching Fund Submission/Resubmission Dates and Certification Dates for 1996 Presidential Candidates.

SUMMARY: The Federal Election Commission is publishing matching fund submission/resubmission dates and certification dates for 1996 Presidential candidates who are eligible to receive Federal matching funds. Eligible candidates may present one submission and/or one resubmission per month on the designated date. Payments will be made by the U.S. Treasury to the candidate generally within 48 hours after certification by the Commission.

FOR FURTHER INFORMATION CONTACT: Mr. Raymond Lisi, Audit Division, 999 E Street NW., Washington, DC 20463, Telephone: (202) 219-3720; (800) 424-9530.

SUPPLEMENTARY INFORMATION: Pursuant to 11 CFR 9036.2(a), Presidential candidates eligible to receive Federal Matching Funds may present submissions and/or resubmissions to the Federal Election Commission once a month on designated submission dates.

The Commission will review the submissions/resubmissions and forward a certification for payment to the Secretary of the Treasury. Since no payments can be made during 1995, all submissions received during 1995 will be certified on December 27, 1995, for payment on January 2, 1996 (11 CFR 9036.2(c)). During 1996 and 1997 certifications and payments will be made on a monthly basis. The last date a candidate may make a submission is March 3, 1997. The submission dates and processing times specified in the following list pertain to non-threshold matching fund submissions and resubmissions after the candidate establishes eligibility. The threshold submission on which that eligibility will be determined may be filed at any time, and will be processed within fifteen business days unless review of the threshold submission determines that eligibility has not been met. The Commission has published proposed rules changing the due date for submissions of statements of net outstanding campaign obligations for ineligible candidates. Under the proposed rules, the statements must be submitted prior to the certification date, on dates to be published by the Commission. Once these rules are promulgated, the due dates will be published in the **Federal Register**.

SCHEDULE OF MATCHING FUND SUBMISSION DATES AND CERTIFICATION DATES FOR THE 1996 PRESIDENTIAL CANDIDATES

Submission date	Certification to treasury
1995	
Monday—May 1, 1995	Wednesday—December 27, 1995.
Thursday—June 1, 1995	Wednesday—December 27, 1995.
Monday—July 3, 1995	Wednesday—December 27, 1995.
Tuesday—August 1, 1995	Wednesday—December 27, 1995.
Friday—September 1, 1995	Wednesday—December 27, 1995.
Monday—October 2, 1995	Wednesday—December 27, 1995.
Wednesday—November 1, 1995	Wednesday—December 27, 1995.
Friday—December 1, 1995	Wednesday—December 27, 1995.
1996	
Tuesday—January 2, 1996	Tuesday—January 30, 1996.
Thursday—February 1, 1996	Wednesday—February 28, 1996
Friday—March 1, 1996	Thursday—March 28, 1996
Monday—April 1, 1996	Monday—April 29, 1996
Wednesday—May 1, 1996	Thursday—May 30, 1996.
Monday—June 3, 1996	Thursday—June 27, 1996.
Monday—July 1, 1996	Tuesday—July 30, 1996.
Thursday—August 1, 1996	Thursday—August 29, 1996.

SCHEDULE OF MATCHING FUND SUBMISSION DATES AND CERTIFICATION DATES FOR THE 1996 PRESIDENTIAL CANDIDATES—Continued

Submission date	Certification to treasury
Tuesday—September 3, 1996	Friday—September 27, 1996.
Tuesday—October 1, 1996	Wednesday—October 30, 1996.
Friday—November 1, 1996	Wednesday—November 27, 1996.
Monday—December 2, 1996	Monday—December 30, 1996.
1997	
Thursday—January 2, 1997	Thursday—January 30, 1997.
Monday—February 3, 1997	Thursday—February 27, 1997.
Monday—March 3, 1997	Friday—March 28, 1997.

Dated: April 27, 1995.

Danny L. McDonald,

Chairman, Federal Election Commission.

[FR Doc. 95-10716 Filed 5-1-95; 8:45 am]

BILLING CODE 6715-01-M

FEDERAL RESERVE SYSTEM

Wendell D. Bruner, et al.; Change in Bank Control Notice; Acquisition of Shares of Banks or Bank Holding Companies

The notificant listed below has applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire a bank or bank holding company. The factors that are considered in acting on notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notice is available for immediate inspection at the Federal Reserve Bank indicated. Once the notice has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for the notice or to the offices of the Board of Governors. Comments must be received not later than May 16, 1995.

A. Federal Reserve Bank of Kansas City (John E. Yorke, Senior Vice President) 925 Grand Avenue, Kansas City, Missouri 64198:

1. *Wendell D. Bruner and Willard D. Heyne*, both of Fremont, Nebraska; each to acquire an additional 6.20 percent, for a total of 26.94 percent, of the voting shares of American Banc Corporation, Fremont, Nebraska, and thereby indirectly acquire American National Bank of Fremont, Fremont, Nebraska.

B. Federal Reserve Bank of Minneapolis (James M. Lyon, Vice President) 250 Marquette Avenue, Minneapolis, Minnesota 55480:

1. *Lois E. Morrison*, Stillwater, Minnesota; to acquire 30.44 percent of

the voting shares of Barron Investment Company, Golden Valley, Minnesota, and thereby indirectly acquire First National Bank of Barron, Barron, Wisconsin.

Board of Governors of the Federal Reserve System, April 26, 1995.

Jennifer J. Johnson,

Deputy Secretary of the Board.

[FR Doc. 95-10720 Filed 5-1-95; 8:45 am]

BILLING CODE 6210-01-F

Deutsche Bank AG; Change in Bank Control Notices; Acquisitions of Shares of Banks or Bank Holding Companies; Correction

This notice corrects a notice (FR Doc. 95-8694) published on page 18103 of the issue for Monday, April 10, 1995.

Under the Federal Reserve Bank of New York heading, the entry for Deutsche Bank AG, Frankfurt (Main), Federal Republic of Germany is revised to read as follows:

1. *Deutsche Bank, AG*, Frankfurt (Main), Federal Republic of Germany; to retain First Call Corporation, Boston, Massachusetts, and thereby engage indirectly in providing data processing activities, pursuant to § 225.25(b)(7) of the Board's Regulation Y. These activities will be conducted worldwide.

Comments on this application must be received by May 16, 1995.

Board of Governors of the Federal Reserve System, April 26, 1995.

Jennifer J. Johnson,

Deputy Secretary of the Board.

[FR Doc. 95-10721 Filed 5-1-95; 8:45 am]

BILLING CODE 6210-01-F

First Bancorp, Inc., et al.; Formations of; Acquisitions by; and Mergers of Bank Holding Companies

The companies listed in this notice have applied for the Board's approval under section 3 of the Bank Holding

Company Act (12 U.S.C. 1842) and § 225.14 of the Board's Regulation Y (12 CFR 225.14) to become a bank holding company or to acquire a bank or bank holding company. The factors that are considered in acting on the applications are set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

Each application is available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank or to the offices of the Board of Governors. Any comment on an application that requests a hearing must include a statement of why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute and summarizing the evidence that would be presented at a hearing.

Unless otherwise noted, comments regarding each of these applications must be received not later than May 26, 1995.

A. Federal Reserve Bank of

Richmond (Lloyd W. Bostian, Jr., Senior Vice President) 701 East Byrd Street, Richmond, Virginia 23261:

1. *First Bancorp, Inc.*, Lebanon, Virginia; to acquire 100 percent of the voting shares of First Bank and Trust of Tennessee, Johnson City, Tennessee, a *de novo* bank.

B. Federal Reserve Bank of St. Louis

(Randall C. Sumner, Vice President) 411 Locust Street, St. Louis, Missouri 63166:

1. *CNB Bancshares, Inc.*, Evansville, Indiana; to acquire 100 percent of the voting shares of Bank of Illinois, National Association, Mount Vernon, Illinois. Applicant proposes to cause its existing federal savings bank subsidiary, King County Federal Savings Bank, Mount Vernon, Illinois, to convert to a

national banking association, under the name of Citizens Bank of Illinois.

2. *Mercantile Bancorporation, Inc.* St. Louis, Missouri; to acquire 100 percent of the voting shares of Amerifirst Bancorporation, Inc., Sikeston, Missouri.

C. Federal Reserve Bank of Dallas
(Genie D. Short, Vice President) 2200 North Pearl Street, Dallas, Texas 75201-2272:

1. *Baylor Bancshares, Inc.*, Seymour, Texas, and Baylor/Delaware Corp., Wilmington, Delaware; to acquire 100 percent of the voting shares of Memphis State Bank, Memphis, Texas.

Board of Governors of the Federal Reserve System, April 26, 1995.

Jennifer J. Johnson,

Deputy Secretary of the Board.

[FR Doc. 95-10722 Filed 5-1-95; 8:45 am]

BILLING CODE 6210-01-F

Grimes County Capital Corporation; Notice of Application To Engage de novo in Permissible Nonbanking Activities

The company listed in this notice has filed an application under § 225.23(a)(1) of the Board's Regulation Y (12 CFR 225.23(a)(1)) for the Board's approval under section 4(c)(8) of the Bank Holding Company Act (12 U.S.C. 1843(c)(8)) and § 225.21(a) of Regulation Y (12 CFR 225.21(a)) to commence or to engage *de novo*, either directly or through a subsidiary, in a nonbanking activity that is listed in § 225.25 of Regulation Y as closely related to banking and permissible for bank holding companies. Unless otherwise noted, such activities will be conducted throughout the United States.

The application is available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether consummation of the proposal can "reasonably be expected to produce benefits to the public, such as greater convenience, increased competition, or gains in efficiency, that outweigh possible adverse effects, such as undue concentration of resources, decreased or unfair competition, conflicts of interests, or unsound banking practices." Any request for a hearing on this question must be accompanied by a statement of the reasons a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute, summarizing the

evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of the proposal.

Comments regarding the application must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than May 16, 1995.

A. Federal Reserve Bank of Dallas
(Genie D. Short, Vice President) 2200 North Pearl Street, Dallas, Texas 75201-2272:

1. *Grimes County Capital Corporation*, doing business as CSB Mortgage Services, Houston, Texas; to engage *de novo* in making and servicing mortgage loans or other extensions of credit for the account of others, pursuant to § 225.25(b)(1)(iii) of the Board's Regulation Y. The geographic scope for these activities is Texas.

Board of Governors of the Federal Reserve System, April 26, 1995.

Jennifer J. Johnson,

Deputy Secretary of the Board.

[FR Doc. 95-10723 Filed 5-1-95; 8:45 am]

BILLING CODE 6210-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Findings of Scientific Misconduct

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: Notice is hereby given that the Office of Research Integrity (ORI) has made final findings of scientific misconduct in the following case:

Denise R. Conrad, University of Iowa: The Division of Research Investigations (DRI) of the Office of Research Integrity (ORI) reviewed an investigation conducted by the University of Iowa into possible scientific misconduct on the part of Ms. Denise R. Conrad, formerly a Research Assistant in the Department of Preventive Medicine, College of Medicine. ORI found that Ms. Conrad committed scientific misconduct by fabricating or falsifying data on questionnaires in biomedical research supported by Public Health Service grant R01 ES05653, "Residential Radon and Lung Cancer Case-Control Study." Ms. Conrad has accepted the ORI findings and agreed to a Voluntary Exclusion Agreement under which Ms. Conrad is not eligible to apply for or receive any Federal grant or contract funds for a three-year period beginning April 10, 1995. The fabricated or falsified data did not appear in any publication.

FOR FURTHER INFORMATION, CONTACT:
Director, Division of Research Investigations, Office of Research Integrity, 301-443-5330.

Lyle W. Bivens,

Director, Office of Research Integrity.

[FR Doc. 95-10762 Filed 5-1-95; 8:45 am]

BILLING CODE 4160-17-P

Findings of Scientific Misconduct

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: Notice is hereby given that the Office of Research Integrity (ORI) has made final findings of scientific misconduct in the following case:

Catherine Coyle, ISOLAB, Inc. An investigation conducted by the ISOLAB found that Ms. Coyle, a former laboratory technician, falsified and misreported the results of assays for fetal hemoglobin data generated for Johns Hopkins' Multicenter Study of Hydroxyurea in Sickle Cell Anemia in biomedical research supported by Public Health Service funds under a cooperative agreement. Ms. Coyle admitted that she misrepresented data submitted to the Johns Hopkins clinical hydroxyurea study. There were no publications involved. Ms. Coyle executed a Voluntary Exclusion and Settlement Agreement in which she has agreed not to apply for Federal grant or contract funds and will not serve on PHS advisory committees, boards or peer review groups for a three-year period beginning March 27, 1995.

FOR FURTHER INFORMATION, CONTACT:
Director, Division of Research Investigations Office of Research Integrity, 301-443-5330.

Lyle W. Bivens,

Director, Office of Research Integrity.

[FR Doc. 95-10763 Filed 5-1-95; 8:45 am]

BILLING CODE 4160-17-P

Centers for Disease Control and Prevention

Advisory Committee for Energy-Related Epidemiologic Research: Cancellation of Meeting

This notice announces the cancellation of a previously announced meeting.

Federal Notice Citation of Previous Announcement: 60 FR 19264, April 17, 1995.

Previously Announced Times and Dates: 9 a.m.-5 p.m., May 4, 1995, 9 a.m.-12 noon, May 5, 1995.

Change In the Meeting: This meeting has been canceled.

Contact Person for More Information: Nadine Dickerson, Program Analyst, Radiation Studies Branch, Division of Environmental Hazards and Health Effects, National Center for Environmental Health, Centers for Disease Control and Prevention, 4770 Buford Highway, NE, Mailstop F-35, Atlanta, Georgia 30341-3724, telephone 404/488-7040.

Dated: April 26, 1995.

John C. Burckhardt,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 95-10827 Filed 4-28-95; 10:33 am]

BILLING CODE 4163-18-M

Health Care Financing Administration

Public Information Collection Requirements Submitted to the Office of Management and Budget (OMB) for Clearance

AGENCY: Health Care Financing Administration, HHS.

The Health Care Financing Administration (HCFA), Department of Health and Human Services, has submitted to OMB the following proposals for the collection of information in compliance with the Paperwork Reduction Act (Public Law 96-511).

1. *Type of Request:* Reinstatement; *Title of Information Collection:* Medicare Intermediary Request to Skilled Nursing Facilities for Medical Information on Claims to Be Processed; *Form Nos.:* NCFA-9031; *Use:* This information is used by the fiscal intermediaries to assure that reimbursement is made only for services that are covered under Medicare Part A or Part B for skilled nursing facilities. The medical information describes the patient's condition and level of medical needs and/or services provided. The records/information are submitted with

claims or as requested; *Respondents:* Business or other for profit; *Number of Respondents:* 12,536; *Total Annual Responses:* 111,925; *Total Annual Hours Requested:* 55,963.

2. *Type of Request:* Revision; *Title of Information Collection:* Clinical Laboratory Improvement Amendments Budget Expenditure Report and Clinical Laboratory Improvement Amendments Planned Workload Report; *Form No.:* HCFA-102-105; *Use:* Information collected will be used by HCFA in determining the amount of Federal reimbursement for compliance surveys. Use of the information includes program evaluation, audit, budget formulation, and budget approval; *Respondents:* State, local, or tribal government; *Number of Respondents:* 53; *Total Annual Responses:* 2,650 (HCFA-102), 1,696 (quarterly); *Total Annual Hours Requested:* 4,346.

3. *Type of Request:* Reinstatement; *Title of Information Collection:* Medicare Home Health Quality Assurance Demonstration; *Form No.:* HCFA-P-11; *Use:* The Medicare Home Health Quality Assurance Demonstration will test the feasibility of collecting patient outcome data in 50 Medicare-certified home health agencies (HHAs) nationally. Respondents will be HHA care providers and patients receiving their services; *Respondents:* Not-for-profit, businesses or other for-profit, and individuals or households; *Number of Respondents:* 27,844; *Total Annual Responses:* 111,376; *Total Annual Hours Requested:* 34,573.

4. *Type of Request:* Revision; *Title of Information Collection:* Medicare/Medicaid Health Insurance Common Claim Form and Instructions; *Form No.:* HCFA-1500; *Use:* This form will become a standardized form for use in the Medicare/Medicaid programs to apply for reimbursement for covered

services. In addition, it will reduce costs and administrative burdens associated with claims since only one coding system will be used and maintained. HCFA does not require exclusive use of this form for Medicaid; *Respondents:* Not-for-profit, businesses or other for-profit, State, local or tribal government; *Number of Respondents:* 1; *Total Annual Responses:* 614,967,982; *Total Annual Hours Requested:* 52,139,385.

5. *Type of Request:* New (Expedited Review); *Title of Information Collection:* Study of the Cost of Administering Childhood Immunizations; *Form No.:* HCFA-R-175; *Use:* The proposed collection is to provide data of the resource costs for childhood immunization procedures to evaluate charge caps for physician practices participating in the recently enacted vaccines for children under the Medicaid program; *Respondents:* Business or other for profit; *Number of Respondents:* 100; *Total Annual Responses:* 100; *Total Annual Hours Requested:* 41.

Additional Information or Comments: Call the Reports Clearance Office on (410) 966-5536 for copies of the clearance request packages. Written comments and recommendations for the proposed information collections should be sent within 30 days of this notice directly to the OMB Desk Officer designated at the following address: OMB Human Resources and Housing Branch, Attention: Allison Eydt, New Executive Office Building, Room 10235, Washington, D.C. 20503.

Dated: April 26, 1995.

Kathleen B. Larson,

Director, Management Planning and Analysis Staff, Office of Financial and Human Resources, Health Care Financing Administration.

BILLING CODE 4120-03-M

(HCFA Letter Requesting Provider Participation)

Name

Title

Multispecialty, Pediatric Group, or Solo Pediatric Practice

Address

Dear (Name of Physician or Administrator):

The Health Care Financing Administration (HCFA) has retained the Center for Health Policy Studies, Columbia, Maryland, to conduct an Immunization Resource Costing Study. The primary objective of this study is to identify costs associated with the administration of childhood immunizations. Once these costs have been identified, results will be used to help establish limits on how much physicians may charge to administer immunizations under the Vaccines for Children (VFC) program recently enacted by Congress.

The study will involve site visits to a combination of 90 multispecialty, pediatric group, and solo pediatric practices located in metropolitan and non-metropolitan areas throughout the country. During site visits, resource use and resource cost data on childhood immunization procedures will be collected. Within each facility, data collection will include interviews with key staff, abstracts of accounting records, review of supplier invoices, and immunization observations. All information received from your facility will be held strictly confidential.

Data collection is scheduled for _____, 1995. HCFA is requesting your facility's participation in the study. Your participation provides an opportunity for you to give input with respect to resource use and resource costs associated with the administration of childhood immunizations. Your cooperation will enhance the accuracy with which payments reflect facility costs.

CHPS may contact you shortly to request participation in the study and to inform you of the site visit schedule. Although participation is strictly voluntary and there are no penalties should you decline participation, we strongly urge you to participate in this important study. Please contact Michael Henesch (410) 966-6685, of the Health Care Financing Administration, or Michael Ellrich (410) 381-4203, of the Center for Health Policy Studies, should you desire further information or have any questions regarding the study. Thank you for your interest in the study.

Sincerely,

(HCFA Representative)

(CHPS Letter Requesting Provider Participation)**Name****Title****Multispecialty, Pediatric Group, or Solo Pediatric Practice****Address****Dear (Name of Physician or Administrator):**

The Center for Health Policy Studies (CHPS), a private health care consulting firm located in Columbia, Maryland, has been retained to perform a cost study for the Health Care Financing Administration (HCFA). The objective of the study is to identify costs associated with the administration of childhood immunizations. Costs derived by this study will be used to evaluate charge caps for physician practices participating in the recently enacted Vaccines for Children (VFC) program. A more detailed project description is enclosed.

We will be conducting on-site visits to 90 multispecialty, pediatric group, and solo pediatric practices located in metropolitan and non-metropolitan areas throughout the country. During site visits, resource use and resource cost data on childhood immunization procedures will be collected. At each facility, data collection will include interviews with key staff, abstracts of accounting records, review of supplier invoices, and immunization observations. A tentative site schedule has been included for your review.

As stated in the letter sent to you by HCFA (copy attached), CHPS is interested in obtaining your participation in this study. Your participation in the study is completely voluntary and there are no penalties should you decline. Data collected from your facility will be used exclusively for the purpose of this study and will be held in strict confidence.

Participation in the study will require you to provide:

- a designated contact person with whom we will coordinate our efforts
- opportunity to work within your facility to accomplish the sample site visit schedule
- access to basic financial records

We realize that these requirements appear substantial, but we have carefully considered your needs before contacting you. CHPS has identified the following points as important elements of our approach.

Data Collection Will Take Place Over a Specified Time Period. Each participating practice will be given on-site data collection instruments in advance to provide staff the opportunity to prepare information before the day of the visit. Based on data collection instrument pre-tests, it has been determined that the interview and unit cost data collection guides can each be completed in 30 minutes or less. The time required to collect resource use data will be largely dictated by the frequency with which immunizations are given at each practice. However, pre-tests have revealed that each site visit will require between two and a half and three hours for one data collector.

Our Data Collectors Include Only Experienced Staff. We have conducted many on-site studies throughout the U.S. and have found that only senior staff can work effectively, quickly and without disrupting day-to-day activities. For this reason, on-site data collection will be performed by seasoned personnel.

Our Approach Assures Participating Facilities that We will not Disrupt their Day-To-Day Activities. We will work at each facility's convenience, and will arrange with you the best time for our visit. During our visit, we will meet whatever needs facility personnel may have. The sample site visit schedule will be adjusted to maximize the convenience of the staff. When data are collected from records, our experienced staff will collect data without facility staff input unless there is interest in providing assistance. Most importantly, we are prepared to meet any constraints or limitations that participating facilities perceive to be important.

All Data will Remain Confidential. All data that we collect will remain confidential. No facility will be specifically identified in any reports. CHPS data collectors will be the only individuals with access to practice-specific information. Primary data collected will not be shared among study participants. To insure the complete anonymity of study participants, each will be assigned a numeric code prior to data base entry and analysis. Participant identity and practice specific data will not be linked or disclosed in any materials published for this study.

Your Participation in Our Study Can be of Great Value to You. Your participation provides an opportunity for you to give input with respect to resource use and resource costs associated with the administration of childhood immunizations. For your participation, you will receive a copy of the study's final report as well as a brief statistical analysis comparing your costs of administering immunizations to the costs of other facilities.

In order to facilitate your consideration of our request, we are enclosing the following materials:

- Attachment 1 - Project Description
- Attachment 2 - HCFA Summary

- Attachment 3 - CHPS Summary
- Attachment 4 - Sample Site Visit Schedule
- Attachment 5 - Participation Agreement Letter
- Attachment 6 - Sample Parent Consent Form

We will be contacting you shortly to discuss your interest in participating in the study. Should you agree to participate, we will ask you to sign and return the Agreement to Participate letter included as Attachment 5 or a similar letter by _____, 1995.

If you have any questions regarding the study, please call me or Michael Ellrich at (410) 381-4203. We look forward to your participation in this important study.

Sincerely,

Henry Miller, Ph.D.
President
Project Director

enclosures

STUDY OF THE COSTS OF ADMINISTERING CHILDHOOD IMMUNIZATIONS

Project Description

The Health Care Financing Administration (HCFA) has been charged by Congress with the responsibility of developing resource costs for the administration of childhood immunizations. Because little cost information relating to childhood immunizations is available at a national level, HCFA has retained the Center for Health Policy Studies (CHPS) to collect and measure these costs. Once costs have been measured, the results will be used to evaluate physician charge limits under the Vaccines for Children (VFC) program recently enacted by Congress.

The primary purpose of the study is to provide data on resource use and costs for a variety of childhood immunization procedures. In preparation for the study, a comprehensive list of immunizations, prescribed throughout childhood, has been identified. Resource utilization and cost data relating to these immunizations will be collected from a representative sample of multispecialty group, pediatric group and solo pediatric practices.

The study will provide HCFA with the following information:

- Direct and indirect costs associated with the administration of a prescribed set of childhood immunizations
- Differences in resource use and unit cost among practice types (multispecialty group, pediatric group, and solo practices)
- Differences in resource use and unit cost among practice settings (metropolitan, non-metropolitan)
- Direct and indirect cost variations by type of immunization and nature of visit
- Marginal costs of immunizations when two or more are performed at the same time

Facility data collection will include interviews with key staff, abstracts of accounting records, review of supplier invoices, and immunization observations. All information collected during site visits will be held strictly confidential.

It is anticipated that the study, initiated in November 1994, will be completed by _____, 1995. Further information can be obtained from Dr. Henry Miller, Project Director, Center for Health Policy Studies (410) 381-4203.

THE HEALTH CARE FINANCING ADMINISTRATION

The Health Care Financing Administration (HCFA) was established to combine health financing and quality assurance programs within a single agency. HCFA is responsible for the Medicare program, Federal participation in the Medicaid program, and a variety of other health care quality assurance programs.

The mission of the Health Care Financing Administration is to promote the timely delivery of appropriate, quality health care to its beneficiaries -- approximately 50 million of the Nation's aged, disabled, and poor. The agency must also ensure that program beneficiaries are aware of the services for which they are eligible, that those services are accessible and of high quality, and that agency policies and actions promote efficiency and quality within the total health care delivery system.

The Office of Research and Demonstrations directs more than 300 research, evaluation, and demonstration projects. A central focus is on program expenditures as they relate to payment, coverage, eligibility, and management alternatives under Medicare and Medicaid. Study activity also examines program impact on beneficiary health status, access to services, utilization, and out-of-pocket expenditures. The behavior and economics of health care providers and the overall health care industry are also topics of investigation.

These activities are carried out by three major components--the Office of Research, the Office of Demonstrations and Evaluations, and the Office of Operations Support. The Office of Research conducts and supports data collection efforts and research on health care providers, payment approaches, beneficiary behavior, and health care utilization. The Office of Demonstrations and Evaluations funds, manages, and evaluates pilot programs that test new ways of delivering and financing Medicare and Medicaid services. The Office of Operations Support provides ORD-wide administrative direction for its research, demonstration, and evaluation projects, which includes the budget and accounting operations; grants, cooperative agreements, and contracts-award process; and publications and information resources program.

CENTER FOR HEALTH POLICY STUDIES

The Center for Health Policy Studies (CHPS) was organized in 1979 to provide research and consulting services to both public and private sector clients. Our capabilities include cost analysis, provider payment system design and evaluation, data system design and implementation, policy analysis, and program design and evaluation. We have conducted projects for several Federal agencies, state governments, health insurers, foundations, employers, and professional and trade associations. Recently we have undertaken projects for hospitals and other health care providers.

The Center's multi-disciplinary staff is based in Columbia, Maryland and Albany, New York. Staff members have academic backgrounds in economics, accounting, health care administration, public health, operations research, public administration, health insurance, medical sociology, geography and information systems.

Our work with the Federal government has included a wide variety of experience using resource costing methods. In a project undertaken in 1982 for the Office of the Assistant Secretary of the Department of Health and Human Services, we developed the resource costing model that will be used in the Health Care Financing Administration's (HCFA) "Study of the Costs of Administering Childhood Immunizations." In the 1982 study, CHPS evaluated alternative measures of hospital costs in over 20 facilities and compared findings to costs reported in Medicare Cost Reports. In 1988, we repeated the study to examine the changes in hospital costs that had occurred. This study also included an analysis of resource costs in an equal number of ambulatory surgery centers. In 1992 CHPS initiated a HCFA-funded study to provide data on resource use and costs for a wide variety of surgical procedures, medical visits and diagnostic tests. Resource utilization and cost data was collected from a representative sample of hospital outpatient departments, ambulatory surgery centers, and physician offices. Data was used to test the equity and adequacy of the relative weights and payment levels to be used in an outpatient prospective payment system.

Additional experience relevant to this HCFA resource costing study includes a study conducted for the Prospective Payment Assessment Commission in which reported inpatient costs were compared to resource costs. This study required the participation of over 90 facilities. In projects conducted for New York State's Department of Health, we assisted in designing and pricing the Products of Ambulatory Care (PACs), and the Products of Ambulatory Surgery (PAS). In the PAS project, we validated resource costs used to price PAS. Similar studies conducted by CHPS have focused on methadone/primary care clinics, hospital and physician office services for mentally retarded and developmentally disabled patients, and hospital and home care services for HIV infected persons.

The Center for Health Policy Studies takes great pride in its ability to work closely with facility staff in an efficient and cooperative manner. Our extensive experience assures that data collection will be accomplished with a minimum disruption to ongoing facility operations. In addition, working with CHPS enables facilities to access comparative data not available elsewhere while being guaranteed data confidentiality.

PHYSICIAN PRACTICE SITE VISIT SCHEDULE
(multispecialty, pediatric group, solo practice)

Time	Activity Description
9:00 - 9:30	Meet with Administrator/Office Manager: 1. briefly review study's objective 2. answer questions 3. ask questions from Interview Guide
9:30 - 11:30*	Conduct Observations & Complete Resource Use Data Collection Guide (minimum five immunizations)
11:30 - 12:15	Meet with Administrator/Office Manager: 1. complete Unit Cost Data Collection Guide 2. make arrangements to obtain unavailable information 3. conduct exit interview

- * Observation time frames will vary from practice to practice depending on immunization volume. The two hour time frame indicated in the schedule is based on the average time required to conduct a minimum of five observations at "test" sites.

**STUDY OF THE COSTS OF ADMINISTERING
CHILDHOOD IMMUNIZATIONS**

AGREEMENT TO PARTICIPATE

I, _____, being authorized to do so, agree to allow
_____ (name of multispecialty, pediatric
group, or solo practice) to participate in a study being conducted by the Center for Health
Policy Studies (CHPS) on behalf of the Health Care Financing Administration (HCFA).
The purpose of the study, as it has been explained to me, is to determine the costs of
administering childhood immunizations. I understand that participation in this study is
strictly voluntary and that there are no penalties for declining participation.

Sincerely,

(Signature)

(Title)

(Date)

PARENT CONSENT FORM**Cost of Administering Childhood Immunizations
On-Site Observation**

The Center for Health Policy Studies (CHPS), a private health care consulting firm located in Columbia, is studying the cost of administering childhood immunizations. The study is sponsored by the Health Care Financing Administration (HCFA), the government agency responsible for Medicare and Medicaid. Once the study determines the range of costs for immunization, the results will be used to set limits on how much physicians may charge under the Vaccines for Children (VFC) program recently enacted by Congress.

CHPS is observing immunizations as they are given to better understand how differences in immunization procedures among practices can lead to differences in cost. National data collection efforts are currently underway. This medical facility has agreed to serve as one of our observation sites. However, parental consent is needed before we can observe the immunization your child is about to receive.

Your child's participation in the test study is completely voluntary and will have no effect on the treatment he or she receives. Any data collected during the observation of your child's immunization will remain completely confidential and neither you or your child will be identified. The observation will be limited to the time required to give the immunization. During that time an observer will simply watch and take notes.

By signing below, you are stating that you have read this document, understand the request that is being made of you, and are willing to allow your child's immunization to be observed for purposes of the study.

Parent's Name

Parent's Signature

Date

STUDY OF THE COSTS OF ADMINISTERING CHILDHOOD IMMUNIZATIONS PHONE SCRIPT TO SCHEDULE PRACTICE SITE VISITS

Once a practice is selected and a recruitment package is sent to the manager/administrator of the practice, the Center for Health Policy Studies will place a call to the office manager/administrator. The following describes the conversation that will take place:

"Hello, my name is _____ (person making the call). I am with the Center for Health Policy Studies in Columbia, Maryland. We are conducting a study of the cost of administering childhood immunizations for the Health Care Financing Administration. Did you receive the information package that was sent to your office? _____"

(If yes, say:) As is stated in the package, the purpose of the study is to determine resource costs associated with the administration of childhood immunizations. The study involves site visits to multispecialty group, pediatric group and sole practices throughout the country. The data collected will be used to evaluate physician charge limits under the Vaccines for Children (VFC) program recently enacted by Congress. (Continue to next question)

(If no, say:) I'd like to send you another package but let me just tell you a little bit about the study. The purpose of the study is to determine resource costs associated with the administration of childhood immunizations. The study involves site visits to multispecialty group, pediatric group and sole practices throughout the country. The data collected will be used to evaluate physician charge limits under the Vaccines for Children (VFC) program recently enacted by Congress. (Confirm the name and address of the office manager and practice and indicate that you will send another package.)

Do you have any questions regarding the study? (If so, answer the questions)

Will your practice participate in the study? (If yes, continue. If no, thank them for their time)

Who will be the contact person? _____ (Obtain name, title and telephone number of the designated contact person)

(If the office manager is the designated contact person continue with the following paragraph. If another person is designated, call them and repeat the first paragraph of this script. Determine if they have received the package sent to the office manager and continue with the following)

The information package includes an introductory letter from HCFA, a letter from the Center for Health Policy Studies, a project description, a HCFA summary, a CHPS summary, a sample site visit schedule, a form letter of participation for a representative of your office to sign, and a sample parent consent form.

As shown on the sample site visit schedule, we need to schedule a three hour visit to your practice for one of our staff members. We will need to collect some financial data on your practice. Financial data needed includes salary information, and supply and equipment costs. An interview will also need to be scheduled with the practice manager/administrator. Immunization observation, however, will account for the majority of time required.

When will your office and the staff indicated on the site visit schedule be available for a site visit? _____ (Determine the office's preference for scheduling the site visit and indicate that you will call back to confirm the date. Check the availability of other practices to be visited in the same area of the country.)

Thank you for your time. We look forward to meeting with you and your staff.

EXHIBIT 3

INTERVIEW GUIDE

Physician Practice Name: _____	Date: _____
Physician Practice Address: _____	Interviewee: _____
_____	Position: _____
Physician Practice Telephone No: _____	Interviewer: _____

Note: Explain purpose of study before initiating discussion. Use questions listed below as a guide to gaining an understanding of how immunizations are given and any unusual attributes of practices.

1. What is the sequence and timing used by this practice in the administration of childhood vaccinations? Is it documented? _____

2. Are immunizations given most frequently separately or together? Which combinations are most common? _____

3. Are immunizations normally part of a visit with a different primary purpose or are they the sole purpose of a visit? What is the percentage (approximate) of visits where immunizations are the sole purpose? _____

4. In this practice, are immunizations given by a physician, nurse or other practitioner? What percentage of immunizations are given by each type of provider? If a practitioner other than a physician or nurse gives an immunization, what is the education and experience of the practitioner? _____

5. Describe the process for immunizations from the time the child arrives at the practice until the child leaves. _____

EXHIBIT 3 (CONT.)

6. Do any circumstances exist for some children that change the normal immunization process? (e.g. sick, distraught, handicapped) Please identify these circumstances? How do they change the process? _____

7. Practice Characteristics:

Type of Practice: • Multispecialty Group ☐ (Staff Model HMO ☐ Other ☐
• Pediatric Group ☐
• Solo Practice ☐

Size of Practice: • Number of Physicians _____
• Number of Pediatricians _____
• Number of Other Practitioners (including nurses) _____
• Number of Total Employees _____
• Approximate Number of Children Immunized Annually _____

Location of Practice: • Metropolitan ☐
• Non-metropolitan ☐

8. Please describe this practice's current process for obtaining vaccines*:

* interviewers should be aware of the fact that Connecticut and Illinois are "universal purchase states". Practices located in UP states should be specifically questioned regarding that program's affect on vaccine acquisition.

9. Comments: _____

EXHIBIT 4

RESOURCE USE DATA COLLECTION GUIDE

Physician Practice Name: _____	Date: _____
Physician Practice Address: _____	Time: _____
	Data Collector: _____
Physician Practice Telephone No: _____	

Note: Separate form to be completed for each patient. Refer to description of process in interview guide to determine whether modifications in data collection are required. Describe any modifications. _____

1. Immunization is:
Sole Purpose of Visit ☐ Part of Visit ☐
2. Type of immunization(s):
DTP ☐ DTaP ☐ HEP B ☐ HIB ☐ MMR ☐ OPV ☐
3. Patient Age/Visit: _____
4. Practitioner Giving Immunization: Physician ☐ Nurse ☐ Other ☐
If other, note job title and duties: _____
5. Times: Time of patient arrival: _____
Time patient entered exam room: _____
Time examination completed (if applicable): _____
Time required to obtain parent/guardian consent: _____
*Time for preparation of vaccine: start: _____ end: _____
Time practitioner initiated immunization: _____
Time immunization began: _____
Time immunization completed: _____
Time practitioner left: _____
Time immunization documentation began: _____
Time immunization documentation completed: _____
Time patient left immunization room: _____
Time patient left practice: _____

*(Practitioner preparing vaccine: Physician ☐ Nurse ☐ Other ☐)

6. Supplies Used (#'s):

Syringe:	_____
Needle:	_____
Alcohol Swab:	_____
Band-Aid:	_____
Gloves:	_____
Other (list):	_____

7. Comments: _____

EXHIBIT 5

UNIT COST DATA COLLECTION GUIDE

Physician Practice Name: _____	Date: _____
Physician Practice Address: _____	Time: _____
_____	Data Collector: _____
Physician Practice Telephone No: _____	

1. Professional Costs:

Salaries: Staff Physician _____
 Nurse _____
 Other A _____
 B _____
 C _____

Source: Payroll register - Record average hourly salary. If more than one class of nurse or if there is substantial variation in a category, record each relevant amount and describe in notes.

Fringe Benefits: Percentage of salary: _____

Source: Office manager or review of general ledger. Be certain that percentage is well documented and includes payroll taxes, health insurance, other insurance, pension and profit-sharing.

2. Supply Costs:

Supply	Gross Count	Gross Cost	Cost per Unit
<i>Syringe</i>			
<i>Needle</i>			
<i>Alcohol Swab</i>			
<i>Band-Aid</i>			
<i>Gloves</i>			
<i>Cotton Balls</i>			
<i>VICP Materials</i>			
<i>Other:</i>			
<i>A</i>			
<i>B</i>			
<i>C</i>			

Source: Most recent purchase invoices from medical supply companies.

EXHIBIT 5 (CONT.)**3. Indirect Costs (not readily available from existing data sources)****3.1 Costs of acquiring vaccines (processing and administration only)**Describe process used to acquire vaccines: _____

Identify staff member (by title) who completes process for acquiring vaccines: _____

Identify costs of staff member:

Salary (per hour) _____

Fringe Benefits (percentage of salary) _____

Identify amount of time allocated per clinical employee for immunization related training (e.g. OSHA blood-borne pathogen, vaccine handling): _____
_____Identify any other resources and their costs associated with acquiring vaccines:

_____**3.2 Identify special equipment and/or practice overhead costs that are related to immunizations but might be overlooked by existing data sources. Describe and list each cost.**

Description	Cost	Unit of Measurement	Cost per Unit
<i>Equipment:</i>			
A			
B			
C			
<i>Overhead:</i>			
A			
B			
C			

Source: Office manager, payroll register, general ledger.

EXHIBIT 5 (CONT.)

4. Comments: _____

CENTER FOR HEALTH POLICY STUDIES

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT**[Docket No. N-95-3853; FR-3833-N-02]****Preferences for Admission to Assisted Housing; Preference for Working Families—Notice of Statutory Amendment; Clarification**

AGENCY: Office of the Assistant Secretary for Housing—Federal Housing Commissioner; and Office of the Assistant Secretary for Public and Indian Housing, HUD.

ACTION: Notice.

SUMMARY: On January 18, 1995, HUD published a notice that advised that sections 6(c)(4)(A)(ii) and (8)(d)(1)(A)(ii) of the U.S. Housing Act of 1937 were amended by the HUD Appropriations Act for Fiscal Year 1995 to provide a discretionary local preference for admission to public housing and HUD-assisted housing for “families that include one or more adult members who are employed.” The amendment by the HUD Appropriations Act provides that this preference for working families “shall be effective only during fiscal year 1995.”

The purpose of this notice is to clarify that preferences for admitting working families to public housing and HUD-assisted housing can continue to be used indefinitely, under the conditions described in HUD final rules published on July 18, 1994, and entitled, respectively, “Preferences for Admission to Assisted Housing” and “Section 8 Certificate and Voucher Programs Conforming Rule: Admissions.”

FOR FURTHER INFORMATION CONTACT: For the public housing and Section 8 Existing Housing programs, Sherone Ivey, Occupancy Division, Office of Public Housing, (202) 708-0744 (voice); (202) 708-0850 (TDD).

For other Section 8 programs, Barbara Hunter, Planning and Procedures Division, Office of Multifamily Housing, Office of Housing (202) 708-3944 (voice); (202) 708-4594 (TDD).

None of these telephone numbers is toll-free. The individuals listed above are located at the Department of Housing and Urban Development, 451 Seventh Street, SW, Washington, DC 20410.

SUPPLEMENTARY INFORMATION:**I. Background**

On January 18, 1995 (60 FR 3646), HUD published a notice that advised that sections 6(c)(4)(A)(ii) and (8)(d)(1)(A)(ii) of the U.S. Housing Act of 1937 (42 U.S.C. 1437d and 42 U.S.C.

1437f) were amended by the HUD Appropriations Act for Fiscal Year 1995 (Pub.L. 103-327, approved September 28, 1994, 108 Stat. 2315) to provide a discretionary local preference for admission to public housing and HUD-assisted housing for “families that include one or more adult members who are employed.” The two statutory amendments cover public housing and section 8 existing housing.

In the January 18, 1995 notice, HUD noted that the preference added by the Congress is consistent with two HUD final rules, both published on July 18, 1994, and entitled, “Preferences for Admission to Assisted Housing” (59 FR 36616), and “Section 8 Certificate and Voucher Programs Conforming Rule: Admissions” (59 FR 36662). The January 18, 1995 notice also advised that the HUD Appropriations Act provides that this preference “shall be effective only during fiscal year 1995.”

Since publication of the January 18, 1995 notice, HUD has received a number of inquiries concerning the HUD Appropriations Act “limitation” of the working family preference to FY 1995.

The purpose of this notice is to clarify that preferences for admitting working families to assisted housing can continue to be used indefinitely, under the conditions described in the two HUD final rules published on July 18, 1994.

The amendments made by the HUD Appropriations Act cover public housing and section 8 existing housing (including section 8 project-based assistance), but not Indian housing. However, all three programs can establish preferences for working families, according to the terms in HUD regulations, and HUD encourages the adoption and continued use of such preferences.

Dated: April 24, 1995.

Jeanne K. Engel,

General Deputy Assistant Secretary for Housing—Federal Housing Commissioner.

Michael B. Janis,

General Deputy Assistant Secretary for Public and Indian Housing.

[FR Doc. 95-10686 Filed 5-1-95; 8:45 am]

BILLING CODE 4210-27-P and 4210-33-P

Office of the Assistant Secretary for Administration**[Docket No. N-95-3914; FR 3896-N-01]****Privacy Act of 1974—Amended System of Records**

AGENCY: Office of the Assistant Secretary for Administration, HUD.

ACTION: Notice; Modification of an existing system of records.

SUMMARY: Pursuant to the provision of the Privacy Act of 1974, as amended (5 U.S.C. 552a) the Assistant Secretary for Public and Indian Housing is amending the system of records titled, “Tenant Eligibility Verification Files”—HUD/PIH-1, previously published at 58 FR 37600; July 12, 1993 and amended at 59 FR 14869; March 30, 1994. This system of records contains computer matching and tenant eligibility verification records necessary to support the identification of tenants who have been or may be obtaining excessive rental housing assistance. The system of records also supports referrals of information concerning those tenants to entities that administer HUD rental assistance programs (i.e., housing agencies [which includes public housing agencies and Indian housing authorities], owners of subsidized multifamily projects, and management agents) and to law enforcement agencies for possible administrative or legal actions, as appropriate. However, HUD may not redisclose to entities that administer HUD programs information that HUD obtains from the Social Security Administration (SSA) and the Internal Revenue Service (IRS), pursuant to 26 U.S.C. 6103(l)(7)(D)(ix)—a section of the Internal Revenue Code added by section 13403 of the Omnibus Budget Reconciliation Act of 1993, Pub. L. 103-66.

Amendments to the system of records: (a) Expand the scope of HUD/PIH-1 to include: Tenant records for all HUD assisted housing programs; earned and unearned income records that HUD will obtain from the SSA and the IRS, respectively; Title II (social security) and Title XVI (supplemental security income) records that HUD will obtain from the SSA; records provided by other Federal agencies for matching to tenant data that may affect determinations of eligibility for, or the amount of, HUD or other Federal benefits that tenants receive, (b) cite legal authorities for the SSA and the IRS records to be included in HUD/PIH-1, (c) cite routine uses for the SSA and the IRS records, (d) delete specific reference to United States Postal Service records, (e) increase the retention period for the HUD/PIH-1 records from 6 months to 1 year, (f) incorporate the additional routine use previously published at 59 FR 14869; March 30, 1994, concerning referral to Federal employers to ensure effective implementation of the Standard of Ethical Conduct for Employees of the Executive Branch, and (g) add a routine use concerning statistical information

needed to evaluate the effectiveness of computer matching, income verification and related administrative or legal actions taken.

The exemptions of HUD/PIH-1 from certain provisions of the Privacy Act of 1994, described at 59 FR 9406; February 28, 1994, continue to apply to HUD/PIH-1, as amended.

EFFECTIVE DATE: This proposal shall become effective without further notice on June 1, 1995, unless comments are received during or before that date which would result in a contrary determination.

ADDRESSES: Interested persons are invited to submit comments regarding this notice to the Rules Docket Clerk, Office of General Counsel, Room 10276, Department of Housing and Urban Development, 451 Seventh Street, SW, Washington, DC 20410-0500.

Communications should refer to the above docket number and title. An original and four copies of comments should be submitted. Facsimile (FAX) comments are not acceptable. A copy of each communication submitted will be available for public inspection and copying between 7:30 a.m. and 5:30 p.m. weekdays at the above address.

FOR FURTHER INFORMATION CONTACT: Jeanette Smith, Departmental Privacy Act Officer, Telephone Number (202) 708-2374, concerning Privacy Act matters. David L. Decker, Director, Computer Matching Activities, Office of the Public and Indian Housing Comptroller, Telephone Number (202) 708-0099, concerning computer matching matters. [These are not toll free numbers.]

SUPPLEMENTARY INFORMATION: The amendments to this system of records are needed to: (a) Expand and improve the effectiveness of HUD's computer matching programs by consolidating responsibilities concerning assisted housing programs into one office, (b) implement provisions of the Omnibus Budget Reconciliation Act of 1993 that permit SSA and IRS disclosure to HUD of earned and unearned income information, respectively, for tenants who receive housing assistance from HUD's programs, (c) develop more efficient and effective methods for verifying social security and supplemental security income information used in determining tenants' eligibility for, and amount of, housing assistance, and (d) permit inclusion of automated records of other Federal agencies for matching to tenant data that may affect determinations of eligibility for, or the amount of, HUD or other Federal benefits that tenants receive.

Regarding item (c) above, entities that administer HUD's assisted housing programs currently request from the SSA social security and supplemental security income information needed to determine tenants' eligibility for, and level of benefits, by submitting a mark sense card to the SSA. Then the SSA processes the card and mails the income information to the entity administering HUD assisted housing programs. The SSA has advised HUD of plans to terminate obsolete mark sense card operations, and requested that HUD work with SSA in developing an alternative process. HUD and the SSA have concluded that computer matching provides a more efficient and more effective technique for providing social security and supplemental security information to entities that administer HUD's assisted housing programs than the mark sense card operations. HUD plans to use HUD/PIH-1 records in identifying tenants who have underreported social security and supplemental security information.

Entities that administer HUD's assisted housing programs may continue to use the mark sense card processing operations, which is also known as the Third Party Query System (TPQS), until further notice. HUD plans to initiate testing of computer matching to verify social security and supplemental income information during Fiscal Year 1995. When HUD has demonstrated success in the computer matching process and is ready for large-scale implementation of the matching, HUD will, in coordination with SSA, inform entities that administer HUD assisted housing programs to discontinue use of the TPQS.

HUD will also use HUD/PIH-1 in reporting potential income disparities to tenants or the entities that administer HUD's assisted housing programs, as permitted under law. A notice of the HUD/SSA/IRS computer matching program concerning earned and unearned income, social security, and supplemental security income is published in today's **Federal Register**.

A report of HUD's intention to establish the system has been submitted to the Office of Management and Budget (OMB), the Senate Committee on Governmental Affairs, and the House Committee on Government Operations pursuant to paragraph 4c of Appendix I to OMB Circular No. A-130, "Federal Agency Responsibilities for Maintaining Records About Individuals," July 25, 1994; 59 FR 37914.

Authority: 5 U.S.C. 552a, 88 Stat. 1896; sec. 7(d) Department of Housing and Urban Development Act (41 U.S.C. 3535(d)).

Issued at Washington, DC, April 20, 1995.

Marilynn A. Davis,

Assistant Secretary for Administration.

HUD/PIH-1

SYSTEM NAME:

Tenant Eligibility Verification Files.

SYSTEM LOCATION:

Headquarters.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Tenants receiving housing assistance provided by programs administered by the Department of Housing and Urban Development, or information concerning those tenants obtained from other Federal or State agencies, housing agencies, owners, and management agents.

CATEGORIES OF RECORDS IN THE SYSTEM:

Records consist of: (1) Automated tenant data obtained from HUD's HUD/H-11, Tenant Housing Assistance and Contract Verification Data, published at 59 FR 6035; February 9, 1994, (two HUD automated systems—the Multifamily Tenant Certification System and the Tenant Rental Assistance Certification System—are the primary components of HUD/H-11); (2) automated tenant data provided by housing agencies, owners or management agents (generally these records are available in HUD/H-11); (3) automated earned income data that the SSA provides under 26 U.S.C. 6103(l)(7)(A); (4) automated unearned income data that the IRS provides to HUD under 26 U.S.C. 6103(l)(7)(B); (5) automated Title II (social security) and Title XVI (supplemental security income) data that the SSA provides to HUD under a routine use; (6) automated wage, salary and annuity data from State wage information collection agencies; (7) automated data from the Office of Personnel Management's General Personnel Records (OPM/GOVT-1), the Civil Service Retirement and Insurance Records System (OPM/Central-1); (8) the Department of Defense's Defense Manpower Data Center Data Base (S322.10.DMDC); (9) automated records from the SSA's Master Files of Social Security Number Holders, known as the Enumeration Verification System; (10) applications for housing assistance and other related documentation obtained from tenant case files maintained by housing agencies, owners, and management; (11) data received from employers confirming income or deductions supporting determinations of eligibility for, and the amount of, housing assistance benefits; (12) automated records provided by other Federal agencies for matching to tenant

data that may affect determinations of eligibility for, or the amount of, HUD or other Federal benefits that tenants receive; (13) automated records provided by other Federal agencies under the investigative exclusion of the Computer Matching and Privacy Protection Act of 1988; and (14) automated records provided by housing agencies, owners and management agents regarding actions taken on computer matching results.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

The records will be obtained to detect excessive assisted housing that tenants receive using income information as provided under sections 3003 and 13403 of the Omnibus Budget Reconciliation Act of 1993, Public Law, 103-66; and section 904 of the Stewart B. McKinney Homeless Assistance Amendments Act of 1988, Public Law 100-628.

The Omnibus Budget Reconciliation Act of 1993, Public Law 103-66, permitted HUD to request from the Commissioner of the SSA and the Secretary of the Treasury, SSA and IRS earned and unearned income information, respectively, needed to verify the incomes of tenants who receive housing assistance. However, the Act precludes HUD from redisclosing that information to entities that administer HUD programs (i.e., housing agencies, owners and management agents). But the Act allows HUD to notify those entities that disparities exist between the tenant-reported incomes and income obtained from independent income sources, i.e., the SSA, the IRS or State wage data. HUD plans to identify disparities between tenant-reported and independent income source information, to notify tenants of disparities, and to request that the tenants disclose independent income source data to entities administering HUD programs.

The McKinney Amendments of 1988 authorized HUD to request wage and claim information from State agencies responsible for the administration of State unemployment law, to permit computer matching in HUD's rental assistance programs.

Section 165 of the Housing and Community Development Act of 1987, Public Law 100-242; the National Housing Act, 12 U.S.C. 1701-1750g authorizes HUD to require applicants and participants (including all members of their household six (6) years of age and older) in HUD-administered programs involving housing assistance to disclose to HUD their social security

numbers as a condition of initial or continuing eligibility for participation.

Applicable laws concerning HUD's assisted housing programs include: The United States Housing Act of 1937, 42 U.S.C. 1437-1437o; and section 101 of the Housing and Urban Development Act of 1965, 12 U.S.C. 1701s.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES:

1. Records included in the system may be used in conducting computer matching to aid in the identification of tenants who have received excessive rental housing assistance.
2. Records that HUD obtains from the SSA and the IRS under the authority of 26 U.S.C. 6103(l)(7), may be disclosed only to the tenant/taxpayer, to HUD employees responsible for investigating or prosecuting such violation or enforcing or implementing a statute, rule or regulation, or as otherwise permitted under 26 U.S.C. 6103.
3. Records that indicate a potential violation of law, whether criminal, civil or regulatory in nature, except for records obtained from the SSA and the IRS under 26 U.S.C. 6103(l)(7), may be disclosed to the appropriate Federal, State or local agency charged with the responsibility for investigating or prosecuting such violation or enforcing or implementing a statute, rule or regulation.
4. Records, except for those obtained from the SSA or IRS under the authority of 26 U.S.C. 6103(l)(7), may be disclosed to a congressional office in response to an inquiry from that congressional office made at the request of the individual who is the subject of the records.
5. Records, with the exception of those obtained pursuant to 26 U.S.C. 6103(l)(7), may be disclosed to housing agencies, owners and management agents in order to assist them in determining tenants' eligibility for housing assistance, and the amount of that assistance and to facilitate recovery of money or property or other administrative actions, i.e., eviction, necessary to promote the integrity of programs.
6. Records, except for those obtained from the SSA and the IRS under 26 U.S.C. 6103(l)(7), may be disclosed during the course of an administrative proceeding where HUD or a housing agency, owner or management agent is a party to the litigation and disclosure is relevant and reasonably necessary to adjudicate the matter.
7. Records, except for those obtained from the SSA and the IRS under 26 U.S.C. 6103(l)(7), may be disclosed to a Federal agency, in response to its

request, in connection with the hiring or retention of an employee, the issuance of a security clearance, the reporting of an investigation of an employee, the letting of a contract, or the issuance of a license, grant or other benefit by the requesting agency, to the extent that the record is relevant and necessary to the requesting agency's decision on the matter.

8. Records, except for those obtained from the SSA and the IRS under 26 U.S.C. 6103(l)(7), may be disclosed to a Federal agency to initiate Federal salary or annuity offsets as necessary to collect excessive housing assistance received by the tenant.

9. Records, except for those obtained from the SSA and the IRS under 26 U.S.C. 6103(l)(7), concerning an individual's receipt of excessive housing assistance, including the individual's actions to repay the same, may be disclosed to the Federal agency that employs such individual, for the purpose of notifying the employer of potential violation of the Standards of Ethical Conduct for Employees of the Executive Branch.

10. Records may be used to provide statistical information for use in evaluating the effectiveness of computer matching, income verification and related administrative or legal actions taken.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are stored manually in tenant case files and electronically in office automation equipment. Records, except for those obtained from the SSA and the IRS under 26 U.S.C. 6103(l)(7)(A) and (B), may also be stored on mainframe computer facilities.

RETRIEVABILITY:

Records may be retrieved by manual or computer search of indices by the name, social security number, housing agency, owner or management agent.

SAFEGUARDS:

Records are maintained in locked file cabinets or in metal file cabinets in secured rooms or premises with access limited to those persons whose official duties require access. Computer files and printed listings are maintained in locked cabinets. Computer terminals are secured in controlled areas which are locked when unoccupied. Access to automated records is limited to authorized personnel who must use a password system to gain access. HUD will safeguard the SSA and the IRS records obtained pursuant to 26 U.S.C.

6103(l)(7)(A) and (B) in accordance with 26 U.S.C. 6103(p)(4) and the IRS's "Tax Information Security Guidelines for Federal, State and Local Agencies."

RETENTION AND DISPOSAL:

Only those computer files and printouts created from the computer matching that meet predetermined criteria are maintained. These records will be destroyed as soon as they have served the matching program's purpose. All other records will be destroyed as soon as possible within 1 year. Paper listings containing personal identifiers will be shredded. Computer source files provided by other organizations will be returned to those organizations or destroyed in accordance with computer matching agreements.

Except for tax return information that HUD may not redisclose to housing agencies, owners or agents, the information may be referred to housing agencies, owners or agents for administrative actions, i.e., recoupment of excessive housing assistance. Information obtained through computer matching and tenant case file reviews will be destroyed as soon as follow-up processing of this information is completed, unless the information is required for evidentiary reasons or needed by housing agencies, owners and agents for use in program eligibility determinations. When needed for evidentiary documentation, the information will be referred to the HUD Office of Inspector General (OIG) or other appropriate Federal, State or local agencies charged with the responsibility for investigating or prosecuting such violations. When referred to the HUD OIG the information then becomes a part of the Investigative Files of the Office of Inspector General, HUD/OIG-1.

SYSTEM MANAGER AND ADDRESS:

Director, Computer Matching Activities, Office of the Public and Indian Housing Comptroller, U.S. Department of Housing and Urban Development, 451 Seventh Street, SW., Room 5156, Washington, DC. 20410.

NOTIFICATION PROCEDURES:

Records are generally exempt from Privacy Act access. However, the System Manager will give consideration to a request from an individual for notification of whether the system contains records pertaining to that individual.

RECORD ACCESS PROCEDURES:

Records are generally exempt from Privacy Act access. However, the System Manager will give consideration

to a request from an individual for access to records pertaining to that individual. The procedures for requesting access to records appear in 24 CFR part 16.

CONTESTING RECORD PROCEDURES:

Records are generally exempt from Privacy Act amendment or correction. However, the System Manager will give consideration to a request from an individual for amendment or correction of records pertaining to that individual. The procedures for amendment or correction of records appear in 24 CFR part 16.

RECORD SOURCE CATEGORIES:

The Assistant Secretary for Public and Indian Housing collects information from a variety of sources, including: Housing agencies, the Assistant Secretary for Housing-Federal Housing Commissioner (tenant information provided by owners and agents), State wage information collection agencies, other Federal and State agencies, law enforcement agencies, program participants, complainants, and other nongovernmental sources.

EXEMPTIONS FROM CERTAIN PROVISIONS OF THE ACT:

This system of records is exempt from the requirements of: subsections (c)(3), (d)(1), (d)(2) and (e)(1) of the Privacy Act pursuant to 5 U.S.C. 552a(k)(2); and from the requirements of subsection (d)(1) of the Privacy Act pursuant to 5 U.S.C. 552a(k)(5).

[FR Doc. 95-10684 Filed 5-1-95; 8:45 am]

BILLING CODE 4210-01-P

[Docket No. N-95-3848; FR 3795-N-01]

Privacy Act of 1974; Matching Program: Matching Tenant Data in Assisted Housing Programs

AGENCY: Office of the Assistant Secretary for Administration, HUD.

ACTION: Notice of matching program.

SUMMARY: Pursuant to the Computer Matching and Privacy Protection Act of 1988, as amended, and the Office of Management and Budget's Guidance on the statute, HUD announces a revised matching program involving comparisons between income data provided by applicants or participants in HUD's assisted housing programs and independent sources of income information. The matching program will be carried out to detect excessive housing assistance under the National Housing Act, the United States Housing Act of 1937, and section 101 of the Housing and Community Development

Act of 1965. The program provides for the verification of the matching results and the initiation of appropriate administrative or legal actions, primarily through public housing agencies, Indian housing authorities, and private owners/management agents for subsidized multifamily projects.

This notice provides an overview of computer matching for HUD's assisted housing programs. Specifically, this notice:

(1) Adds Social Security Administration (SSA) and Internal Revenue Service (IRS) data concerning earned and unearned income to the matching program as independent sources for computer matching;

(2) Describes verification processes for the SSA and IRS matching that differ from processes previously used;

(3) Expands the matching to cover social security and supplemental social security income data maintained by the SSA; and

(4) Recognizes the transfer of computer matching/tenant income verification functions from HUD's Office of Inspector General to offices that administer the assisted housing programs. Those offices include the Office of the Assistant Secretary for Public and Indian Housing and the Office of the Assistant Secretary for Housing—Federal Housing Commissioner.

This notice also sets forth new starting and ending dates for the matching program.

EFFECTIVE DATES: HUD anticipates that during the third quarter of calendar year 1995 it will: (a) Request that SSA and IRS conduct the initial computer matching, and (b) compare SSA and IRS matching results to its tenant data.

During the third quarter of calendar year 1995, HUD plans to initiate the tenant income verification process for a limited number of organizations that administer HUD assisted housing programs. HUD anticipates that the tenant income verification process will be expanded in Fiscal Year 1996 to include more organizations that administer HUD assisted housing programs. The projected dates for SSA and IRS matching are effective unless comments are received that result in a contrary determination, and HUD withdraws this notice.

The computer matching described in this notice may begin after compliance with the reporting requirements cited in section 4 of Appendix I to OMB Circular No. A-130—Federal Agency Responsibilities for Maintaining Records About Individuals (59 FR 37916; July 25, 1994). That section

requires that Federal agencies provide the Chair of the House Committee on Government Operations, the Chair of the Senate Committee on Government Affairs, and the Office of Management and Budget with notice of the matching program and computer matching agreements 40 days before operating the program.

ADDRESSES: Interested persons are invited to submit comments regarding this notice to the Rules Docket Clerk, Office of General Counsel, Room 10276, Department of Housing and Urban Development, 451 Seventh Street, SW, Washington, DC 20410-0500.

Communications should refer to the above docket number and title.

Facsimile (FAX) comments are not acceptable. A copy of each communication submitted will be available for public inspection and copying between 7:30 a.m. and 5:30 p.m. weekdays at the above address.

FOR FURTHER INFORMATION CONTACT: *For Privacy Act:* Jeanette Smith, Departmental Privacy Act Officer, Room 4178, Department of Housing and Urban Development, 451 Seventh Street, SW, Washington, DC 20410, telephone number (202) 708-2374. Hearing- or speech-impaired individuals may call (202) 708-1112 (Federal Information Relay Service—TDD). *For further information from recipient agency:* David L. Decker, Director, Computer Matching Activities, Office of the Public and Indian Housing Comptroller, Room 5156, Department of Housing and Urban Development, 451 Seventh Street, SW, Washington, DC 20410, telephone number (202) 708-0099, TDD—(202) 708-0850; or Barbara D. Hunter, Acting Director, Planning and Procedures Division, Office of Multifamily Housing Management, Room 6180, Department of Housing and Urban Development, 451 Seventh Street, SW, Washington, DC 20410, telephone number (202) 708-3944, TDD—(202) 708-4594. (These telephone numbers are not toll-free.)

SUPPLEMENTARY INFORMATION: This notice supersedes a similar notice published in the **Federal Register** on December 12, 1991 (56 FR 64793).

The Computer Matching and Privacy Protection Act of 1988, as amended (5 U.S.C. 552a) (the CMPP Act), the Office of Management and Budget's (OMB's) guidance on this statute entitled "Final Guidance Interpreting the Provisions of Public Law 100-503, the Computer Matching and Privacy Protection Act of 1988" (OMB Guidance), and OMB Circular No. A-130 require publication of notices of computer matching programs. OMB's Guidance augments the "OMB Guidelines on the

Administration of the Privacy Act of 1974" that were issued July 1, 1975. Appendix I to OMB's Revision of Circular No. A-130, "Transmittal 2, Management of Federal Information Resources," prescribes Federal agency responsibilities for maintaining records about individuals. In accordance with the CMPP Act and Appendix I to OMB Circular No. A-130, copies of this notice are being provided to the Committee on Government Operations of the House of Representatives, the Committee on Governmental Affairs of the Senate, and OMB's Office of Information and Regulatory Affairs.

I. Authority

This matching program is being conducted pursuant to sections 3003 and 13403 of the Omnibus Budget Reconciliation Act of 1993 (Pub. L. 103-66, approved August 10, 1993); section 904 of the Stewart B. McKinney Homeless Assistance Amendments Act of 1988 (42 U.S.C. 3544); section 165 of the Housing and Community Development Act of 1987 (42 U.S.C. 3543); the National Housing Act (12 U.S.C. 1701-1750g); the United States Housing Act of 1937 (42 U.S.C. 1437-1437o); and section 101 of the Housing and Urban Development Act of 1965 (12 U.S.C. 1701s).

The Omnibus Budget Reconciliation Act of 1993 (Budget Reconciliation Act) authorizes HUD to request from the Social Security Administration (SSA) and the Internal Revenue Service (IRS) return information as prescribed in section 6103(l)(7) of title 26 of the United States Code (Internal Revenue Code). The Budget Reconciliation Act limits HUD's access to tax return data and prohibits HUD's redisclosure of tax return data to public housing agencies and Indian housing authorities (collectively referred to as HAs), and private owners/management agents for subsidized multifamily projects. However, it allows HUD to disclose the fact that discrepancies exist between information provided by the tenant and other sources, and to request reverification of income in light of the tenant's uncertain eligibility for, or level of, benefits.

The Budget Reconciliation Act requires that applicants and participants in assisted housing programs sign a consent form authorizing the Secretary of HUD to request that the Commissioner of Social Security and the Secretary of the Treasury release the return information. A final rule regarding participants' consent to the release of information was published by HUD in the **Federal Register** on March 20, 1995 (60 FR 14632).

The Stewart B. McKinney Homeless Assistance Amendments Act of 1988 authorizes HUD and HAs (but not private owners/management agents for subsidized multifamily projects) to request wage and claim information from State Wage Information Collection Agencies (SWICAs) responsible for administering State unemployment laws in order to undertake computer matching. This Act authorizes HUD to require applicants and participants to sign a consent form authorizing HUD or the HA to request wage and claim information from the SWICAs.

The Housing and Community Development Act of 1987 authorizes HUD to require applicants and participants (as well as members of their households six years of age and older) in HUD-administered programs involving rental assistance to disclose to HUD their social security numbers (SSNs) as a condition of initial or continuing eligibility for participation in the programs.

II. Objectives To Be Met by the Matching Program

HUD's primary objective in implementing the computer matching program is to increase the availability of housing assistance to individuals who meet the requirements of the housing assistance programs. Other objectives include identifying and recouping excessive housing assistance received by tenants, and deterring future abuses of assisted housing programs.

HUD's various assisted housing programs, available through HAs or subsidized multifamily project owners/management agents, require that applicants meet certain income and other criteria to be eligible for housing assistance. In addition, tenants are required to report the amount and sources of their income on at least an annual basis. The matching program will identify tenants receiving excessive housing assistance resulting from unreported or underreported family income. When the excessive housing assistance is identified, these tenants frequently move out of assisted housing units, increasing funds or units available to serve the intended beneficiaries of HUD programs. Further, program administrators may collect excessive housing assistance from those tenants. Some tenants may continue to receive housing assistance but will be required to increase their contributions toward rent, and to re-pay excessive housing assistance.

III. Program Description

In this computer matching program, tenant-provided information included

in HUD's automated files will be compared to data from the SSA and the IRS, as well as from SWICAs and the Office of Personnel Management (OPM). HUD intends the SSA and IRS matching to be a continuing program for assisted housing programs nationwide. HUD will normally request that the SSA conduct matching of earned income information, and that the IRS conduct matching of unearned income information, on an annual basis. HUD will request SSA matching of social security and supplemental social security income information monthly. Initially HUD may limit the matching or the verification process to selected HAs and private owners/management agents to test the effectiveness of the computer matching and tenant income verification processes.

HUD anticipates that it will only conduct SWICA matching in selected States. Furthermore, HUD anticipates that the extent of SWICA and OPM matching will decrease in future years, after the effectiveness of SSA and IRS matching and income verification has been demonstrated. HAs may also request SWICA matching.

HUD will disclose to the SSA, IRS, and SWICAs only tenant personal identifiers, i.e., SSNs, surnames, dates of birth, and sex. The SSA, IRS, and SWICAs will conduct the matching of the HUD-provided personal identifiers to personal identifiers included in their automated files. Those agencies will provide income data to HUD only for individuals with matching personal identifiers.

The process of income matching between HUD and the OPM varies from the above. The OPM will disclose its data to HUD, and HUD will actually conduct the computer matching to OPM data.

HUD will then compare the SSA, IRS, OPM, and SWICA income data to tenant-reported income data included in HUD's system of records known as the Tenant Housing Assistance and Contract Verification Data (HUD H-11). This comparison will identify, based on criteria established by HUD, tenants whose income(s) require further verification.

A. Income Verification

HUD will normally request that HAs or private owners/management agents verify matching results as described below. However, under certain limited circumstances HUD may verify tenant income(s) with independent income sources. For example, such circumstances may include when: (a) HUD declares an HA in breach of an annual contributions contract; or (b) the

tenant fails to disclose SSA and IRS data, the tenant has committed other serious violations, and HUD's analysis of the data could support legal actions. HUD may send letters to employers to request income data, but HUD will not disclose tax return data to HAs, private owners/management agents, employers, or payors.

(1) Verification of SSA and IRS Data Referenced in Section 6103(l)(7) of the Internal Revenue Code

Since HUD cannot redisclose tax return data directly to HAs or private owners/management agents, HUD plans to notify tenants of discrepancies between the tenant-reported income and the SSA and IRS data. HUD will supply the tenant with income information taken directly from SSA and IRS data and request that the tenant provide this information to the HA or private owner/management agent. Concurrently, HUD will notify the HA or the private owner/management agent that a discrepancy exists between information provided by the tenant and other sources and will request reverification of the tenant's income. This notification will not include any tax return information.

Income information that tenants disclose to the HA or private owners/management agents will be verified directly with the income source or with the tenant. Tenants who fail to report to the HA or private owner/management agent after HUD's initial notice will receive a second notice sent by the HA or private owner/management agent. If the tenant still fails to provide the information to the HA or private owner/management agent, the HA or private owner/management agent may then terminate housing assistance, after providing the tenant an opportunity to grieve any adverse action.

The SSA and the IRS have advised HUD that the process described in the preceding paragraph is consistent with the intent of section 6103(l)(7) of the Internal Revenue Code, as the intent of the matching is to create a dialogue between the benefit recipient and the benefit provider.

(2) Verification of Social Security and Supplemental Social Security Income Data

Unlike the income return information supplied by the SSA and the IRS, HUD may disclose SSA Title 2 (social security) and Title 16 (supplemental social security income) data to HAs and private owners/management agents. Therefore, after receiving this data from the SSA and comparing it to tenant-reported income, HUD will disclose the SSA social security and supplemental

social security income data to HAs and private owners/management agents. These disclosures will be limited to those instances in which a significant disparity exists between the SSA and the tenant-reported data. HAs and private owners/management agents will then notify the tenant if a disparity exists that affects the tenant's housing assistance.

(3) Verification of SWICA Data

HUD will disclose matching results for SWICA wage and unemployment claim data directly to HAs, but not to private owners/management agents. The comparison of SWICA wage information and the tenant-reported data will reveal whether income verification is necessary. The HA must then obtain wage information directly from the tenants' employer(s), including information from prior years when appropriate. The SWICA unemployment claim data must be verified with the tenant. Verification with the SWICA would only be required if the tenant disputes the SWICA claim data.

(4) Verification of OPM Data

HUD will disclose matching results for OPM data to HAs and private owners/management agents. The OPM data, when compared to the tenant-reported data, provides an indicator that income verification is necessary. The HAs and private owners/management agents may then obtain wage information directly from the employer(s), including information from prior years when appropriate.

B. Administrative or Legal Actions

Regarding all the matching described in this notice, HUD anticipates that HAs and private owners/management agents will take appropriate actions in consultation with the tenant to resolve the disparities between tenant-reported and independent income source data. If appropriate, the HAs and private owners/management agents will increase the tenant's contribution toward rent, i.e., reduce the housing assistance provided.

After verifying that the tenant had access to income that the tenant did not report, the HA or project owner/management agent will:

- (1) Notify the tenant in writing of any findings;
- (2) Calculate the unreported income and excessive housing assistance received by the family;
- (3) Offer the tenant an opportunity to contest any findings;
- (4) Provide a grievance hearing or a right to contest to the tenant, if requested; and

(5) Initiate, as appropriate, administrative or legal actions to resolve the tenant's underpayment of rent, using guidelines in HUD regulations and handbooks.

The HAs and private owners/management agents may not suspend, terminate, reduce, or make a final denial of any housing assistance to any individual as the result of information produced by this matching program until: (a) The individual has received notice from that agency containing a statement of its findings and informing the individual of the opportunity to contest such findings; and (b) either the notice period provided in applicable regulations of the program, or 30 days, whichever is later, has expired. In most cases, the discrepancy will be resolved through consultation between the tenant and the HA or private owner/management agent.

In legal actions, HAs and private owners/management agents may refer cases to local law enforcement entities or HUD's Office of Inspector General (OIG) for possible investigation and prosecution, either criminally or civilly. Referrals to the OIG should involve only egregious cases.

C. Reporting on Computer Matching/Income Verification Results

HUD plans to prescribe a methodology (probably electronic) for HAs and private owners/management agents to report computer matching/income verification results to HUD. The reporting methodology will measure the effectiveness of the computer matching program. In developing the methodology, HUD will avoid imposing any unnecessary burden on HAs and private owners/management agents. The reporting requirement will be submitted to OMB for approval under the Paperwork Reduction Act of 1980 (44 U.S.C. Chapter 35), and a notice of this submission will be published in the **Federal Register**.

IV. Records To Be Matched

SSA and IRS will actually conduct the matching of tenant SSNs and additional identifiers (such as surnames and dates of birth) to tenant data that HUD supplies from its system of records known as the Tenant Housing Assistance and Contract Verification Data (HUD H-11). Within HUD, this system of records includes two automated systems known as the Multifamily Tenant Characteristics System (a system for programs under the Office of the Assistant Secretary for Public and Indian Housing) and the Tenant Rental Assistance Certification System (a system for programs under

the Office of the Assistant Secretary for Housing—Federal Housing Commissioner). HAs and private owners/management agents for subsidized multifamily projects provide HUD with the data included in HUD H-11.

The SSA will match the HUD H-11 records to the SSA's Earnings Recording and Self-Employment Income System (HHS/SSA/OSR, 09-60-0059) (Earnings Record); Master Beneficiary Record (HHS/SSA/OSR, 09-60-0090) (MBR); and Supplemental Security Income Record (HHS/SSA/OSR, 09-60-0103) (SSR). The IRS will match the HUD H-11 records to its Wage and Information Returns (IRP) Master File (Treas/IRS 22.061). The IRS also refers to this file as the Information Return Master File (IRMF).

HUD's Assistant Secretary for Public and Indian Housing (PIH) will place matching data into its Tenant Eligibility Verification Files (HUD/PIH-1), as provided in a notice published in today's **Federal Register**. The HUD/PIH-1 files are specifically exempt from certain provisions of the Privacy Act, as described in a notice published on February 28, 1994 (59 FR 9406) and a notice published on March 30, 1994 (59 FR 14869). HUD's Assistant Secretary for Housing—Federal Housing Commissioner will consider matching data as a component of HUD H-11.

HUD may also coordinate SWICA income computer matches for its rental assistance programs using tenants' SSNs and surnames. SWICAs will match tenant records to machine-readable files of quarterly wage data and unemployment insurance benefit data. Results from this matching will be provided to HUD or HAs, which will then determine whether tenants have unreported or underreported income. The matching will be done in accordance with a written agreement between the SWICA and HUD.

In addition, tenants' SSNs may be matched to the OPM's General Personnel Records (OPM/GOVT-1), the Civil Service Retirement and Insurance Records System (OPM/Central-1), and the Department of Defense's Defense Manpower Data Center Data Base (S322.10.DMDC). The tenant data may be matched to the SSA's Master Files of Social Security Number Holders (HHS/SSA/OSR, 09-60-0058) and Death Master Files for the purpose of validating SSNs contained in tenant records. These records will also be used to validate SSNs for all applicants, tenants, and household members who are six (6) years of age and over to identify noncompliance with program eligibility requirements. HUD will

compare tenant SSNs provided by HAs or private owners/management agents to reveal duplicate SSNs and potential duplicate housing assistance.

V. Period of the Match

The computer matching program will be conducted according to agreements between HUD and the SSA, IRS, OPM, and SWICAs. The computer matching agreements for the planned matches will terminate either when the purpose of the computer matching program is accomplished, or 18 months from the date the agreement is signed, whichever comes first.

The agreement may be extended for one 12-month period, with the mutual agreement of all involved parties, if the following conditions are met:

(1) Within 3 months of the expiration date, all Data Integrity Boards review the agreement, find that the program will be conducted without change, and find a continued favorable examination of benefit/cost results; and

(2) All parties certify that the program has been conducted in compliance with the agreement.

The agreement may be terminated, prior to accomplishment of the computer matching purpose or 18 months from the date the agreement is signed (whichever comes first), by the mutual agreement of all involved parties within 30 days of written notice.

Dated: March 22, 1995.

Marilynn A. Davis,

Assistant Secretary for Administration.

[FR Doc. 95-10685 Filed 5-1-95; 8:45 am]

BILLING CODE 4210-01-P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[AK-962-1410-00-P; AA-6687-A]

Alaska Native Claims Selection

In accordance with Departmental regulation 43 CFR 2650.7(d), notice is hereby given that a decision to issue conveyance under the provisions of Sec. 14(a) of the Alaska Native Claims Settlement Act of December 18, 1971, 43 U.S.C. 1601, 1613(a), will be issued to Old Harbor Native Corporation for approximately 915 acres. The lands involved are in the vicinity of Kodiak National Wildlife Refuge, Alaska.

Seward Meridian, Alaska

T. 34 S., R. 23 W.,

Secs. 4, 8, 9, and 17.

A notice of the decision will be published once a week, for four (4) consecutive weeks, in the Kodiak Daily

Mirror. Copies of the decision may be obtained by contacting the Alaska State Office of the Bureau of Land Management, 222 West Seventh Avenue, #13, Anchorage, Alaska 99513-7599 ((907) 271-5960).

Any party claiming a property interest which is adversely affected by the decision, an agency of the Federal government or regional corporation, shall have until June 1, 1995 to file an appeal. However, parties receiving service by certified mail shall have 30 days from the date of receipt to file an appeal. Appeals must be filed in the Bureau of Land Management at the address identified above, where the requirements for filing an appeal may be obtained. Parties who do not file an appeal in accordance with the requirements of 43 CFR Part 4, Subpart E, shall be deemed to have waived their rights.

Margaret J. McDaniel,
*Acting Chief, Branch of Gulf Rim
Adjudication.*

[FR Doc. 95-10708 Filed 5-2-95; 8:45 am]

BILLING CODE 4310-JA-P

[CA-064-05-1430-00, CACA 33785]

Realty Action; Sale of Public Land, San Bernardino County, CA

AGENCY: Bureau of Land Management, Department of the Interior.

ACTION: Notice of realty action; sale of public land.

SUMMARY: The following described land has been examined and found suitable for direct sale under Section 203 of the Federal Land Policy and Management Act of 1976 (43 U.S.C. 1713), at not less than the appraised fair market value of \$5,400. The land will not be offered for sale until 60 days after the publication of this notice.

San Bernardino Meridian

T. 1 N., R. 18 E.,

Unsurveyed lands within section 29, described as follows: commencing at Bureau of Land Management corner AP4 per Plat of the dependent resurvey approved October 29, 1974; thence northwest 0 degrees, 35 minutes, 49 seconds, 211.56 feet, thence northeast 89 degrees, 23 minutes, 54 seconds, 1,853.04 feet; thence southeast 0 degrees, 35 minutes, 49 seconds, 211.56 feet; thence southwest 89 degrees, 23 minutes, 54 seconds, 1,853.04 feet to the point of beginning.

Containing 9 acres of public lands, more or less. The land will not be sold until it is officially surveyed under the public land survey system of the United States.

This land is being offered for direct sale to the Metropolitan Water District of Southern California to resolve inadvertent solid waste

disposal on the land. The sale is consistent with the California Desert Conservation Area Plan. The Metropolitan Water District has applied to acquire the mineral interests under section 209 of the Federal Land Policy and Management Act. The land contains no known mineral values, and the mineral interest will be conveyed simultaneously with the land.

SUPPLEMENTARY INFORMATION:

Publication of this Notice in the **Federal Register** segregates the public land from the operation of the public land laws and the general mining laws. The segregative effect will end upon issuance of patent, or two years from the date of publication, whichever occurs first. The patent, when issued, will contain a reservation of ditches and canals to the United States. Detailed information concerning the specific conditions of the sale is available for review at the California Desert District Office, Bureau of Land Management, 6221 Box Springs, Riverside, California 92507. For a period of 45 days after publication of this notice in the **Federal Register** interested parties may submit comments to the District Manager, California Desert District, in care of the above address. Objections will be reviewed by the State Director, who may sustain, vacate, or modify this realty action. In the absence of any objections, this realty action will become the final determination of the Department of the Interior.

Dated: April 18, 1995.

Lucia Kuizon,

Acting District Manager.

[FR Doc. 95-10753 Filed 5-1-95; 8:45 am]

BILLING CODE 4310-40-M

National Park Service

National Register of Historic Places; Notification of Pending Nominations

Nominations for the following properties being considered for listing in the National Register were received by the National Park Service before April 22, 1995. Pursuant to section 60.13 of 36 CFR part 60 written comments concerning the significance of these properties under the National Register criteria for evaluation may be forwarded to the National Register, National Park Service, P.O. Box 37127, Washington, DC 20013-7127. Written comments should be submitted by May 17, 1995.

Carol D. Shull,

Chief of Registration, National Register.

ARKANSAS

Calhoun County

State Highway 274 Bridge (Historic Bridges of Arkansas MPS), AR 274 over Little Cypress Cr., Thornton vicinity, 95000610

Craighead County

Craighead County Road 513C Bridge (Historic Bridges of Arkansas MPS), Co. Rd. 513C over unnamed ditch, approximately 1.5 E of Dixie, just E of jct. of Co. Rds. 513C and 669. Dixie vicinity, 95000614

Independence County

Cedar Creek Bridge (Historic Bridges of Arkansas MPS), Co. Rd. 235 over Cedar Cr., approximately 1.5 mi. S of jct. of Co. Rd. 235 and AR 14, Rosie vicinity, 95000613

Jefferson County

West James Street Overpass (Historic Bridges of Arkansas MPS), W. James St. over Union—Pacific RR tracks, Redfield vicinity, 95000609

Phillips County

Little Cypress Creek Bridge (Historic Bridges of Arkansas MPS), Co. Rd. 66G over Little Cypress Cr., Postelle vicinity, 95000611
Warrens Bridge (Historic Bridges of Arkansas MPS), Co. Rd. 14I over Lambrook Levee Ditch, Lambrook vicinity, 95000612

Pulaski County

Amboy Overpass (Historic Bridges of Arkansas MPS), AR 365 over Union—Pacific RR tracks, N of jct. of AR 365 and AR 176. North Little Rock, 95000608

DISTRICT OF COLUMBIA

District of Columbia State Equivalent

George Washington Memorial Parkway (Parkways of the National Capital Region MPS), Roughly, S side of the Potomac R. from American Legion to Memorial Bridge and N side from Brickyard Rd. to Chain Bridge, Washington, 95000605
Suitland Parkway (Parkways of the National Capital Region MPS), From the Anacostia R. in the District of Columbia to Pennsylvania Ave. in Prince George's County, Maryland, Washington, 95000604

IOWA

Story County

Wood, William Kennison, House, Co. Rd. off S27. Iowa Center, 95000622

Wapello County

Big 4 Fair Art Hall, Water St., at Wapello County Regional Fair Grounds, Eldon, 95000621

KANSAS

Allen County

Schleichers Branch Stone Arch Bridge (Masonry Arch Bridges of Kansas MPS), Unnamed rd. over Slack Cr. (Schleichers Br.), E of Humboldt, Humboldt vicinity, 95000620

Johnson County

Voigts, Herman J. and Ella B., House, 2405 W. 103rd St., Leawood, 95000603

MINNESOTA

Hennepin County

Fournier, Lawrence A. and Mary, House,
3505 Sheridan Ave. N., Minneapolis,
95000618

Van Dusen, George H. and Nancy B., House,
1900 LaSalle Ave., Minneapolis, 95000607

Lac Qui Parle County

Dawson Armory and Community Building,
676 Pine St., Dawson, 95000615

Martin County

Chubb, Orville P. and Sarah, House, 209 Lake Ave., Fairmont, 95000616

Rice County

*Den Svenska Evangeliska Lutherska
Christdala Forsamlingen,* 4695 Millersburg Rd., Forest Township, Lonsdale vicinity,
95000617

Wadena County

Wadena Memorial Auditorium, Jct. of Dayton Ave. SW., and Third St. SW., Wadena,
95000619

NEW YORK

Essex County

Central Powerhouse (Moriah MPS), Jct. of Tracy Rd. and New Bed Rd., SE corner, Town of Moriah, Witherbee, 95000591

Delaware & Hudson Railroad Depot (Moriah MPS), Park Pl., Town of Moriah, Port Henry, 95000593

Moriah Town Office Building (Moriah MPS), Cedar St., Town of Moriah, Port Henry, 95000594

Mount Moriah Presbyterian Church (Moriah MPS), Jct. of Church and S. Main Sts., NW corner, Town of Moriah, Port Henry, 95000592

Port Henry Fire Department Building (Moriah MPS), 33 Broad St., Town of Moriah, Port Henry, 95000590

Sherman Free Library (Moriah MPS), 4 Church St., Town of Moriah, Port Henry, 95000595

Ulster County

Rest Plaus Historic District, Roughly, along Old Kings Hwy., Rest Plaus Rd., and Lucas Tpk. (Co. Rt. 1), Marletown, 95000602

PUERTO RICO

Humacao Municipality

Humacao Customs House, Marina St. at jct. with Aduana St., Humacao, 95000599

Humacao District Courthouse, Jct. of Dr. Vidal St. and Antonio Lopez St., Humacao, 95000596

Saez, Antonia, School, Font Martelo St. at jct. with Isidro St., Humacao, 95000597

SOUTH CAROLINA

Horry County

Atlantic Coast Line Railroad Depot (Conway MRA), N side of US 701, Conway, 86003839

TEXAS

Navarro County

Corsicana Commercial Historic District, Roughly bounded by 2nd Ave., the Southern Pacific RR tracks, 7th Ave. and Main St., Corsicana, 95000601

VIRGINIA

Suffolk Independent City

Holland Historic District, Jct. of US 58 with VA 189 and VA 653, Suffolk (Independent City), 95000600

[FR Doc. 95-10713 Filed 5-1-95; 8:45 am]

BILLING CODE 4310-70-M

Office of Surface Mining Reclamation and Enforcement

Information Collection Submitted to the Office of Management and Budget for Review Under the Paperwork Reduction Act

The proposal for the collection of information listed below has been submitted to the Office of Management and Budget for approval under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35). Copies of the proposed collection of information and related form and explanatory material may be obtained by contacting the Bureau's clearance officer at the phone number listed below. Comments and suggestions on the requirements should be made directly to the bureau clearance officer and to the Office of Management and Budget, Paperwork Reduction Project (1029-0057), Washington, D.C. 20503, telephone 202-395-7340.

Title: 30 CFR Part 882—Reclamation on Private Lands

OMB Number: 1029-0057

Abstract: The information requirement is pursuant to Public Law 95-87, which mandates procedures for States and Indian Tribes to request appraisals and liens under certain circumstances on private property that has been reclaimed. These procedures are intended to ensure that States and Indian Tribes have sufficient capability to file liens so that certain landowners will not receive a windfall from the reclamation

Bureau Form Number: Not applicable

Frequency: As required

Descriptions of Respondents: States and Indian tribes

Estimated Completion Time: One hour

Annual Responses: None

Annual Reporting Burden: One

Bureau Clearance Officer: John A. Trelease (202) 343-1475

Date: March 30, 1995.

Andrew F. DeVito,

Chief, Branch of Environmental and Economic Analysis.

[FR Doc. 95-10714 Filed 5-1-95; 8:45 am]

BILLING CODE 4310-05-M

INTERSTATE COMMERCE COMMISSION

[Finance Docket No. 32670]

Consolidated Rail Corporation—Trackage Rights Exemption—Vaughan Railroad Company

Vaughan Railroad Company (Vaughan) has agreed to grant nonexclusive trackage rights to Consolidated Rail Corporation (Conrail) in Nicholas and Fayette Counties, WV, as follows: (1) Beginning at the connection between Conrail and the Vaughan Interconnect at milepost 0.00± and ending at Plus Station 672 + 82± (16' short of milepost CAY-13.0) near Vaughan, WV; and (2) beginning at Vaughan on the Twentymile Creek Extension Track at Station 643 + 00± (milepost 12.4±) and extending 9.13 miles to the terminating point of the Twentymile Creek Extension Track at Robinson Fork of Twentymile Creek (Station 482 + 00±).¹ The proposed transaction will enable Conrail to provide nonexclusive transportation of coal by allowing it to access AMVEST Minerals Corporation or any of its corporate affiliates located on the involved trackage.

The proposed transaction is scheduled to take effect on the date the parties agree in writing, but not sooner than seven days after the filing of the notice of exemption.

This notice is filed under 49 CFR 1180.2(d)(7). If the notice contains false or misleading information, the exemption is void *ab initio*. Petitions to revoke the exemption under 49 U.S.C. 10505(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the transaction. Pleadings must be filed with the Commission and served on: Anne E. Treadway, 2001 Market St., 16A, P.O. Box 41416, Philadelphia, PA 19101-1416.

As a condition to the use of this exemption, any employees adversely affected by the trackage rights will be protected under *Norfolk and Western Ry. Co.—Trackage Rights—BN*, 354 I.C.C. 605 (1978), as modified in *Mendocino Coast Ry., Inc.—Lease and Operate*, 360 I.C.C. 653 (1980).

Decided: April 25, 1995.

¹ The line segments involve "original" trackage (original trackage agreement) dated October 18, 1993, and "extension" trackage (amended agreement) dated April 10, 1995. A notice of exemption seeking approval for the original trackage was not filed with the Commission because, at the time of agreement, the line was not operable.

By the Commission, David M. Konschnik,
Director, Office of Proceedings.

Vernon A. Williams,
Secretary.

[FR Doc. 95-10785 Filed 5-1-95; 8:45 am]

BILLING CODE 7035-01-P

[Ex Parte No. 388 (Sub-No. 5)]

Intrastate Rail Rate Authority—Georgia

AGENCY: Interstate Commerce Commission.

ACTION: Notice of provisional recertification.

SUMMARY: The State of Georgia has filed an application for recertification. The Commission, under *State Intrastate Rail Rate Authority*, 5 I.C.C.2d 680, 685 (1989), provisionally recertifies the State of Georgia to regulate intra-state rail rates, classifications, rules, and practices. After its review, the Commission will issue a recertification decision or take other appropriate action.

DATES: This provisional recertification will be effective on May 2, 1995.

FOR FURTHER INFORMATION CONTACT: Elaine Sehrt-Green (202) 927-5269 or Beryl Gordon (202) 927-5610 [TDD for hearing impaired: (202) 927-5721].

Decided: April 26, 1995.

By the Commission, David M. Konschnik,
Director, Office of Proceedings.

Vernon A. Williams,
Secretary.

[FR Doc. 95-10784 Filed 5-1-95; 8:45 am]

BILLING CODE 7035-01-P

DEPARTMENT OF JUSTICE

Information Collection Under Review

The Office of Management and Budget (OMB) has been sent the following collection(s) of information proposals for review under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35) and the Paperwork Reduction Reauthorization Act since the last list was published. Entries are grouped into submission categories, with each entry containing the following information:

- (1) The title of the form/collection;
- (2) The agency form number, if any, and the applicable component of the Department sponsoring the collection;
- (3) Who will be asked or required to respond, as well as a brief abstract;
- (4) An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond;

(5) An estimate of the total public burden (in hours) associated with the collection; and,

(6) An indication as to whether Section 3504(h) of Public Law 96-511 applies.

Comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the OMB reviewer, Mr. Jeff Hill on (202) 395-7340 and to the Department of Justice's Clearance Officer, Mr. Robert B. Briggs, on (202) 514-4319. If you anticipate commenting on a form/collection, but find that time to prepare such comments will prevent you from prompt submission, you should notify the OMB reviewer and the Department of Justice Clearance Officer of your intent as soon as possible. Written comments regarding the burden estimate or any other aspect of the collection may be submitted to Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503, and to Mr. Robert B. Briggs, Department of Justice Clearance Officer, Systems Policy Staff/Information Resources Management/Justice Management Division Suite 850, WCTR, Washington, DC 20530.

Reinstatement with changes, of a previously approved collection for which approval has expired.

(1) 1995 Census of State and Federal Adult Correctional Facilities.

(2) Form CJ-43. Bureau of Justice Statistics, Office of Justice Programs, United States Department of Justice.

(3) Primary=Federal, State, local or Tribal Government. Others=None. This 1995 Census of State and Federal Correctional Facilities will provide current information on inmate population and correctional facilities throughout the country, including inmate growth and its effects on confinement space and facility building plans. The last census was conducted in 1990. Respondents are State and Federal correctional administrators.

(4) 1,400 annual respondents at 1.0 hours per response.

(5) 1,400 annual burden hours.

(6) Not applicable under Section 3504(h) of Public Law 96-511.

Public comment on this item is encouraged.

Dated: April 26, 1995.

Robert B. Briggs,

Department Clearance Officer, United States Department of Justice.

[FR Doc. 95-10687 Filed 5-1-95; 8:45 am]

BILLING CODE 4410-18-M

NUCLEAR REGULATORY COMMISSION

[Docket No. 50-397]

Washington Public Power Supply System, Nuclear Project No. 2; Notice of Issuance of Environmental Assessment and Finding of No Significant Impact

The U.S. Nuclear Regulatory Commission (the Commission) is considering issuance of an amendment to Facility Operating License No. NPF-21, issued to Washington Public Power Supply System, (the licensee), for operation of the Nuclear Project No. 2, located in Benton County, Washington.

Environmental Assessment

Identification of the Proposed Action

This Environmental Assessment is written in connection with the proposed core uprate for the Nuclear Project No. 2 in response to the licensee's application dated July 9, 1993, as supplemented by letters of October 9, and October 25, 1993, January 6, February 2, May 3, May 13, September 26, and October 12, 1994. The proposed action would increase the rated core power level for Nuclear Project No. 2 from the current level of 3323 Megawatts-thermal (MWt) to 3486 MWt. The Nuclear Steam Supply System (NSSS) power level would be increased accordingly. This uprate represents an authorized thermal power level increase of approximately 4.9 percent. This will require resetting of the safety relief valve setpoints to accommodate the slight operating pressure increase (less than 20 psi). Operating temperature will also increase slightly (less than 5 °F). The result of these changes will be an approximate 5 percent increase in rated steam flow. Plant instrumentation will be recalibrated to reflect the uprated power. The licensee will implement these changes during the current refueling outage, which began on April 22, 1995.

These changes will be achieved by (1) increasing the core thermal power to increase steam flow, (2) increasing reactor pressure to ensure adequate turbine control margin, (3) not increasing the current maximum core flow, and (4) operating the reactor along higher flow control lines. The increased core power will be achieved by utilizing a flatter radial power distribution while still maintaining limiting fuel bundles within their constraints.

The Need for the Proposed Action

The proposed action would increase the thermal output by 163 MWt, which

corresponds to approximately 52 megawatts-electrical (MWe). This would provide additional electrical power to the grids which service the commercial and residential areas of the distribution utility.

Environmental Impacts of the Proposed Action

A slight change in the environmental impact can be expected for an increase in plant power level, but the effects were found to be minimal and did not alter the findings stated in NUREG-0812, "Final Environmental Statement Related to Operation of Nuclear Project No. 2" (FES), December 1981.

The proposed core uprating is projected to increase the rejected heat by approximately 5 percent. However, the thermal discharges from the circulating and service water systems remain bounded by the values evaluated in the FES. Thus, the 5 percent increase in rejected heat has been evaluated and determined not to significantly impact on the quality of the human environment.

The licensing basis analyses related to radiological source terms were originally performed assuming a core power of 3486 MWt which corresponds to the proposed rerate conditions. The NRC review of these calculations was documented in NUREG-0892, "Safety Evaluation Report Related to the Operation of Nuclear Project No. 2." Additional assessments by the licensee related to the rerated conditions (power level and reactor coolant temperature) and other changes related to plant operation determined there would be no significant increase in the potential radioactive releases resulting from plant operation or design basis reactor accidents. In addition, no significant increases in individual or cumulative occupational radiation exposure would result from the proposed changes in operating conditions. Also, he proposed increase in the NSSS power involves no significant change in the amount of any non-radiological effluents that may be released offsite compared to those evaluated and approved in the FES.

Therefore, the Commission concludes that there is no significant radiological or non-radiological environmental impacts associated with the proposed amendment.

Alternatives to the Proposed Action

Since the Commission has concluded there is no measurable environmental impact associated with the proposed action, any alternatives with equal or greater environmental impact need not be evaluated. As an alternative to the proposed action, the staff considered

denial of the proposed action. Denial of the amendment would not significantly reduce the environmental impact of plant operation and would restrict operation of the Nuclear Project No. 2 to the currently licensed power level, thereby reducing operational flexibility.

Alternative Use of Resources

This action does not involve the use of any resources not previously considered in the Final Environmental Statement for the Nuclear Project No. 2.

Agencies and Persons Consulted

By letter of September 26, 1994, Mr. Jason J. Zeller of the Energy Facility Site Evaluation Council of the State of Washington informed the staff that the State official had no comments.

Finding of No Significant Impact

Based upon the environmental assessment, the Commission concludes that the proposed action will not have a significant effect on the quality of the human environment. Accordingly, the Commission has determined not to prepare an environmental impact statement for the proposed action.

For further details with respect to the proposed action, see the licensee's letter dated July 9, 1993, as supplemented by letters dated October 9, and October 25, 1993, January 6, January 6, February 2, May 3, May 13, September 26, and October 12, 1994, which are available for public inspection at the Commission's Public Document Room, The Gelman Building, 2120 L Street, NW., Washington, DC, and at the local public document room located at the Richland Public Library, 955 Northgate Street, Richland, Washington 99352.

Dated at Rockville, Maryland, this 28th day of April 1995.

For the Nuclear Regulatory Commission.

William H. Bateman,

Director, Project Directorate IV-2, Division of Reactor Projects III/IV, Office of Nuclear Reactor Regulation.

[FR Doc. 95-10886 Filed 5-1-95; 8:45 am]

BILLING CODE 7590-01-M

Advisory Committee on Nuclear Waste; Notice of Meeting

The Advisory Committee on Nuclear Waste (ACNW) will hold its 74th meeting on May 10, 1995, in Room T-2B3 and May 11, 1995, in Room T-2B1, at 11545 Rockville Pike, Rockville, Maryland.

The entire meeting will be open to public attendance.

The agenda for this meeting shall be as follows:

Wednesday, May 10, 1995—8:30 A.M. until 6:00 P.M. and Thursday, May 11, 1995—8:30 A.M. until 6:00 P.M.

During this meeting the Committee plans to consider the following:

*A. NRC staff Position on Substantially Complete Containment—*The Committee will review the NRC staff position on the meaning of substantially complete containment as used in the Commission's regulations for the disposal of high-level radioactive wastes in geologic repositories.

*B. Electronic Data Transfer—*Representatives from the U.S. Department of Energy will discuss the electronic transfer of site characterization data from the DOE to the NRC and Center for Nuclear Waste Regulatory Analyses staffs.

*C. Meeting with the Director, NRC's Division of Waste Management, Nuclear Materials Safety and Safeguards—*The Director will provide information to the Committee on current waste management issues, which may include the progress of site characterization at the proposed Yucca Mountain site and a preview of the NRC staff's review strategy for DOE seismic hazard analysis.

*D. National Performance Review Phase 2—*The Committee will hear presentations by and hold discussions with the NRC staff on initiatives to streamline the Federal government and regulatory process.

*E. Preparation of ACNW Reports—*The Committee will discuss proposed reports on the Approach to Groundwater Travel Time at Yucca Mountain and comments on a low-level waste branch technical position on performance assessment. Additional topics will be considered as time permits.

*F. Committee Activities/Future Agenda—*The Committee will consider topics proposed for future consideration by the full Committee and Working Groups. The Committee will also discuss ACNW-related activities of individual members.

*G. Miscellaneous—*The Committee will discuss miscellaneous matters related to the conduct of Committee activities and organizational activities and complete discussion of matters and specific issues that were not completed during previous meetings, as time and availability of information permit.

Procedures for the conduct of and participation in ACNW meetings were published in the **Federal Register** on October 7, 1994 (59 FR 51219). In accordance with these procedures, oral or written statements may be presented by members of the public, electronic

recordings will be permitted only during those portions of the meeting that are open to the public, and questions may be asked only by members of the Committee, its consultants, and staff. Persons desiring to make oral statements should notify the ACNW Executive Director, Dr. John T. Larkins, as far in advance as practicable so that appropriate arrangements can be made to allow the necessary time during the meeting for such statements. Use of still, motion picture, and television cameras during this meeting may be limited to selected portions of the meeting as determined by the ACNW Chairman. Information regarding the time to be set aside for this purpose may be obtained by contacting the ACNW Executive Director prior to the meeting. In view of the possibility that the schedule for ACNW meetings may be adjusted by the Chairman as necessary to facilitate the conduct of the meeting, persons planning to attend should check with the ACNW Executive Director if such rescheduling would result in major inconvenience.

Further information regarding topics to be discussed, whether the meeting has been cancelled or rescheduled, the Chairman's ruling on requests for the opportunity to present oral statements and the time allotted therefor can be obtained by contacting the ACNW Executive Director, Dr. John T. Larkins (telephone 301/415-7360), between 7:30 a.m. and 4:15 p.m. EDT.

Dated: April 26, 1995.

Andrew L. Bates,

Advisory Committee Management Officer.

[FR Doc. 95-10724 Filed 5-1-95; 8:45 am]

BILLING CODE 7590-01-M

[Docket No. 50-293]

Boston Edison Company; Pilgrim Nuclear Power Station; Receipt of Petition for Director's Decision Under 10 CFR 2.206

Notice is hereby given that by letter dated March 10, 1995, Mary Elizabeth Lampert and 62 other persons request that the U.S. Nuclear Regulatory Commission (NRC) take action with regard to the Pilgrim Nuclear Power Station operated by the Boston Edison Company (the licensee).

Petitioners request that during the March 25, 1995, refueling outage and In-Vessel Visual Inspection conducted by the licensee, certain technical concerns be addressed, and that before Pilgrim goes back on-line, appropriate repairs be made or corrective action be taken, and that the NRC discuss the status of such repairs and corrective actions with the

public in Plymouth, Massachusetts. Petitioners also request that the NRC terminate its policy of issuing Notices of Enforcement Discretion (NOED) and commence enforcing NRC regulations again. Finally, Petitioners request that the letter be treated as a Petition pursuant to 10 CFR 2.206.

As the bases for their requests, Petitioners identify three groups of technical concerns: (1) Age-related deterioration of 25 safety related reactor internals; (2) parts and components "known to be a problem at Pilgrim," including the core shroud, water level indicators, QA for fuel pool cooling system during loss-of-coolant accident/loss-of-coolant protection, coolant protection, motor-operated valves, containment integrity, drywell liner corrosion vulnerability, station blackout vulnerability, and Rosemount transmitters; and (3) parts and components "potentially a problem at Pilgrim," including potential fuel rod corrosion and substandard and/or counterfeit parts. Additionally, Petitioners contend that allowing a reactor to operate under an NOED cannot pose less risk to the public health and safety than keeping the reactor shut down until NRC regulations are met.

The Petition is being evaluated pursuant to 10 CFR 2.206 of the Commission's regulations. The Petition has been referred to the Director of the Office of Nuclear Reactor Regulation. As provided by Section 2.206, appropriate action will be taken on this Petition within a reasonable time.

A copy of the Petition is available for inspection at the Commission's Public Document Room at 2120 L Street, NW., Washington, DC 20001.

Dated at Rockville, Maryland, this 19th day of April 1995.

For the Nuclear Regulatory Commission.

William T. Russell,

Director, Office of Nuclear Reactor Regulation.

[FR Doc. 95-10732 Filed 5-1-95; 8:45 am]

BILLING CODE 7590-01-M

Appointments to Performance Review Boards for Senior Executive Service

AGENCY: U.S. Nuclear Regulatory Commission.

ACTION: Appointment to Performance Review Boards for Senior Executive Service.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) has announced the following appointments to the NRC Performance Review Boards.

The following individuals are appointed as members of the NRC Performance Review Board (PRB) responsible for making recommendations to the appointing and awarding authorities on performance appraisal ratings and performance awards for Senior Executives:

New Appointees:

Lawrence J. Chandler, Assistant General Counsel, Office of the General Counsel

Richard L. Bangart, Director, Office of State Programs

Leonard J. Callan, Regional Administrator, Region IV

Ronald M. Scroggins, Deputy Chief Financial Officer/Controller, Office of the Controller

Ashok Thadani, Associate Director for Technical Assessment, Office of Nuclear Reactor Regulation

In addition to the above new appointments, the following members are continuing on the PRB:

Stephen G. Burns, Associate General Counsel, Office of the General Counsel

John C. Hoyle, Secretary of the Commission, Office of the Secretary
James L. Blaha, Assistant for Operations, Office of the Executive Director for Operations

Frank J. Miraglia, Deputy Director, Office of Nuclear Reactor Regulation

Bill M. Morris, Director, Division of Regulatory Applications, Office of Nuclear Regulatory Research

Elizabeth Q. Ten Eyck, Deputy Director, Division of Fuel Cycle Safety and Safeguards, Office of Nuclear Material Safety and Safeguards

The following individuals will continue as members of the NRC PRB Panel that was established to review appraisals and make recommendations to the appointing and awarding authorities for NRC PRB members:

Hugh L. Thompson, Jr., Deputy Executive Director for Nuclear Materials Safety, Safeguards and Operations Support, Office of the Executive Director for Operations
Karen D. Cyr, General Counsel, Office of the General Counsel

James L. Milhoan, Deputy Executive Director for Nuclear Reactor Operations, Regulatory Operations, and Research, Office of the Executive Director for Operations

All appointments are made pursuant to Section 4314 of Chapter 43 of Title 5 of the United States Code.

EFFECTIVE DATE: May 2, 1995.

FOR FURTHER INFORMATION CONTACT: James F. McDermott, Secretary, Executive Resources Board, U.S.

Nuclear Regulatory Commission,
Washington, DC 20555, (301) 415-7516.

Dated at Rockville, Maryland, this 25th day
of April 1995.

For the Nuclear Regulatory Commission.

James F. McDermott,

Secretary, Executive Resources Board.

[FR Doc. 95-10728 Filed 5-1-95; 8:45 am]

BILLING CODE 7590-01-M

[Docket No. 50-410]

**Niagara Mohawk Power Corp. (Nine
Mile Point Nuclear Station Unit 2);
Exemption**

I

Niagara Mohawk Power Corporation (NMPC or the licensee) is the holder of Facility Operating License No. NPF-69, which authorizes operation of Nine Mile Point Nuclear Station Unit 2 (the facility/NMP2), at a steady-state reactor power level not in excess of 3323 megawatts thermal. The facility is a boiling water reactor located at the licensee's site in Oswego County, New York. The license provides among other things, that it is subject to all rules, regulations, and Orders of the U.S. Nuclear Regulatory Commission (the Commission or NRC) now or hereafter in effect.

II

Section III.D.1.(a) of Appendix J to 10 CFR Part 50 requires the performance of three Type A containment integrated leakage rate tests (ILRTs), at approximately equal intervals during each 10-year service period of the primary containment. The third test of each set shall be conducted when the plant is shutdown for the 10-year inservice inspection of the primary containment.

III

By letter dated March 9, 1995, NMPC requested temporary relief for NMP2 from the requirement to perform a set of three Type A tests at approximately equal intervals during each 10-year service period of the primary containment. The requested exemption would permit a one-time interval extension of the second Type A test by approximately 18 months (from the April 1995 refueling outage, to the late 1996 refueling outage).

The licensee's request cites the special circumstances of 10 CFR 50.12, paragraph (a)(2)(ii), as the basis for the exemption. The existing Type B and C testing programs are not being modified by this request and will continue to effectively detect containment leakage caused by the degradation of active

containment isolation components as well as containment penetrations. The licensee has analyzed the results of the previous Type A tests performed at NMP2. Two Type A tests (including the preoperational test) have been conducted from 1986 to date with no failures. Therefore, application of the regulation in the particular circumstances is not necessary to achieve the underlying purpose of the rule.

IV

Section III.D.1.(a) of Appendix J to 10 CFR Part 50 states that a set of three Type A leakage rate tests shall be performed at approximately equal intervals during each 10-year service period.

The licensee proposes an exemption to this section which would provide a one-time interval extension for the second Type A test by approximately 18 months. The Commission has determined, for the reasons discussed below, that pursuant to 10 CFR 50.12(a)(1) this exemption is authorized by law, will not present an undue risk to the public health and safety, and is consistent with the common defense and security. The Commission further determines that special circumstances, as provided in 10 CFR 50.12(a)(2)(ii), are present justifying the exemption; namely, that application of the regulation in the particular circumstances is not necessary to achieve the underlying purpose of the rule.

The underlying purpose of the requirement to perform Type A containment leak rate tests at approximately equal intervals during the 10-year service period, is to ensure that any potential leakage pathways through the containment boundary are identified within a time span that prevents significant degradation from continuing or becoming unknown. The NRC staff has reviewed the basis and supporting information provided by the licensee in the exemption request. The NRC staff has noted that the licensee has a good record of ensuring a leak-tight containment. All Type A tests have passed with significant margin and the licensee has noted that the results of the Type A testing have been confirmatory of the Type B and C tests which will continue to be performed. The licensee stated in its submittal that a visual internal and external inspection of the mechanical and structural integrity of the containment shell is completed during every refueling outage. The NRC staff considers these inspections provide an important added level of confidence

in the continued integrity of the containment boundary.

The NRC staff has also made use of the information in a draft staff report, NUREG-1493, which provides the technical justification for the present Appendix J rulemaking effort which also includes a 10-year test interval for Type A tests. The integrated leakage rate test, or Type A test, measures overall containment leakage. However, operating experience with all types of containments used in this country demonstrates that essentially all containment leakage can be detected by local leakage rate tests (Type B and C). According to results given in NUREG-1493, out of 180 ILRT reports covering 110 individual reactors and approximately 770 years of operating history, only 5 ILRT failures were found which local leakage rate testing could not detect. This is 3 percent of all failures. This study agrees well with previous NRC staff studies which show that Type B and C testing can detect a very large percentage of containment leaks. The NMP2 experience has also been consistent with these results as previously noted.

The Nuclear Management and Resources Council (NUMARC), now the Nuclear Energy Institute (NEI), collected and provided the NRC staff with summaries of data to assist in the Appendix J rulemaking effort. NUMARC collected results of 144 ILRTs from 33 units; 23 ILRTs exceeded 1.0L_a. Of these, only nine were not due to Type B or C leakage penalties. The NEI data also added another perspective. The NEI data show that in about one-third of the cases exceeding allowable leakage, the as-found leakage was less than 2L_a; in one case the leakage was found to be approximately 2L_a; in one case the as-found leakage was less than 3L_a; one case approached 10L_a; and in one case the leakage was found to be approximately 21L_a. For about half of the failed ILRTs the as-found leakage was not quantified. These data show that, for those ILRTs for which the leakage was quantified, the leakage values are small in comparison to the leakage value at which the risk to the public starts to increase over the value of risk corresponding to L_a (approximately 200L_a, as discussed in NUREG-1493). Therefore, based on these considerations, it is unlikely that an extension of one cycle for the performance of the Appendix J, Type A test at NMP2 would result in significant degradation of the overall containment integrity. As a result, the application of the regulation in these particular circumstances is not necessary to

achieve the underlying purpose of the rule.

Based on generic and plant specific data, the NRC staff finds the basis for the licensee's proposed exemption to allow a one-time exemption to permit a scheduler extension for NMP2 of one cycle for the performance of the Appendix J, Type A test, provided that the visual containment inspection is performed, to be acceptable.

Pursuant to 10 CFR 51.32, the Commission has determined that granting this Exemption will not have a significant impact on the environment (60 FR 17374).

This Exemption is effective upon issuance and shall expire at the completion of the late 1996 refueling outage.

Dated at Rockville, Maryland, this 24th day of April 1995.

For the Nuclear Regulatory Commission.

Steven A. Varga,

*Director, Division of Reactor Projects—I/II,
Office of Nuclear Reactor Regulation.*

[FR Doc. 95-10729 Filed 5-1-95; 8:45 am]

BILLING CODE 7590-01-M

[Docket No. 50-336]

Northeast Nuclear Energy Co.; Notice of Consideration of Issuance of Amendment to Facility Operating License, Proposed No Significant Hazards Consideration Determination, and Opportunity for a Hearing

The U.S. Nuclear Regulatory Commission (the Commission) is considering issuance of an amendment to Facility Operating License No. DPR-21, issued to the Northeast Nuclear Energy Company (NNECO/the licensee), for operation of the Millstone Nuclear Power Station, Unit No. 2, located in New London County, Connecticut.

The proposed amendment would revise the Technical Specification (TS) 3.1.2.4, "Charging Pumps—Operating," by adding a note that indicates that the provisions of TS 3.0.4 and 4.0.4 are not applicable for entry into MODE 4 from MODE 5.

Currently Millstone Unit 2 is in an extended shutdown, but is scheduled to start up in the near future. The current TS 3.1.2.3 limits Millstone Unit No. 2 to only one charging pump and one high pressure safety injection (HPSI) pump for MODES 4 and 6. TS 3.1.2.4 requires that two charging pumps be operable in MODES 1, 2, 3 and 4. The ACTION statement requires that if one charging pump is operable, that an additional charging pump must be restored to an operable status or the unit must be shut down. TS 3.0.4 prohibits entrance into

an operational MODE when the limiting condition for operation (LCO) is not met and the ACTION statement requires a shutdown. Similarly, TS 4.0.4 prohibits entry into an operational MODE if the Surveillance Requirement cannot be met. The proposed change would permit Millstone Unit 2 to enter MODE 4 as planned. Exigent action is justified in order to avoid an unnecessary delay in reactor startup.

Before issuance of the proposed license amendment, the Commission will have made findings required by the Atomic Energy Act of 1954, as amended (the Act) and the Commission's regulations.

Pursuant to 10 CFR 50.91(a)(6) for amendments to be granted under exigent circumstances, the NRC staff must determine that the amendment request involves no significant hazards consideration. Under the Commission's regulations in 10 CFR 50.92, this means that operation of the facility in accordance with the proposed amendment would not (1) involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety. As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards (SHC) consideration, which is presented below:

* * * The proposed changes do not involve a SHC because the changes would not:

1. Involve a significant increase in the probability or consequences of an accident previously evaluated.

The proposed technical specification change will require that a second charging pump be returned to service within four hours of entering MODE 4 or prior to entering MODE 3, whichever occurs first. The addition of the footnote indicating that Technical Specifications 3.0.4 and 4.0.4 are not applicable for entry into MODE 4 from MODE 5 will allow for the testing and subsequent return to service of a charging pump that was required to be inoperable in MODE 5. The testing is necessary to restore the pump to operable status.

The need to restrict charging pump availability in MODE 5 is for LTOP protection. The restriction contained in the Technical Specification 3.1.2.4 to have a maximum of two charging pumps operable when the RCS [reactor coolant system] is less than 300°F is provided for the boron dilution analysis. Maximizing charging pump flow is desirable from shutdown risk management schemes. However, all three events, LTOP [low-temperature overpressure protection], boron dilution, and shutdown risk management must be integrated to maximize overall safety. The short (less than 4 hours) delay in verifying the operability of the

second charging pump after entry into MODE 4 does not significantly affect the overall risk. The technical specification as proposed, balances all three events and will allow the plant to operate.

The addition of the proposed footnote to Technical Specification 3.1.2.4 will not significantly increase the probability or consequences of an accident previously evaluated. The charging systems safety related functions are not being impacted by the proposed change.

2. Create the possibility of a new or different kind of accident from any previously evaluated.

The proposed change does not alter or affect the design, function, failure MODE, or operation of the plant. The proposed change will allow NNECO to perform the required operability tests to support the restoration of a charging pump to an operable status.

3. Involve a significant reduction in a margin of safety.

The proposed modification will allow for the restoration of a second charging pump to support plant operation in MODES 1, 2, 3, and 4. Testing of the charging pump is necessary to verify operability of the pump. Sufficient flow is provided by the remaining available pumps to address shutdown risk issues. This proposed change will not negatively impact the LTOP evaluation or boron dilution analysis.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

The Commission is seeking public comments on this proposed determination. Any comments received within 15 days after the date of publication of this notice will be considered in making any final determination.

Normally, the Commission will not issue the amendment until the expiration of the 15-day notice period. However, should circumstances change during the notice period, such that failure to act in a timely way would result, for example, in derating or shutdown of the facility, the Commission may issue the license amendment before the expiration of the 15-day notice period, provided that its final determination is that the amendment involves no significant hazards consideration. The final determination will consider all public and State comments received. Should the Commission take this action, it will publish in the **Federal Register** a notice of issuance. The Commission expects that the need to take this action will occur very infrequently.

Written comments may be submitted by mail to the Rules Review and Directives Branch, Division of Freedom

of Information and Publications Services, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555, and should cite the publication date and page number of this **Federal Register** notice. Written comments may also be delivered to Room 6D22, Two White Flint North, 11545 Rockville Pike, Rockville, Maryland, from 7:30 a.m. to 4:15 p.m. Federal workdays. Copies of written comments received may be examined at the NRC Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC.

The filing of requests for hearing and petitions for leave to intervene is discussed below.

By June 1, 1995, the licensee may file a request for a hearing with respect to issuance of the amendment to the subject facility operating license and any person whose interest may be affected by this proceeding and who wishes to participate as a party in the proceeding must file a written request for a hearing and a petition for leave to intervene. Requests for a hearing and a petition for leave to intervene shall be filed in accordance with the Commission's "Rules of Practice for Domestic Licensing Proceedings" in 10 CFR Part 2. Interested persons should consult a current copy of 10 CFR 2.714 which is available at the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC and at the local public document room located at the Learning Resource Center, Three Rivers Community-Technical College, Thames Valley Campus, 574 New London Turnpike, Norwich, CT 06360. If a request for a hearing or petition for leave to intervene is filed by the above date, the Commission or an Atomic Safety and Licensing Board, designated by the Commission or by the Chairman of the Atomic Safety and Licensing Board Panel, will rule on the request and/or petition; and the Secretary or the designated Atomic Safety and Licensing Board will issue a notice of hearing or an appropriate order.

As required by 10 CFR 2.714, a petition for leave to intervene shall set forth with particularity the interest of the petitioner in the proceeding, and how that interest may be affected by the results of the proceeding. The petition should specifically explain the reasons why intervention should be permitted with particular reference to the following factors: (1) The nature of the petitioner's right under the Act to be made a party to the proceeding; (2) the nature and extent of the petitioner's property, financial, or other interest in the proceeding; and (3) the possible

effect of any order which may be entered in the proceeding on the petitioner's interest. The petition should also identify the specific aspect(s) of the subject matter of the proceeding as to which petitioner wishes to intervene. Any person who has filed a petition for leave to intervene or who has been admitted as a party may amend the petition without requesting leave of the Board up to 15 days prior to the first prehearing conference scheduled in the proceeding, but such an amended petition must satisfy the specificity requirements described above.

Not later than 15 days prior to the first prehearing conference scheduled in the proceeding, a petitioner shall file a supplement to the petition to intervene which must include a list of the contentions which are sought to be litigated in the matter. Each contention must consist of a specific statement of the issue of law or fact to be raised or controverted. In addition, the petitioner shall provide a brief explanation of the bases of the contention and a concise statement of the alleged facts or expert opinion which support the contention and on which the petitioner intends to rely in proving the contention at the hearing. The petitioner must also provide references to those specific sources and documents of which the petitioner is aware and on which the petitioner intends to rely to establish those facts or expert opinion. Petitioner must provide sufficient information to show that a genuine dispute exists with the applicant on a material issue of law or fact. Contentions shall be limited to matters within the scope of the amendment under consideration. The contention must be one which, if proven, would entitle the petitioner to relief. A petitioner who fails to file such a supplement which satisfies these requirements with respect to at least one contention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene, and have the opportunity to participate fully in the conduct of the hearing, including the opportunity to present evidence and cross-examine witnesses.

If the amendment is issued before the expiration of the 30-day hearing period, the Commission will make a final determination on the issue of no significant hazards consideration. If a hearing is requested, the final determination will serve to decide when the hearing is held.

If the final determination is that the amendment request involves no significant hazards consideration, the

Commission may issue the amendment and make it immediately effective, notwithstanding the request for a hearing. Any hearing held would take place after issuance of the amendment.

If the final determination is that the amendment request involves a significant hazards consideration, any hearing held would take place before the issuance of any amendment.

A request for a hearing or a petition for leave to intervene must be filed with the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Docketing and Services Branch, or may be delivered to the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC, by the above date. Where petitions are filed during the last 10 days of the notice period, it is requested that the petitioner promptly so inform the Commission by a toll-free telephone call to Western Union at 1-(800) 248-5100 (in Missouri 1-(800) 342-6700). The Western Union operator should be given Datagram Identification Number N1023 and the following message addressed to Phillip F. McKee, Director, Project Directorate I-3: Petitioner's name and telephone number, date petition was mailed, plant name, and publication date and page number of this **Federal Register** notice. A copy of the petition should also be sent to the Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, DC 20555, and to Ms. L.M. Cuoco, Senior Nuclear Counsel, Northeast Utilities Service Company, Post Office Box 270, Hartford, CT 06141-0270 for the licensee.

Untimely filings of petitions for leave to intervene, amended petitions, supplemental petitions and/or requests for hearing will not be entertained absent a determination by the Commission, the presiding officer or the presiding Atomic Safety and Licensing Board that the petition and/or request should be granted based upon a balancing of the factors specified in 10 CFR 2.714(a)(1)(i)-(v) and 2.714(d).

For further details with respect to this action, see the application for amendment dated June 24, 1994, which is available for public inspection at the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC and at the local public document room, located at the Learning Resource Center, Three Rivers Community-Technical College, Thames Valley Campus, 574 New London Turnpike, Norwich, CT 06360.

Dated at Rockville, Maryland, this 26th day of April 1995.

For the Nuclear Regulatory Commission.
Guy S. Vissing,
Senior Project Manager, Project Directorate I-4, Division of Reactor Projects—I/II, Office of Nuclear Reactor Regulation.
 [FR Doc. 95-10726 Filed 5-1-95; 8:45 am]
 BILLING CODE 7590-01-M

[Docket No. 030-31765, License No. 37-28540-01, EA 94-006]

Oncology Services Corp., Harrisburg, PA; Order Imposing Civil Monetary Penalties

I

Oncology Services Corporation (Licensee) was the holder of Byproduct Materials License No. 37-28540-01 (License) issued by the Nuclear Regulatory Commission (NRC or Commission) on August 3, 1990. The License authorized the Licensee to possess and use certain byproduct materials in accordance with the conditions specified therein at six facilities in Pennsylvania. The License was due to expire on August 31, 1995. However, on December 13, 1993, the Licensee requested termination of the License, with the License to be replaced by individual licenses issued to the facilities named as locations of use on the License. On August 24, 1994, License No. 37-28540-01 was terminated, and the NRC subsequently issued separate licenses for the following facilities previously named as locations of use under License No. 37-28540-01: Greater Pittsburgh Cancer Center (License No. 37-30163-01); Mahoning Valley Cancer Center (License No. 37-30086-01); Stoneboro Oncology Associates, P.C. (License No. 37-30092-01); Greater Harrisburg Cancer Center (License No. 37-30084-01); Indiana Regional Cancer Center (License No. 37-28179-02); and Exton Cancer Center (License No. 37-30087-01). In addition, a license was issued to Jefferson Radiation Oncology Center (License No. 37-30085-01).

II

An inspection of the Licensee's activities at its facilities located in Indiana, Pennsylvania and Pittsburgh, Pennsylvania was conducted on December 3-18, 1992, by an NRC Incident Investigation Team, following an event involving the Indiana, Pennsylvania facility in which there was a significant misadministration to a patient who died five days later, and significant radiological exposures to members of the public. In addition, NRC Region I performed an inspection on December 8, 1992, at the Licensee's

Exton and Lehigh, Pennsylvania facilities. The results of these inspections indicated that the Licensee had not conducted its activities in full compliance with NRC requirements. A written Notice of Violation and Proposed Imposition of Civil Penalties (Notice) was served upon the Licensee by letter dated May 31, 1994. The Notice states the nature of the violations, the provisions of the NRC requirements that the Licensee had violated, and the amount of the civil penalties proposed for the violations.

The Licensee responded to the Notice in letters dated August 31, 1994 and October 4, 1994. In its responses, the Licensee admits Violations III.C.2, III.D.5, III.E, III.F, and III.I; denies Violations I.A, I.B, II.A, II.B, III.A, III.B, III.C.1, III.D.1-4, III.D.6, III.G, III.H, and III.J.1-3 protests the amount of civil penalties proposed; and requests mitigation of the penalties, as appropriate.

III

After consideration of the Licensee's responses and the statements of fact, explanation, and argument for mitigation contained therein, the NRC staff has determined, as set forth in the Appendix to this Order, that the violations occurred as stated in the Notice, and that the penalties proposed for the violations designated in the Notice should be imposed.

IV

In view of the foregoing and pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205, *it is hereby ordered that:*

The Licensee pay civil penalties in the cumulative amount of \$280,000 within 30 days of the date of this Order, by check, draft, money order, or electronic transfer, payable to the Treasurer of the United States and mailed to James Lieberman, Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852-2738.

V

The Licensee may request a hearing within 30 days of the date of this Order. A request for a hearing should be clearly marked as a "Request for an Enforcement Hearing" and shall be addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, with a copy to the Commission's Document Control Desk, Washington, D.C. 20555. Copies also shall be sent to the Assistant General Counsel for Hearings and Enforcement at the same address and to the Regional

Administrator, NRC Region I, 475 Allendale Road, King of Prussia, PA 19406.

If a hearing is requested, the Commission will issue an Order designating the time and place of the hearing. If the Licensee fails to request a hearing within 30 days of the date of this Order, the provisions of this Order shall be effective without further proceedings. If payment has not been made by that time, the matter may be referred to the Attorney General for collection.

In the event the Licensee requests a hearing as provided above, the issues to be considered at such hearing shall be:

(a) Whether the Licensee was in violation of the Commission's requirements as set forth in Violations I.A, I.B, II.A, II.B, III.A, III.B, III.C.1, III.D.1-4, III.D.6, III.G, III.H, and III.J.1-3 of the Notice referenced in Section II above, and

(b) Whether, on the basis of such violations and the additional violations set forth in the Notice of Violation that the Licensee admitted, this Order should be sustained.

Dated at Rockville, Maryland this 24th day of April 1995.

For the Nuclear Regulatory Commission.

Hugh L. Thompson, Jr.,
Deputy Executive Director for Nuclear Materials Safety, Safeguards and Operations Support.

Appendix—Evaluations and Conclusion

On May 31, 1994, a Notice of Violation and Proposed Imposition of Civil Penalties (Notice) was issued for violations identified during NRC inspections (including an Incident Investigation Team (IIT) inspection) at several Oncology Services Corporation (Licensee) facilities. The Licensee responded to the Notice on August 31, 1994 and October 4, 1994. The Licensee admitted Violations III.C.2, III.D.5, III.E, III.F, and III.I; denied Violations I.A, I.B, II.A, II.B, III.A, III.B, III.C.1, III.D.1-4, III.D.6, III.G, III.H, and III.J.1-3; and requested remission of the civil penalties. The NRC's evaluation and conclusion regarding the Licensee's requests are as follows:

Restatement of Violations in Section I of the Notice

I. A. 10 CFR 20.201(b) requires that each Licensee make such surveys as may be necessary to comply with the requirements of 10 CFR Part 20 and which are reasonable under the circumstances to evaluate the extent of radiation hazards that may be present. As defined in 10 CFR 20.201(a), "survey" means an evaluation of the radiation hazards incident to the

production, use, release, disposal, or presence of radioactive materials or other sources of radiation under a specific set of conditions.

Contrary to the above, on November 16, 1992, the Licensee did not make a survey necessary to comply with the requirements of 10 CFR 20.101 which limits radiation exposure to individuals in restricted areas, and 10 CFR 20.105(b) which limits radiation levels in unrestricted areas. Specifically, although the room radiation monitor in the treatment room (restricted area) at the Indiana Regional Cancer Center (IRCC), flashed the red alarm signal even after the console of the High Dose Rate (HDR) afterloader unit showed that a 4.2 Curie iridium-192 source was safely retracted (because the source had broken off inside the patient), a radiation survey was not performed to confirm or discount the presence of a radiation hazard in the room or the patient as indicated by the alarming room monitor.

B. Condition 17 of License No. 37-28540-01, Amendment No. 3 dated August 19, 1992, requires, in part, that the Licensee conduct its program in accordance with the statements, representations, and procedures contained in the application dated June 1, 1990, and the letter dated August 2, 1990.

Item 9.C.3 of the application dated June 1, 1990, requires, in part, that a radiation monitor (PrimAlert or equivalent) be mounted on the wall [in the HDR afterloader treatment room] and will remain in place as a means of verifying a source "safe" or "out" condition.

Item 10.15.A.3 of the application dated June 1, 1990, requires, in part, that all attending personnel must remain in the control area during actual treatment and may not re-enter the treatment room until the room radiation detector (PrimAlert) indicates a safe condition prevails.

Item 6 of the letter dated August 2, 1990, states that failure of the radiation monitor will result in termination of the treatment until the monitor is replaced or repaired and, in the event of failure of the room monitor, no personnel will enter the room without a portable survey meter or audible dosimeter.

Contrary to the above, on November 16, 1992, during a patient treatment utilizing an iridium-192 source in a HDR afterloader, at the IRCC, when the wall-mounted radiation monitor flashed the red alarm signal to indicate a source "out" condition, a physician authorized user, who had been informed that the red alarm signal was flashing, entered the treatment room without a portable

survey meter or audible dosimeter; and, at some point during the event, a Licensee technologist entered the treatment room and unplugged and replugged the power supply of the room radiation monitor to reset the alarm.

These violations represent a Severity Level I problem (Supplement IV and VI) Civil Penalty—\$100,000.

Summary of Licensee's Response to Violation I.A

The Licensee in its responses, denies Violation I.A and states that the treatment room at the Indiana Regional Cancer Center was surveyed with what the Licensee terms "a wall mounted survey instrument ('WMSI')", the WMSI did not flash red in the presence of the authorized user, and the WMSI stopped flashing when the electrical connection was touched. The Licensee further asserts that the authorized user was not aware, prior to entering the treatment room, that the WMSI had flashed. The Licensee also asserts that all output on the Omnitron unit and console indicated that the source was parked and safe; no alarm went off on the Omnitron unit; and all personnel acted in accordance with what the Licensee terms its "NRC approved Omnitron training." The Licensee states that the conduct of the authorized user and the Licensee was reasonable at all times and in conformity with NRC regulations.

The Licensee also states that the Omnitron machine failed; that failure was neither expected nor intended; and that the Licensee could not have prevented the failure. The Licensee also notes that it believes the NRC was in a much better position to understand the need for adequate surveys, yet the NRC license application reviewer did not find it necessary to require, or even request, the Licensee modify its license application or procedure to include a patient survey with a hand held survey meter after each treatment. The Licensee states that it believes that at all times it followed the applicable regulations, and that it was the victim of a machine failure and inadequate and/or outdated regulations. The Licensee further states that there was no intent to violate any regulations and that personnel were not reckless. The Licensee states that since the WMSI was not flashing when the authorized user was in the treatment room, to expect the authorized user to act other than as he did is not rational under the existing circumstances. The Licensee believes that, in any event, this violation would be classified at Severity Level IV.

NRC Evaluation of Licensee's Response to Violation I.A

The specific issue addressed in Violation I.A is whether the Licensee performed a survey as required by 10 CFR 20.101 to confirm or discount the presence of a radiation hazard in the room or the patient as indicated by the alarming room monitor. The fact that the wall mounted radiation monitor flashed the red alarm signal even though the Omnitron console showed that the source was safely retracted is the condition that triggered the requirement to conduct a survey pursuant to § 20.201. Thus, the Licensee cannot point to the same wall mounted radiation monitor as fulfilling the requirement to conduct the survey pursuant to § 20.201. Rather, the Licensee was required under those circumstances, pursuant to § 20.201, to perform an independent survey, such as by using a hand held radiation survey instrument, to determine which indicator was correct—the wall mounted radiation monitor, or the Omnitron console. The Licensee failed to do this and chose instead to discount the alarm from the wall mounted radiation monitor and to rely on the Omnitron console indicator.

As to the Licensee's statement that the regulations are inadequate or outdated, the Licensee does not identify any particular regulation. However, only 10 CFR 20.201 is cited in Violation I.A. An extensive revision of 10 CFR Part 20 became effective January 1, 1994, and the survey requirement of 10 CFR 20.201 is now codified at 10 CFR 20.1501. The language of the specific requirement has been changed only slightly. The survey requirement of 10 CFR 20.201 is not outdated or inadequate. It would have been a simple matter for the Licensee to comply with the requirement using the hand held survey instrument that the Licensee had on hand, which is a basic radiation protection practice.

Even before the authorized user (AU) arrived at the treatment room, Licensee technologists noticed that the wall mounted radiation monitor was flashing, knew that the Omnitron console indicated that the source was retracted safely, and yet they were present in the treatment room without having performed the survey required pursuant to § 20.201. At this point, such a survey was necessary to comply with the requirements of 10 CFR 20.101, which limits exposure to individuals in restricted areas. Thus, Violation I.A was occurring even before the AU entered the room.

Although knowledge on the part of the AU that the wall mounted radiation monitor had been flashing is not necessary to prove the violation, the fact that the AU was aware that the wall mounted radiation monitor was flashing as he entered the treatment room is corroborated by his testimony, as well as the testimony of others, in transcribed interviews. Additionally, the transcribed interviews of the AU consistently show that, while he was in the treatment room, he was aware that: (1) The wall mounted radiation monitor had been flashing; and (2) the Omnitron console showed that the source was safely retracted.

NRC agrees that the Omnitron source broke off and was not retracted, that this was neither expected nor intended by the Licensee, and that the Licensee could not have prevented the break. However, that does not change the fact that the survey required by 10 CFR 20.201 was not performed, which is a matter that was within the Licensee's control. Given the conflicting information from the flashing wall mounted radiation monitor and the Omnitron control panel, such a survey was reasonable under the circumstances to evaluate the extent of the radiation hazards that were present. Since such a survey was not performed, the NRC concludes that Violation I.A occurred as stated in the Notice. The issue of the severity level of the violation is addressed in the evaluation of the Licensee's Response to Violation I.B, below.

Summary of Licensee's Response to Violation I.B

The Licensee denies Violation I.B; incorporates its response to Violation I.A, summarized above; and asserts that Violation I.B would be a Severity Level IV violation. The Licensee states that the wall mounted radiation monitor should have continued to alarm, and that if the monitor had done so, the technologist and authorized user would have acted accordingly.

NRC Evaluation of Licensee's Response to Violation I.B

Licensee employees entered the treatment room while the wall mounted radiation monitor was alarming, indicating a non-safe condition, and they did so without a portable survey meter or audible dosimeter. If the employees believed that the wall mounted radiation monitor was functioning properly, they should not have entered the treatment room while it was alarming, which is a violation of License Condition 17. If the employees discounted the alarm because they

believed that the wall mounted radiation monitor was not functioning properly (i.e., spuriously alarming), they should not have entered the treatment room without a portable survey meter or audible dosimeter, which is also a violation of License Condition 17.

Moreover, the requirements of License Condition 17 as cited in Violation I.B were being violated even before the authorized user entered the treatment room. The transcribed interviews clearly show that the monitor was alarming when the technologists entered the treatment room. The violation occurred upon entry. Thus, whether the monitor should have continued to alarm after the technologist entered the treatment room and manipulated its plug is not relevant to the existence of the violation. Accordingly, the NRC concludes that Violation I.B occurred as stated in the Notice.

Among other things, Violations I.A and I.B were classified in the aggregate as a Severity Level I problem in accordance with Supplements IV and VI of the NRC Enforcement Policy because: (1) Conducting the survey and complying with the requirements of License Condition 17 regarding the wall mounted radiation monitor, and the use of a portable survey meter or audible dosimeter in the event of a failure of the wall mounted radiation monitor, constitute a system designed to prevent or mitigate a serious safety event, and in this case, the system was not operable when actually required to perform; and (2) the violations resulted in acute radiation exposure and subsequent death of a patient. See Enforcement Policy (1993), Supplement IV, Example A.2; and Supplement VI, Examples A.2 and A.4.

Restatement of Violations in Section II of the Notice

II.A. 10 CFR 20.207(a) requires that licensed materials stored in an unrestricted area be secured against unauthorized removal from the place of storage. 10 CFR 20.207(b) requires that licensed materials in an unrestricted area and not in storage be tended under constant surveillance and immediate control of the Licensee. As defined in 10 CFR 20.3(a)(17), an unrestricted area is any area access to which is not controlled by the Licensee for purposes of protection of individuals from exposure to radiation and radioactive materials.

Contrary to the above, from November 16, 1992 to December 1, 1992, licensed material consisting of Curie quantities of iridium-192 was located at a nursing home, a waste disposal facility, and several vehicles, which are unrestricted

areas, and the licensed material was not secured against unauthorized removal nor was it under the constant surveillance and immediate control of the Licensee.

B. 10 CFR 20.105(b) requires that, except as authorized by the Commission in 10 CFR 20.105(a), no Licensee shall possess, use, or transfer licensed material in such a manner as to create radiation levels in unrestricted areas which, if an individual were continuously present in the area, could result in his receiving a dose in excess of 2 millirems in any one hour or 100 millirems in any seven consecutive days.

Contrary to the above, from November 16, 1992 to December 1, 1992, the Licensee allowed the creation of radiation levels in unrestricted areas, such that if an individual were continuously present in the area, he could have received a dose in excess of 2 millirems in any one hour or 100 millirems in any seven consecutive days. Specifically, the Licensee allowed the creation of radiation levels of approximately 2000 millirem per hour at a distance of one meter in unrestricted areas, specifically a nursing home, a waste disposal facility, and several vehicles.

These violations represent a Severity Level I problem (Supplement IV) Civil Penalty—\$100,000.

Summary of Licensee Response to Violations II.A and II.B

The Licensee denies Violations II.A and II.B and incorporates by reference its response to the violations in Section I. The Licensee contends that the source was lost, not possessed, used, transferred or stored. According to the Licensee, loss is an accidental act, while, as used in NRC regulations, possession, use, transfer and storage are deliberate acts. The Licensee asserts that the cited violations would have required knowledge of attending personnel that the source was still in the patient, but since they did not know the source was still inside the patient, the Licensee did not possess, use, transfer or store material in violation of any regulations.

NRC Evaluation of Licensee's Response to Violations II.A and II.B

The Notice does not assert, expressly or otherwise, that the violations were knowing or deliberate. Neither 10 CFR § 20.207 nor § 20.105 require a knowing failure to maintain control of licensed material, or knowing exposure of individuals to radiation, in order to establish a violation. Under the regulations in 10 CFR part 20, licensees are strictly held accountable for loss of

radioactive material and for radiation levels in unrestricted areas caused by such loss. As a result of the Licensee's use of the source on November 16, 1992, the source escaped the Licensee's control and was transferred to the nursing home and, subsequently, to other unrestricted areas, where it created radiation levels far in excess of the allowable limits. Therefore, the NRC concludes that Violations II.A and II.B occurred as stated in the Notice.

Restatement of Violations in Section III of the Notice

III.A. 10 CFR 19.12 requires, in part, that all individuals working in a restricted area be instructed in the precautions and procedures to minimize exposure to radioactive materials, in the purpose and functions of protective devices employed, and in the applicable provisions of the Commission's regulations and licenses.

10 CFR 35.25(a)(1) requires, in part, that a Licensee that permits the use of byproduct material under the supervision of an authorized user shall instruct the supervised individual in the principles of radiation safety appropriate to that individual's use of byproduct material.

Condition 17 of License No. 37-28540-01, Amendment No. 3 dated August 19, 1992, requires, in part, that the Licensee conduct its program in accordance with the statements, representations, and procedures contained in the application dated June 1, 1990.

Item 8 of the application dated June 1, 1990, requires, in part, that training for HDR device operators will include emergency training where the device operator will demonstrate emergency routine competence during a "dry run" emergency of the source not retracting.

Contrary to the above, individuals who were working in the HDR afterloader treatment room, a restricted area, at three of the Licensee's six facilities in Pennsylvania, had not been adequately instructed in the precautions and procedures to minimize exposure to radioactive materials, in the purpose and functions of protective devices employed, and in the applicable provisions of the Commission's regulations and the conditions of the license, as evidenced by the following examples:

1. As of December 18, 1992, technologists working in a restricted area at the Indiana facility were not adequately instructed in how to use a survey meter, the meaning of a high radiation area, the methods of performing HDR afterloader door interlock checks, the significance of the

alarm setpoint (the preset value) of the wall-mounted radiation monitor, the meaning of HDR afterloader error messages, the activity of the sources contained in the HDR unit and their potential radioactive hazard, or the corporate policy that requires the staff to survey each patient treated with the HDR afterloader unit with a portable survey meter before the patient's release, and in addition, individuals who operated the HDR device had not performed a "dry run" emergency; and

2. As of December 8, 1992, Licensee personnel working in restricted areas at the Exton and Lehighton facilities had not been instructed in the applicable provisions of the Commission's regulations and the NRC license, and individuals who operated the HDR device had not performed a "dry run" emergency of the source not retracting.

B. 10 CFR 35.25(a)(1) requires, in part, that a Licensee that permits the use of byproduct material by an individual under the supervision of an authorized user shall instruct the supervised individual in the Licensee's written quality management program.

Contrary to the above, as of December 8, 1992, the Licensee did not instruct personnel who used iridium-192 under the supervision of an authorized user at the Exton facility in the Licensee's written quality management program.

C. 10 CFR 20.202(a) (1) and (3) requires, in part, that: Each Licensee supply appropriate personnel monitoring equipment to, and require the use of such equipment by, each individual who enters a restricted area under such circumstances that he receives, or is likely to receive, a dose in any calendar quarter in excess of 25 percent of the applicable value specified in 10 CFR 20.101(a); and each Licensee supply appropriate personnel monitoring equipment to, and require the use of, such equipment by each individual who enters a high radiation area.

Contrary to the above,

1. On November 16, 1992, during a treatment of a patient with iridium-192 in a HDR afterloader unit, the physician authorized user at the Indiana facility entered the treatment room, a restricted area, and, although the wall-mounted radiation monitor had flashed the red alarm signal to indicate the presence of a radiation field, the authorized user did not wear his personal monitoring equipment; and,

2. On December 1, 1992, the authorized user at the Indiana facility, in efforts to retrieve the iridium-192 radioactive source, entered a high radiation area at the Browning-Ferris Industries waste facility in Carnegie,

Pennsylvania, and did not wear his personnel monitoring equipment.

D. Condition 17 of License No. 37-28540-01 requires, in part, that licensed material be possessed and used in accordance with statements, representations, and procedures contained in an application dated June 1, 1990, and a letter dated August 16, 1991.

1. Item 10.2 of the application dated June 1, 1990, states that the Licensee will establish and implement the ALARA program that was published in Appendix G to Regulatory Guide 10.8, Revision 2.

Appendix G to Regulatory Guide 10.8, Revision 2, requires, in part, that the RSO [Radiation Safety Officer] be in close contact with all users and workers in order to develop ALARA procedures for working with radioactive materials.

Contrary to the above, as of December 3, 1992, the RSO did not maintain close contact with all users and workers. For example, Medical Director/Authorized Users at the Indiana and Lehighton facilities were not aware of who the RSO was. Additionally, the RSO had not visited the Lehighton facility in the past 6-9 months.

2. Item No. 10.15.A.1 of the June 1, 1990, application requires that emergency procedures be conspicuously posted near the control console.

Contrary to the above, on December 8, 1992, the emergency procedures were not posted at the Exton facility.

3. Item No. 10.15.B.1 of the June 1, 1990, application requires that the calibration of the HDR afterloader source and device include a check of source travel time error and accuracy of the timing device.

Contrary to the above, as of December 8, 1992, the calibration of the HDR afterloader source and device at the Exton facility did not include a check of source travel time error and accuracy of the timing device.

4. Item No. 10.12 of the June 1, 1990, application requires that surveys of radiation levels in adjacent and control areas be performed at each source exchange and logged.

Contrary to the above, as of December 8, 1992, surveys of radiation levels in adjacent and control areas were not performed at each source exchange at the Exton facility.

5. The Licensee's letter dated August 16, 1991, requires, in part, that the key for the linear accelerator and the key for the HDR afterloader unit be on the same ring to prohibit the simultaneous activation of these units.

Contrary to the above, on December 8, 1992, the key for the linear accelerator and the key for the HDR afterloader unit

were not on the same ring at the Exton facility and the Leighton facility. At each facility, the inspector noted that the linear accelerator key was in the linear accelerator console and the HDR key was in the HDR console.

6. Item 4 of the letter dated August 2, 1990, requires, in part, that ancillary personnel will receive an orientation program and an annual review of the basic principles related to identifying, and proper procedures in working in, areas controlled under this license. Instructions for individuals will include the subjects listed on page A-1 of NRC Regulatory Guide 10.8, Rev. 2.

Regulatory Guide 10.8, Rev. 2, page A-1, requires instruction in potential hazards associated with radioactive material in each area where the employee will work.

Contrary to the above, as of December 4, 1992, ancillary personnel at the IRCC facility were not informed about radiation hazards associated with a 3.7 Curie iridium-192 source in a source container located in the HDR afterloader treatment room. Specifically, housekeeping personnel had access to the keys to the treatment room and offered to move the source container which measured approximately 80 millirem per hour at the surface.

E. 10 CFR 20.203(c)(1) requires that each high radiation area be conspicuously posted with a sign or signs bearing the radiation caution symbol and the words: "Caution High Radiation Area."

Contrary to the above, on December 8, 1992, the high radiation area in the HDR afterloader treatment room at the Exton facility was not posted as required with the required sign bearing the radiation caution symbol and the words: "Caution High Radiation Area."

F. 10 CFR 35.51(c) requires, in part, that a Licensee check each survey instrument for proper operation with the dedicated check source each day of use.

Contrary to the above, as of December 8, 1992, the Licensee at the Exton facility routinely did not check its survey meter with a dedicated check source on days when the instrument was used.

G. 10 CFR 35.25(a)(3) requires, in part, that a Licensee that permits the use of byproduct material by an individual under the supervision of an authorized user shall periodically review the supervised individual's use of byproduct material and the records kept to reflect this use.

Condition 17 of License No. 37-28540-01 requires, in part, that licensed material be possessed and used in accordance with statements,

representations, and procedures contained in an application dated June 1, 1990, and a letter dated August 16, 1991.

Item 10.15.A.4 of the application dated June 1, 1990, requires, in part, that daily checks of interlocks, safety systems, and alarms be performed and logged.

Contrary to the above, as of December 3, 1992, supervised individuals at the IRCC facility routinely did not perform daily interlock checks as required in conjunction with operating the HDR afterloader containing iridium-192, and the Licensee did not review their performance of this procedure.

H. 10 CFR 35.21(b)(2) requires, in part, that the RSO establish, collect in one binder or file, and implement written policy and procedures for:

(v) Using byproduct material safely,
(vi) Taking emergency action if control of byproduct material is lost,
(viii) Performing checks of survey instruments and other safety equipment, and
(x) Training personnel who work in or frequent areas where byproduct material is used or stored.

Contrary to the above, as of November 16, 1992:

1. The RSO did not establish and implement written policy and procedures for using byproduct material safely. Specifically, although iridium-192 was in use in HDR afterloader units at the Indiana, Exton, and Leighton facilities, written procedures entitled, "Oncology Services Corporation, Department of Physics, HDR Treatment Manual", existed only in draft form and the RSO had not distributed them to the staff.

2. The RSO did not establish and implement procedures for taking emergency action if control of byproduct material was lost. Specifically, the RSO had not established or implemented such procedures as of December 1, 1992, when the Licensee retrieved a 3.7 Curie iridium-192 source from a waste disposal facility and transported it back to the Licensee's facility.

3. The RSO did not implement procedures at the IRCC for performing checks of survey instruments and other safety equipment. Specifically, the RSO did not implement procedures for checking survey instruments for proper operation with a dedicated check source on days when the instrument was used, as required by 10 CFR 35.51(c); and for checking the treatment room door interlock in conjunction with operating the HDR afterloader, as required by License Condition 17, application dated June 1, 1990, Item 10.15.A.4.

4. The RSO did not establish and implement written policy and procedures for training personnel who work in or frequent areas where byproduct material is used or stored. For example, the RSO believed that it was the responsibility of the physicist at the Indiana, PA, facility to provide such training to the individuals there; however, the medical physicist stated that his contract did not indicate that he should provide training.

I. 10 CFR 35.13(e) requires that a Licensee apply for and must receive a license amendment before it adds to or changes the areas of use or address or addresses of use identified in the application or on the license.

Contrary to the above, on or about April 23, 1991, the Licensee's RSO changed the area of use of iridium-192 in a HDR afterloader for a shielding experiment from the shielded therapy room at the Greater Harrisburg Cancer Center, the area of use identified in the application, to an area outside of the building and, as of that date, the Licensee had not applied for or received a license amendment authorizing the change.

J. 10 CFR 71.5(a) requires that a Licensee who transports licensed material outside the confines of its plant or other place of use, or who delivers licensed material to a carrier for transport, shall comply with the applicable requirements of the regulations appropriate to the mode of transport of the Department of Transportation (DOT) in 49 CFR Parts 170 through 189.

1. 49 CFR 173.24(f)(ii) requires, in part, that closures on packagings shall be so designed and closed that under conditions normally incident to transportation, the closure is secure.

49 CFR 173.475(c) requires, in part, that before each shipment of any radioactive materials package, the shipper shall ensure by examination or appropriate tests that each closure device of the packaging is properly installed, secured, and free of defects.

Contrary to the above, on December 1, 1992, the Licensee transported a radioactive materials package containing 3.7 Curies of iridium-192 and there was no closure device on the packaging.

2. 49 CFR 177.817(a) requires that a carrier not transport a hazardous material unless it is accompanied by a shipping paper prepared in accordance with 49 CFR 172.200-203. Pursuant to 49 CFR 172.101, radioactive material is classified as hazardous material.

Contrary to the above, on December 1, 1992, the Licensee transported 3.7

Curies of iridium-192, a radioactive material, without a shipping paper.

3. 49 CFR 172.504 prescribes requirements for placarding vehicles used to transport hazardous materials. Specifically, Table 1 requires that the transport vehicle be placarded on each side and each end with a "RADIOACTIVE" placard when transporting packages bearing a "RADIOACTIVE YELLOW-III" label (footnote 4).

Contrary to the above, on December 1, 1992, the Licensee transported 3.7 Curies of iridium-192 outside the confines of its plant in a package with the required YELLOW-III label, and the transport vehicle was not placarded with a "RADIOACTIVE" placard.

These violations represent a Security Level II problem (Supplement IV, V and VI) Civil Penalty—\$80,000.

Summary of Licensee's Response to Violations III.A and III.B

The Licensee denies Violations III.A and III.B and states that at all times it adequately instructed all personnel in relevant areas consistent with 10 CFR 19.12, 10 CFR 35.25(a)(1), and the license, and that it would be incorrect for NRC to take the position that each and every individual must be knowledgeable about each and every regulation and/or license condition. The Licensee believes that, in any event, these violations would be classified at Severity Level III.

NRC Evaluation of Licensee Response to Violations III.A and III.B

The Licensee was not cited for failure to instruct each and every individual in every NRC requirement. 10 CFR 19.12 requires that training for workers be commensurate with potential radiological health protection problems in restricted areas. Additionally, training must fulfill specific regulations such as 10 CFR 35.25(a)(1), as well as specific commitments made by the Licensee and incorporated into the license by condition. Violations III.A and III.B were identified as a result of discussions between OSC personnel and NRC inspectors or investigators. NRC does not dispute that some training did occur. However, as documented in the inspection report, the Incident Investigation Team (IIT) report, and the investigation by NRC's Office of Investigations (OI), the training that was given was not adequate to meet the requirements. The Licensee's general assertion that it complied with all requirements does not refute the fact that the specific subjects described in Violations III.A and III.B were not covered adequately in the training that

the Licensee gave to the personnel described in Violations III.A and III.B. Thus, the NRC concludes that the violations occurred as stated in the Notice.

The NRC did not categorize the individual violations and examples of violations in Section III of the Notice by severity level. Rather, the NRC considered the violations in the aggregate as a single problem categorized at Severity Level II. The Enforcement Policy defines a Severity Level II violation or problem as one of very significant concern. Clearly, this severity level is appropriate here because the number and nature of the violations represent a very significant corporate management breakdown in the control of licensed activities; and the lack of attention to, and understanding of, regulatory requirements on the part of Licensee management and its RSO contributed to the November 1992 event. The purpose of aggregating violations is to focus the Licensee's attention on the fundamental underlying causes for which enforcement action is warranted, and to reflect the fact that several violations with a common cause are more significant collectively than individually, and therefore, warrant a more substantial enforcement action. See Enforcement Policy, Section IV.A. In this case it was necessary to focus the Licensee's attention on the importance of meticulous oversight of the corporate radiation safety program, the lack of which was a common causative factor in the violations.

Summary of Licensee's Response to Violation III.C

The Licensee denies Example III.C.1 and states that it supplied and required the use of personnel monitoring equipment; however, the authorized user had no reason to believe that it was necessary to wear a film badge. The Licensee further incorporates by reference its response to Violations A and B in Section I of the Notice. The Licensee believes that, in any event, Example III.C.1 would constitute a Severity Level V violation. The Licensee admits Example III.C.2 but believes that it constitutes a Severity Level V violation.

NRC Evaluation of Licensee Response to Violation III.C

10 CFR 20.202(a)(1) requires that the Licensee require the use of appropriate personnel monitoring equipment by each individual who enters a restricted area (the HDR treatment room) under such circumstances that he receives, or is likely to receive, a dose in any

calendar quarter in excess of 25 percent of the occupational dose limits specified in 10 CFR 20.101(a). The treatment room constituted a restricted area because access to this area was controlled by the Licensee for purposes of protection of individuals from exposure to radiation and radioactive materials. See 10 CFR 20.3(a)(14). With a 4.2 Curie iridium-192 source in the unshielded configuration, an individual entering the treatment room would be likely to receive a dose in excess of 25% of the occupational dose limits specified in 10 CFR 20.101(a).

Moreover, 10 CFR 20.202(a)(3) requires that the Licensee require the use of personnel monitoring equipment by each individual who enters a high radiation area. The treatment room constituted a high radiation area because, when the source is in an unshielded configuration, radiation levels in the treatment room are such that a major portion of the body could receive in any one hour a dose in excess of 100 millirem. See 10 CFR 20.202(b)(3). The Licensee was well aware of this fact, because it had posted the room as a high radiation area at the time of the November 16, 1992 event.

The requirement that the Licensee supply and require the use of appropriate personnel monitoring equipment does not depend on the individual's perception of a radiation hazard, but rather on the fact of a radiation hazard that may result in an exposure in excess of the limit in § 20.202(a)(1), or that requires posting as a high radiation area as per § 20.202(a)(3). Any time that the authorized user (AU) supervised the use of the HDR unit, he could be called upon to make an emergency entry into the treatment room with the source in an unshielded configuration. The Licensee should have been well aware of this fact, because the license application specifies training for its employees in emergency procedures involving entry into the treatment room with the source in an unshielded configuration. See License Condition 17, Application dated June 1, 1990, Item 10.15.C. Thus, the Licensee should have assured that the AU wore his personnel monitoring equipment whenever he supervised the use of the HDR unit. The AU did enter the treatment room with the source in an unshielded configuration and he was not wearing his personnel monitoring equipment. Therefore, the NRC concludes that Example III.C.1 occurred as stated in the Notice. Moreover, even if the Licensee had provided an adequate reason to withdraw Example III.C.1, Violation III.C still occurred as evidenced by the

Licensee's admission of Example III.C.2. The issue of the Severity Level of the violation is addressed in the evaluation of the Licensee's response to Violations III.A and III.B, above.

Summary of Licensee's Response to Violation III.D.1

The Licensee denies Violation III.D.1, states that *the RSO* did not fail to discharge his duties, states that the RSO did not violate any regulation relating thereto, and notes that the NRC has not cited any such specific regulation and that the RSO had an ALARA program in place. The Licensee states that there is no requirement that the Licensee have any physical presence at any facility. In addition, the Licensee states that the RSO and a physicist were in communication with the Lehighton facility by telephone and fax.

NRC Evaluation of the Licensee Response to Violation III.D.1

The Licensee was required, pursuant to License Condition 17, to follow the commitments it made in the June 1, 1990, application to the NRC. Item 10.2 of the application required that Appendix G of Regulatory Guide 10.8 be followed which in turn required the RSO to be in "close contact" with all users and workers in order to develop ALARA procedures for working with radioactive materials. The Licensee specifically committed in its license application that *the RSO* would do this. The development of ALARA procedures is a continuing and evolving process and requires firsthand observations and audits of employee knowledge, work, and work conditions. The fact that some ALARA procedures may have been in place does not relieve the Licensee of full compliance with this requirement.

The mere fact that the RSO may have been in communication by telephone or facsimile does not disprove the violation. In order for that fact to be relevant at all, the Licensee would have to show that such communications were with all users and workers and were for the purpose of developing ALARA procedures, which the Licensee has not done. Clearly, communications concerning, for example, patient treatment parameters, would have no bearing at all.

The NRC determined, via interviews, that the Medical Director and authorized user at the Indiana, Pennsylvania and Lehighton, Pennsylvania facilities were not aware, at the time of the IIT and the NRC inspection in December 1992, who the RSO was. Additionally, the RSO had not visited the Lehighton facility in the past 6–9 months. Also, as determined during

the inspection of the Exton facility, the technologist and the medical physicist at the Exton facility both believed that the medical physicist was the RSO. Accordingly, it is appropriate to conclude that the RSO did not maintain close contact with all users and workers as required by License Condition 17. Therefore, the NRC concludes that Violation III.D.1 occurred as stated in the Notice.

Summary of Licensee's Response to Violation III.D.2

The Licensee denies Violation III.D.2 and states that emergency procedures were available but not vertically posted because they kept falling down, and that it immediately posted the procedures following the inspection. The Licensee believes that, in any event, this constitutes a Severity Level V violation.

NRC Evaluation of Licensee Response to Violation III.D.2

The Licensee stated that the emergency procedures kept falling down. The inspection report states that the procedures were available but not posted at the time of the inspection, and that this was corrected before the inspectors left the facility. During the inspection, the medical physicist obtained a copy of a set of emergency procedures which was incomplete (contained blanks), and the Licensee had to fill in the blanks with Licensee specific information, and post the procedures conspicuously near the control console so that appropriate staff would have access to the procedures. The Licensee specific information had not been entered on the emergency procedures prior to the inspection. Therefore, even the emergency procedures that were available, but not posted, were incomplete.

At the time that the Licensee established its HDR brachytherapy program, the blanks in the emergency procedures should have been filled in with Licensee specific information and the procedures should have been conspicuously and durably posted near the control console so that appropriate staff would have immediate access to it. This was not done. Therefore, the NRC concludes that Violation III.D.2 occurred as stated in the Notice. The issue of the Severity Level of the violation is addressed in the evaluation of the Licensee's response to Violations III.A and III.B, above.

Summary of Licensee's Response to Violation III.D.3

The Licensee denies Violation III.D.3 and states that Exton personnel always did hand calculations and always

checked the source travel time error and accuracy of the timing device by using the clock on the wall and their wrist watches. The Licensee believes that, in any event, Violation III.D.3 would constitute a Severity Level V violation.

NRC Evaluation of Licensee Response to Violation III.D.3

The Licensee's unsupported general assertion that the calculations and checks for timing device accuracy and travel time error were in fact performed does not demonstrate that the violation did not occur. During the inspection, the NRC found evidence that the checks of the source travel time error and accuracy of the timing device were not done. Specifically, as noted in Section 7 of NRC Inspection Report 30–31765/92–001, issued on December 23, 1992, the record of the HDR calibration performed at Exton indicated that the source output was checked but that the source travel time error and accuracy of the timing device were not checked. Therefore, the NRC concludes that the violation occurred as stated in the Notice. The issue of the Severity Level of the violation is addressed in the evaluation of the Licensee's response to Violations III.A and III.B, above.

Summary of Licensee's Response to Violation III.D.4

The Licensee denies Violation III.D.4 and states its belief that Omnitron personnel performed surveys for the benefit of the Licensee. The Licensee believes that, in any event, Violation III.D.4 would constitute a Severity Level IV violation.

NRC Evaluation of Licensee Response to Violation III.D.4

The Licensee's response provides no facts or records to support the Licensee's assertion that the surveys in question were ever performed by Omnitron. While Omnitron personnel may have performed some surveys in connection with their work during source exchanges, the Licensee provides no evidence that any such surveys included all adjacent areas as well as control areas. Therefore, the NRC concludes that Violation III.D.4 occurred as stated in the Notice. The issue of the Severity Level of the violation is addressed in the evaluation of the Licensee's response to Violations III.A and III.B, above.

Summary of Licensee's Response to Violation III.D.5

The Licensee admits the violation but believes that it would constitute a Severity Level IV violation.

NRC Evaluation of Licensee Response to Violation III.D.5

The issue of the Severity Level of the violation is addressed in the evaluation of the Licensee's response to Violations III.A and III.B above.

Summary of Licensee's Response to Violation III.D.6

The Licensee states that since it does not have sufficient knowledge as to the specific truth regarding whether ancillary personnel (specifically, housekeeping personnel) were informed about radiation hazards associated with a 3.7 curie iridium-192 source in a source container located in the High Dose Rate (HDR) afterloader treatment room, it must deny this violation. The Licensee believes that, in any event, Violation III.D.6 would constitute a Severity Level IV violation.

NRC Evaluation of Licensee Response to Violation III.D.6

Housekeeping personnel interviewed by the NRC staff were not aware of the radiation hazards associated with a 3.7 curie iridium-192 source. Specifically, on December 4, 1992, OSC housekeeping personnel unlocked the area where the iridium source was being stored following the source retrieval operation and accompanied NRC inspectors into the area, and the housekeeping personnel had not been informed about the radiation hazards associated with the source. Therefore, the NRC concludes that Violation III.D.6 occurred as stated in the Notice. The issue of the Severity Level of the violation is addressed in the evaluation of the Licensee's response to Violations III.A and III.B, above.

Summary of Licensee's Responses to Violations III.E-F

The Licensee admits the violations but believes that Violation III.E would constitute a Severity Level V violation and that Violation III.F would constitute a Severity Level IV violation.

NRC Evaluation of Licensee Response to Violation III.E-F

The issue of the Severity Level of the violations is addressed in the evaluation of the Licensee's response to Violations III.A and III.B, above.

Summary of Licensee's Response to Violation III.G

The Licensee states that daily interlock checks were consistently done by individuals at IRCC, and that there was no requirement for the Licensee to review such completed checks as of December 1992. In addition, the Licensee notes that such checks would

have been reviewed at an annual audit. The Licensee believes that, in any event, Violation III.G would constitute a Severity Level IV violation.

NRC Evaluation of Licensee's Response to Violation III.G

Licensee technologists interviewed by the Incident Investigation Team (IIT) indicated that daily HDR interlock checks routinely were not performed as required. This is corroborated by the fact that there is not a log record for every check required. The Statements of Consideration for 10 CFR 35.25, "Supervision", state: "The purpose of supervision is to provide assurance that technologists and physicians do not use byproduct materials in a manner that is contrary to the requirements of the license, the regulations, or that is hazardous to the public health and safety [emphasis added]." See 51 Fed. Reg. 36940. While the Licensee was not required to review each and every check on a daily basis, it was required, pursuant to 10 CFR §§ 35.11, 35.25(a)(2), and 35.25(a)(3), to perform periodic reviews at a frequency sufficient to provide reasonable assurance that individuals working under the supervision of an authorized user were complying with, among other things, License Condition 17 with respect to the performance of daily interlock checks. It is clear from the fact that the noncompliance was occurring, undetected to the Licensee, that a single audit at the end of the year would not suffice. The NRC concludes that Violation III.G occurred as stated in the Notice. The issue of the Severity Level of the violation is addressed in the evaluation of the Licensee's response to Violations III.A and III.B, above.

Summary of Licensee's Response to Violation III.H

The Licensee denies the violation and states that at all times the RSO fully complied with relevant regulatory requirements, including implementing and distributing policies and procedures, and gathering materials. The Licensee also states that the RSO was immediately notified about the November 16, 1992 incident and instructed personnel how to respond appropriately.

NRC Evaluation of Licensee Response to Violation III.H

The Licensee provides no information to support its general assertion that it complied with all regulatory requirements or to refute the facts documented in the Incident Investigation Team (IIT) report, and the investigation by NRC's Office of

Investigations (OI), upon which the violations are based. Accordingly, the NRC concludes that the violation occurred as stated in the Notice.

Summary of Licensee's Response to Violation III.I

The Licensee admits that the RSO conducted the experiment, but states that the RSO took all measures to assure that such experiment was done safely and without risk, and this was not a willful violation but was done for the purpose, in part, of radiation safety. The Licensee believes that, in any event, Violation III.I would constitute a Severity Level IV violation.

NRC Evaluation of Licensee Response to Violation III.I

The Licensee admits that the RSO conducted the experiment and does not deny that the RSO changed the area of use of iridium-192 from the shielded therapy room to an area outside the building without first applying for or receiving a license amendment authorizing the change. The Licensee and its RSO may not pick and choose which regulatory requirements they will follow, even if they believe that noncompliance would somehow further radiation safety. 10 CFR 35.13(e) requires that the Licensee apply for and receive a license amendment before changing the area of use specified in the license. Moreover, willfulness is not a necessary element of a violation of 10 CFR 35.13(e). Accordingly, the NRC concludes that Violation III.I occurred as stated in the Notice. The issue of the Severity Level of the violation is addressed in the evaluation of the Licensee's response to Violations III.A and III.B, above.

Summary of Licensee's Response to Violations III/J.1-3

The Licensee states that its intent was not to become a shipper or a carrier of licensed material but under the extenuating circumstances, the Licensee contacted the NRC and was told what to do to retrieve the source. In addition, the Licensee states that at no time did the NRC attempt to alert the Licensee about the regulations cited in the Notice. The Licensee states that at the time of the incident, it did not transport sources, and as such was not generally knowledgeable about such. The Licensee further states that the Licensee took extreme precautions and brought the source back in a safe, secured container. Finally, the Licensee states that since it quickly retrieved the source after the NRC specifically told the Licensee to get the source, it would be unfair to cite the Licensee for these

violations. The Licensee believes that, in any event, Violations III.J.1–3 would constitute Severity Level V violations.

NRC Evaluation of Licensee Response to Violations III.J.1–3

Prior to the incident, the Licensee requested a license amendment to permit it to transport licensed material as part of its licensed activities. License Condition No. 15 of Amendment No. 03, dated August 19, 1992, authorized the Licensee to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material". Therefore, the Licensee should have been familiar with the provisions of 10 CFR Part 71. In any case, the Licensee transported the radioactive source on December 1, 1992, and therefore was bound by the requirements in 10 CFR 71.5(a). The fact that the NRC advised the Licensee to retrieve the Licensee's source does not excuse the Licensee from the requirements of Part 71, nor does it excuse the Licensee from its ignorance of the requirements of Part 71. At no time did NRC suggest that applicable regulations should not be followed. Since these requirements were not met, the NRC concludes that Violations III.J.1–3 occurred as stated in the Notice. The issue of the Severity Level of the violations is addressed in the evaluation of the Licensee's response to Violations III.A and III.B, above.

Summary of Licensee's Request for Mitigation

The Licensee states that subsequent to the Indiana event, Licensee management took corrective action by: immediately and voluntarily suspending HDR treatments at the Licensee's facilities that did not have full-time physicists for HDR treatments in order to review its entire HDR program; fully and timely complying with any and all Confirmatory Action Letters (CALs); replacing its RSO with a brachytherapy specialist; replacing multiple contract physicists; and hiring additional, qualified full-time physicists. The Licensee states that its proposed replacement of the RSO constitutes corrective action regarding all issues raised by the NRC, and notes that its new RSO has regularly been physically present at the Greater Pittsburgh and Greater Harrisburg facilities to review the entire HDR program.

The Licensee also notes that it has completely modified its HDR program, that the revised program has been approved by the NRC, and that Licensee management has been highly involved with the HDR program and has met on

a regular basis with the new RSO. In addition, the Licensee notes that it has restructured its physics program, which has resulted in at least quarterly training/refreshers courses in radiation safety and regulatory compliance at all facilities for all staff. Further, the Licensee notes that it is authorized users have attended an intensive training session with the new RSO regarding HDR usage, safety and emergency responses. The Licensee also notes that it hired a Certified Health Physicist (CHP) as Vice President of Regulatory Affairs and gave the CHP broad management authority, and that the CHP is responsible for the day-to-day radiation safety program company-wide.

The Licensee also states that it believes that the fines imposed are inappropriate and unsupported by the facts and applicable law. The Licensee states that to apply the \$100,000 per violation discretionary fine on the Licensee is now warranted and is unfair. In addition, the Licensee states that the NRC has attempted to impose the \$100,000 fine twice for one alleged failure, that being the alleged failure by the authorized user to do a survey with a hand held survey meter; and asserts that the loss of the source was not a separate action and cannot be separated from the alleged survey failure. With respect to the \$80,000 fine for the violations in Section III, the Licensee submits that the alleged violations, even if true, do not constitute a Severity Level II problem. The Licensee claims that it appears that NRC has not taken the past exemplary conduct of the Licensee into consideration and the Licensee requests that this conduct be reviewed again.

The Licensee cites a number of enforcement sanctions taken by the NRC against other licensees, which the Licensee believes supports its claim that the sanction imposed on the Licensee is not only unfair and inappropriate, but unlawful. The Licensee requests that the fines be reduced to \$14,000.

NRC Evaluation of Licensee's Request for Mitigation

Pursuant to Section 234 of the Atomic Energy Act, as amended, the NRC is authorized to impose civil penalties of up to \$100,000 per violation per day for each day that a violation continues. Normally, proposed civil penalties are determined after application to the base civil penalty of the mitigating and escalating factors in Section VI of the Enforcement Policy, including corrective action and licensee performance. Section VII.A of the Enforcement Policy provides, however, that notwithstanding the outcome of the

normal civil penalty adjustment process, the NRC may exercise its full enforcement authority to ensure that the resulting enforcement action appropriately reflects the level of NRC concern regarding the violations at issue and conveys the appropriate message to the licensee, in order to provide an appropriate sanction when particularly serious violations or serious breakdowns in management controls have occurred. In view of the particularly serious violations, which resulted in the death of a patient and exposure of numerous members of the public to radiation in excess of regulatory limits, and in view of the necessity of emphasizing to the Licensee the importance of meticulous management oversight of the radiation safety program, a very significant civil penalty was warranted. The NRC appropriately exercised its statutory authority when it proposed a \$100,000 civil penalty each for the violations in Section I and II of the NOV, and an \$80,000 civil penalty for the violations in Section III. The NRC also expects that these penalties will give all other similar licensees, including the successor licensees to OSC, an incentive to closely scrutinize their operations to avoid similar violations.

The Licensee's assertion that Problems I and II constitute a single violation is mistaken. Problems I and II involve violations of separate and distinct NRC requirements, with separate and distinct facts and consequences. Problem I involves a failure to perform surveys and to use radiation safety devices in violation of 10 CFR 20.201(b) and License Condition 17, which led to a misadministration resulting in acute radiation exposure and subsequent death of the patient. Problem II involves a loss of control of a radioactive source and the creation of radiation levels in unrestricted areas in violation of 10 CFR 20.206 and 10 CFR 20.105, which led to exposures of numerous members of the public to radiation in excess of regulatory limits. Therefore, separate violations are clearly justified. *Atlantic Research Corporation*, ALJ-78-2, 7 NRC 701 (1978).

The issue of the severity level of the violations in Section III of the NOV was addressed under "NRC Evaluation of Licensee's Response to Violations III.A and III.B."

The NRC acknowledges that the Licensee has taken corrective actions and is aware of the Licensee's past performance. However, in this case, the NRC exercised discretion to escalate the civil penalties, which supersedes the normal application of the adjustment factors, as explained above. In addition,

civil penalties are imposed, in part, to deter future violations by not only the involved licensee, but other licensees conducting similar activities. See Enforcement Policy, Section VI.B.

Contrary to the Licensee's statements, the civil penalties proposed in this case are within the authority of the NRC. The Licensee's comparison of the civil penalties in this case with civil penalties in other cases does not bring the NRC's exercise of its lawful authority into question. Of decisive importance is the NRC's clear authority to exercise discretion in the choice of enforcement sanctions and the ordering of enforcement priorities. *Advanced Medical Systems, Inc.*, (CLI-94-6), 39 NRC 285, 320 (1994). A sanction is not rendered invalid because it is more severe than that issued in other cases. *Id.* As explained above, the NRC acted within its statutory authority and the bounds of the Enforcement Policy when NRC exercised its discretion to escalate the civil penalties in this case. A rigid uniformity is not required in enforcement decisions, which inherently involve the exercise of informed judgment on a case-by-case basis. *Id.* See also, *Radiation Technology, Inc.*, (ALAB-567), 10 NRC 533, 541 (1979).

NRC Conclusion

The NRC has concluded that the violations occurred as stated in the Notice and an adequate basis for mitigation of the civil penalties was not provided by the Licensee. Consequently, the proposed civil penalties in the amount of \$280,000 should be imposed.

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BILLING CODE 7590-01-M

[Docket No. 50-278]

PECO Energy Company; Public Service Electric and Gas Company; Delmarva Power and Light Company; Atlantic City Electric Company (Peach Bottom Atomic Power Station, Unit 3); Exemption

I

PECO Energy Company, et al. (PECo, the licensee), is the holder of Operating License No. DPR-56, which authorizes operation of the Peach Bottom Atomic Power Station, Unit 3, at steady state reactor core power levels not in excess of 3293 megawatts thermal. The license provides, among other things, that the licensee is subject to the rules, regulations and order of the Commission now or hereafter in effect.

The plant is a boiling water reactor located at the licensee's site in York County, Pennsylvania.

II

Section 50.54(o) of 10 CFR Part 50 requires that primary reactor containments for water cooled power reactors be subject to the requirements of Appendix J to 10 CFR Part 50. Appendix J contains the leakage test requirements, schedules, and acceptance criteria for tests of the leak tight integrity of the primary reactor containment and systems and components which penetrate the containment.

Section III.D.2(a) of Appendix J to 10 CFR Part 50 requires that Type B leak rate tests, except for air locks, be performed during reactor shutdown for refueling, or other convenient intervals, but in no case at intervals greater than 2 years. Type B tests are intended to detect local leaks and to measure leakage across each pressure-containing or leakage-limiting boundary for certain reactor containment penetrations.

Section III.D.3 of Appendix J to 10 CFR Part 50 requires that Type C leak rate tests be performed during each reactor shutdown for refueling but in no case at intervals greater than 2 years. Type C tests are intended to measure containment isolation valve leakage rates for certain containment isolation valves.

III

By letter dated February 22, 1995, the licensee requested a one-time exemption from the requirements of Appendix J, Sections III.D.2(a) and III.D.3 for a period of 60 days for the isolation valves or leakage boundaries for 80 penetrations. In its request, the licensee provided a list of the affected penetrations and associated plant-specific leak test procedures, the date when the leak tests had last been performed and the date when the current leak test will expire.

The licensee has implemented a 24-month operating cycle schedule at the Peach Bottom facility. The last refueling outage for Unit 3, 3R09, commenced in September 1993 and ended in November 1993 and the next refueling outage, 3R10 is scheduled to commence no later than September 30, 1995. The leak tests for which the licensee has requested scheduler exemption were last conducted during the refueling outage 3R09, based on the information provided in the licensee's application. The licensee has stated that the affected leak test require either that safety systems be isolated or require access to

the drywell, either of which would require the reactor to be shutdown.

The licensee has divided the affected leak tests into two categories: (1) Those that require shutdown reactor conditions but come due prior to the latest scheduled commencement of 3R10 on September 30, 1995, and (2) those that require reactor shutdown conditions and come due after the scheduled commencement of 3R10. There are 52 leak test surveillance procedures affecting 47 penetrations or penetration groups in the first category. These tests and penetrations are listed in Table 1 of the licensee's February 22, 1995 request. The earliest of these tests falls due on August 12, 1995, up to 49 days prior to the scheduled shutdown. The licensee has requested an exemption for 60 days which will allow the unit to operate until the beginning of the planned outage without shutting down to perform leak tests and which will allow for flexibility in planning the leak tests during the outage.

There are 28 leak test surveillance procedures affecting 29 penetrations in the second category described previously. These tests are listed in Table 2 of the licensee's February 22, 1995 submittal. The licensee has requested an exemption of 60 days to allow for flexibility in planning these leak tests during the outage. The licensee stated that all of the affected penetrations will be leak tested prior to restart from 3R10.

IV

The licensee presented information in support of its request for a 60-day extension of the Type B and C test intervals. The maximum allowable leakage rate for maintaining primary containment (L_a —minimum pathway leakage) is 125,417 cc/min. The as-found total Type B and C minimum pathway leakage rate observed during Unit 3 refueling outage 3R09 during the fall of 1993 was 33,434 cc/min. The as-left leak rate for that same outage was 27,188 cc/min.

PECo stated that an extension of the leak test interval to allow for 49 days of operation is not likely to significantly decrease the margin between as-found leak rates and L_a .

PECo also stated that the remainder of the total 60-day extension, requested for outage planning flexibility, will have minimal safety significance since the unit will be in cold shutdown. Primary containment integrity is not required during cold shutdown.

The licensee provided information regarding the requirements of 10 CFR 50.12, "Specific Exemptions." With respect to the requirements of 10 CFR

50.12(a)(1), the licensee stated that the requested action is authorized by law in that no prohibition of law exists which would preclude the activities which would be authorized by the exemption. In addition, the licensee stated that, for the reasons discussed above, the requested exemption does not present an undue risk to the public health and safety. Finally, the licensee stated that containment leak rate testing is not considered in the common defense and security of the nation.

With respect to the requirements of 10 CFR 50.12(a)(2)(iii), the licensee stated that special circumstances are present because compliance with the strict requirements of Appendix J would result in hardships significantly in excess of those contemplated when the regulation was adopted. The licensee stated that at the time the regulation was adopted, a presumption was made that a 2-year test interval would easily accommodate performance of the required tests during an operating cycle. However, development of new core designs have resulted in cycles of 24 months, or longer. Performance of the tests at the 24-month frequency would result in undue financial hardship resulting from extended reactor shutdown beyond that intended by the regulation with little or no compensatory increase in the level of safety or quality.

V

Based on the above, the staff finds there is reasonable assurance that the containment leakage-limiting function will be maintained and that a forced outage to perform Type B and C tests is not necessary. Therefore, the staff finds the requested exemption, to allow the Type B and C test intervals for the penetrations listed in the licensee's February 22, 1995 request to be extended for 60 days from their current expiration date, to be acceptable. The exemption request has been evaluated in a safety evaluation dated April 25, 1995.

Accordingly, the Commission has determined that, pursuant to 10 CFR 50.12(a), the requested exemption is authorized by law, will not present an undue risk to the public health and safety, and is consistent with the common defense and security. The Commission finds that the special circumstances as required by 10 CFR 50.12(a)(2) are present. The Commission's finding is based on the information provided by the licensee regarding 10 CFR 50.12(a)(2)(iii). In addition, as specified in 50.12(a)(2)(ii), special circumstances are present whenever the application of the

regulation in the particular circumstance would not serve the underlying purpose of the rule or is not necessary to achieve the underlying purpose of the rule. The underlying purpose of the rule is to ensure that the components comprising the primary containment boundary are maintained and leak tested at periodic and appropriate intervals. The 24-month maximum interval was originally expected to bound the typical operating cycle, including a limited amount of mid-cycle outage time. The advent of advanced fuel types has made it possible to operate the facility for the 24 months with minimal, if any mid-cycle outage time. Strict adherence to the 24-month maximum interval is not necessary to meet the underlying purpose of the rule in that, taking into consideration the 60-day extension, the components that comprise the primary containment boundary will still be tested at a frequency that is appropriate to those components and their application. In addition, the 60-day extension represents a minimal increase in the existing 24-month interval required by the rule. Therefore, the staff finds the requested temporary exemption, to allow the Type B and C test intervals for penetrations described in the licensee's February 22, 1995 letter, to be extended for 60 days, to be acceptable.

An exemption is hereby granted from the requirements of Sections III.D.2(a) and III.D.3 of Appendix J to 10 CFR Part 50, which requires that Type B and C tests be performed during each reactor shutdown for refueling but in no case at intervals greater than 2 years, for a period of 60 days from the expiration of the current leak test for the affected penetrations.

Pursuant to 10 CFR 51.32, the Commission has determined that the granting of this exemption will have no significant impact on the quality of the human environment (60 FR 19968).

This exemption is effective upon issuance.

Dated at Rockville, Maryland this 25th day of April 1995.

For the Nuclear Regulatory Commission.

Steven A. Varga,

*Director, Division of Reactor Projects—I/II,
Office of Nuclear Reactor Regulation.*

[FR Doc. 95-10733 Filed 5-1-95; 8:45 am]

BILLING CODE 7590-01-M

[Docket No. 030-32493; License No. 29-28685-01; EA 93-072]

Radiation Oncology Center at Marlton, Marlton, New Jersey; Order Imposing a Civil Monetary Penalty

I

Radiation Oncology Center at Marlton (Licensee) is the holder of Byproduct Materials License No. 29-28685-01 (License) issued by the Nuclear Regulatory Commission (NRC or Commission) on January 17, 1992. The License authorizes the Licensee to possess and use certain byproduct materials in accordance with the conditions specified therein. The License is due to expire on January 31, 1997. By a Confirmatory Action Letter dated February 5, 1993, the Licensee agreed to not obtain any sources of radioactive material authorized under the License until specifically authorized by NRC Region I. By a Confirmatory Order Modifying License (Effective Immediately) dated March 9, 1993, the Licensee was required to maintain any NRC-licensed material in a locked, stored, and shielded condition, and was prohibited from receiving any NRC-licensed material.

II

An NRC inspection of the Licensee's activities was conducted on February 2 and 4, 1993. The results of this inspection indicated that the Licensee has not conducted its activities in full compliance with NRC requirements. A written Notice of Violation and Proposed Imposition of Civil Penalty (Notice) was served upon the Licensee by letter dated May 31, 1994. The Notice states the nature of the violation, the provisions of the NRC requirements that the Licensee had violated, and the amount of the civil penalty proposed for the violation.

The Licensee responded to the Notice in letters dated August 31, 1994, October 4, 1994, and December 1, 1994. In its responses the Licensee denies Examples A.3, A.4, B.1, B.2, D., and G. of the violations, denies in part and admits in part Examples A.1, A.2, and C. of the violation, and admits Examples A.5, E., and F. of the violation. The Licensee also protests the amount of the civil penalty proposed and requests mitigation of the penalty as appropriate.

III

After consideration of the Licensee's response and the statements of fact, explanation, and argument for mitigation contained therein, the NRC staff has determined, as set forth in the Appendix to this Order, that, with the

exceptions of Examples A.3 and G of the violation, the violation occurred as stated in the Notice; the Examples A.3 and G of the violation will be withdrawn; and the penalty proposed for the violation designated in the Notice should be imposed.

IV

In view of the foregoing and pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205, *It is hereby ordered That:*

The Licensee pay a civil penalty in the amount of \$80,000 within 30 days of the date of this Order, by check, draft, money order, or electronic transfer, payable to the Treasurer of the United States and mailed to James Lieberman, Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852-2738.

V

The Licensee may request a hearing within 30 days of the date of this Order. A request for a hearing should be clearly marked as a "Request for an Enforcement Hearing" and shall be addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, with a copy to the Commission's Document Control Desk, Washington, D.C. 20555. Copies also shall be sent to the Assistant General Counsel for Hearings and Enforcement at the same address and to the Regional Administrator, NRC Region I, 475 Allendale Road, King of Prussia, Pennsylvania 19406.

If a hearing is requested, the Commission will issue an Order designating the time and place of the hearing. If the Licensee fails to request a hearing within 30 days of the date of this Order, the provisions of this Order shall be effective without further proceedings. If payment has not been made by that time, the matter may be referred to the Attorney General for collection.

In the event the Licensee requests a hearing as provided above, the issues to be considered at such hearing shall be:

(a) whether the Licensee was in violation of the Commission's requirements as set forth in the violation in the Notice referenced in Section II above, and the following specific examples given with the violation: Examples A.1, A.2, A.4, B.1, B.2, C., and D.; and

(b) whether, on the basis of the violation set forth in the Notice of Violation, this Order should be sustained.

Dated at Rockville, Maryland this 24th day of April 1995.

For the Nuclear Regulatory Commission.

Hugh L. Thompson, Jr.,

Deputy Executive Director for Nuclear Materials Safety, Safeguards and Operations Support.

Appendix—Evaluations and Conclusion

On May 31, 1994, a Notice of Violation and Proposed Imposition of Civil Penalty (Notice) was issued for a violation identified during an NRC inspection of Radiation Oncology Center at Marlton (ROCM) (Licensee). The licensee responded to the Notice on August 31, 1994, October 4, 1994, and December 1, 1994. The Licensee denies Examples A.3, A.4, B.1, B.2, D., and G. of the violation, denies in part and admits in part Examples A.1, A.2, and C. of the violation, and admits Examples A.5, E., and F. of the violation. In addition, the Licensee protests the amount of the civil penalty proposed and requests mitigation of the civil penalty as appropriate. The NRC's evaluation and conclusion regarding the Licensee's requests are as follows:

Restatement of Violation

10 CFR 35.21(a) requires, in part, that the licensee, through the Radiation Safety Officer (RSO), shall ensure that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements in the daily operation of the licensee's byproduct material program.

Contrary to the above, the Licensee, through the RSO, did not ensure that radiation safety activities were performed in accordance with approved procedures and regulatory requirements in the daily operation of the Licensee's byproduct material program. Specifically, the RSO named on the Radiation Oncology Center at Marlton (ROCM) license stated at the enforcement conference that, although she had signed the license submittal, she believed that her responsibilities and authorities were primarily a medical function and not a regulatory function. She said that she was aware that she was named as the RSO on the license and added, "I was told that being—I was the fixed fixture there, that was the easiest thing to do, and that is all I was told. I had no concept of what that entailed." The following are specific examples of the failure of the Licensee, through the RSO, to ensure that radiation safety activities were performed in accordance with approved procedures and regulatory requirements in the daily operation of the Licensee's byproduct material program:

A. Condition 14 of License No. 29-28685-01 requires that the Licensee conduct its program in accordance with the statements, representations, and procedures contained in the application dated July 11, 1991, letter received December 18, 1991, and letter dated January 15, 1992.

1. Item 8.B of the Licensee's application, dated July 11, 1991, requires that all source exchanges be carried out by Omnitron Factory Personnel under the observation of the RSO.

Contrary to this requirement, source exchanges carried out by Omnitron Factory Personnel were not always under the observation of the RSO. Specifically, the RSO stated that although she observed the first source exchange at the facility on March 5, 1992, she did not observe the three subsequent source exchanges on June 4, September 16, and December 9, 1992.

2. Item 10.12 of the Licensee's application, dated July 11, 1991, requires that surveys of radiation levels in all adjacent areas and controlled areas be performed at initial installation and then quarterly thereafter at source exchanges and that results of the surveys be maintained.

Contrary to this requirement, surveys of radiation levels in all adjacent areas and controlled areas were not performed during the source exchanges which occurred on March 5, June 4, and September 16, 1992. In addition, the Licensee was unable to supply the inspectors with documentation demonstrating that surveys were performed in any adjacent areas following the December 9, 1992 source change.

3. Item 10.15.A.4 of the Licensee's application, dated July 11, 1991, requires, in part, that a daily check of all interlocks, safety systems and alarms be performed and documented in log books, that daily operational system checks be recorded, and that source position indicators (visual and radiation detection) be checked before each use and recorded.

Contrary to this requirement, as of February 4, 1993, daily checks of all interlocks, safety systems and alarms were not performed and documented in log books. Specifically, Licensee personnel believed that the performance of these checks was the responsibility of the physics consultant even though the physics consultant was only present for approximately one half of the total patient treatments, and the ROCM staff did not perform these daily checks when the physics consultant was not present. In addition, the Licensee was unable to provide any documentation indicating that daily checks of all the interlocks, safety systems and alarms; daily operational system checks; and daily checks of source position indicators (visual and radiation detection) were performed on the occasions when the physicist was present.

4. Item 8.E.5 of the Licensee's application, dated July 11, 1991, requires, in part, that each operator/user of the HDR individually demonstrate competence in the emergency procedures during "dry run" emergencies using several failure modes for each operator.

Contrary to this requirement, as of February 4, 1993, each operator/user of the HDR did not individually demonstrate competence in the emergency procedures during "dry run" emergencies using several failure modes for each operator.

5. Item 9.1.C.4 of the Licensee's application, dated July 11, 1991, requires, in part, that the radiation monitor (PrimAlert) have a battery backup.

Contrary to this requirement, as of February 4, 1993, the Licensee did not have a battery back-up to operate the radiation monitor (PrimAlert).

B. 10 CFR 19.12 requires, in part, that all individuals working in or frequenting any

portion of a restricted area be instructed in the purposes and functions of protective devices employed, and in the appropriate response to warning made in the event of any unusual occurrence or malfunction that may involve exposure to radiation or radioactive material.

10 CFR 35.25(a)(1) requires, in part, that a Licensee that permits the use of byproduct material under the supervision of an authorized user shall instruct the supervised individual in the principles of radiation safety appropriate to that individual's use of byproduct material.

Contrary to these requirements,

1. As of February 4, 1993, individuals working in or frequenting portions of a restricted area were not instructed in the purposes and functions of protective devices employed. Specifically, the Licensee failed to instruct the dosimetrist in the proper use of the radiation survey meter. The dosimetrist, when questioned by the inspector on the operation and use of the survey meter, stated that the X1000 setting was the instrument's "lowest strength" scale. The X1000 setting is actually the highest scale setting on the instrument.

2. As of February 4, 1993, individuals working in or frequenting portions of a restricted area were not instructed in the appropriate response to a warning made in the event of any unusual occurrence or malfunction that may involve exposure to radiation or radioactive material. Specifically, the Licensee failed to adequately train the dosimetrist to identify and respond to HDR error messages.

When questioned by the inspector on February 4, 1993, the dosimetrist did not know the meaning of the error messages from a random printout of a treatment execution record, dated May 7, 1992, which contained several error messages.

C. 10 CFR 35.31(b) requires that a licensee that makes minor changes in radiation safety procedures, as permitted under 10 CFR 35.31(a), retain a record of each change until the license has been renewed or terminated. The record shall include the effective date of the change, a copy of the old and new radiation safety procedures, the reason for the change, a summary of radiation safety matters that were considered before making the change, the signature of the RSO, and the signatures of the affected authorized users, and of management or, in a medical institution, the Radiation Safety Committee's chairman and the management representative.

Contrary to this requirement, prior to February 2, 1993:

1. The Licensee made a minor change in its radiation safety procedures, as permitted under 10 CFR 35.31(a), by posting emergency procedures that differed from those procedures submitted to the NRC in support of the license application, and the Licensee did not retain a record of the change that included the effective date of the change, the reasons for the change, a summary of the radiation matters that were considered before making the change, the signature of the RSO, and the signatures of the affected authorized users, and of management.

2. The Licensee made a minor change in its radiation safety procedures, as permitted

under 10 CFR 35.31(a), by using HDR calibration procedures that differed from those procedures submitted to the NRC in support of the license application, and the Licensee did not retain a record of the change that included the effective date of the change, the reason for the change, a summary of the radiation matters that were considered before making the change, the signature of the RSO, and the signatures of the affected authorized users, and of management.

D. 10 CFR 35.32 requires, in part, that each licensee, as applicable, establish and maintain a written quality management program to provide high confidence that byproduct material or radiation from byproduct material will be administered as directed by the authorized user.

Contrary to this requirement, from March through December 1992, the Licensee engaged in licensed activities (namely, the administration of brachytherapy radiation doses using an iridium-192 source in an HDR unit) which required the establishment of a quality management program, and as of February 5, 1993, the Licensee had not established a written quality management program.

E. 10 CFR 35.51(a)(3) requires that the apparent exposure rate from a dedicated check source as determined at the time of calibration, be conspicuously noted on the instrument with the date of calibration.

Contrary to this requirement, as of February 4, 1993, the apparent exposure rate from a dedicated check source as determined at the time of calibration, was not conspicuously noted on the instrument with the date of calibration.

F. 10 CFR 19.11 (a) and (b) require, in part, that the Licensee post current copies of Part 19 and 20, and the license, or post a notice describing these documents and where they may be examined. 10 CFR 19.11(c) also requires that the licensee post a Form NRC-3, "Notice to Employees."

Contrary to this requirement, as of February 4, 1993, the Licensee did not post current copies of Parts 19 and 20, and the license, or a notice describing the documents and where they could be examined, and did not post a Form NRC-3.

G. 10 CFR 30.51(a) requires each licensee to keep records showing the receipt, transfer, and disposal of byproduct material.

Contrary to this requirement, as of February 4, 1993, the Licensee did not keep records showing the receipt, transfer, and disposal of byproduct material. Specifically, the Licensee did not maintain records of the source receipt and transfer for disposal.

This is a Severity Level II violation (Supplement VI).

Summary of Licensee's Response to Example A.1 of the Violation

The Licensee admits this example in part and denies it in part, but does not state specifically what it admits or denies. The Licensee states that, although the RSO was not present in the room during the source exchange, the RSO or the physicist was physically present at the facility during the source exchanges, or readily available in case of an emergency, and thus the RSO was overseeing the source exchanges. The

Licensee believes that this was all that was intended by its license application, that the RSO may delegate duties, and that the physical presence of the RSO during a source exchange would violate ALARA principles. The Licensee believes that, in any event, this example would constitute a Severity Level IV violation.

NRC Evaluation of Licensee's Response to Example A.1 of the Violation

The Licensee's application is clear in requiring that all source exchanges be carried out by Omnitron Factory Personnel under the observation of the RSO. With proper planning and the application of common radiation protection methods, the RSO could observe source exchanges without violating ALARA principles. At the transcribed enforcement conference, the RSO confirmed that she observed the first source exchange but did not observe the three subsequent source exchanges. Since source exchanges occurred that were not under the observation of the RSO, the NRC concludes that this example of the violation occurred as stated in the Notice. The issue of severity level is addressed below under "NRC Evaluation of Licensee's Request for Mitigation."

Summary of Licensee Response to Example A.2 of the Violation

The Licensee admits this example in part and denies it in part, but does not state specifically what it admits or denies. The Licensee states its belief that surveys of radiation levels in adjacent areas and/or controlled areas were performed during the source exchanges which occurred on March 5, June 4, and September 16, 1992, by Omnitron for the Licensee's benefit. The Licensee, in its letter dated December 1, 1994, provided Omnitron's record of surveys conducted during the source exchange on December 9, 1992, as well as other records of surveys conducted on March 5, June 4, and September 16, 1992. The Licensee believes that, in any event, this would constitute a Severity Level IV violation.

NRC Evaluation of Licensee's Response to Example A.2 of the Violation

Omnitron's record of surveys conducted on December 9, 1992 does not show that all adjacent areas were surveyed as required by License Condition 14. Regarding the records of other surveys that the Licensee submitted, the NRC inspection report indicates that the inspectors did see documentation of partial surveys for March 5, 1992, June 4, 1992, and September 16, 1992. With the exception of the survey record for December 17, 1992, the survey records that the Licensee submitted show that the surveys did not include all adjacent areas as required by the license condition. As noted in the inspection report, examples of adjacent areas that were not surveyed include a staff restroom, a utility room, the patient examination room, and the patient dressing room. Therefore, the NRC concludes that this example of the violation occurred as stated in the Notice. The issue of severity level is addressed below under "NRC Evaluation of Licensee's Request for Mitigation."

Summary of Licensee Response to Example A.3 of the Violation

The Licensee states that it denies this example. The Licensee states that, contrary to the NRC findings, checks were performed and an entire log indicating that certain checks were performed does exist. In its letter dated December 1, 1994, the Licensee provided numerous log entries to show that checks were performed.

NRC Evaluation of Licensee's Response to Example A.3 of the Violation

The NRC staff has reviewed the log entries provided by the Licensee on December 1, 1994. Based on those records, which were not provided during the inspection or the transcribed enforcement conference, the NRC staff is withdrawing this example of the violation. The withdrawal of this example of the violation does not change the fact that the violation occurred, nor does it affect the appropriateness of the amount of the civil penalty assessed for the violation in this case, given the nature of the violation and the numerous other examples of the violation that are not being retracted.

Summary of Licensee Response to Example A.4 of the Violation

The Licensee denies the example and asserts that relevant personnel attended Omnitron training where dry runs were performed and emergency situations and procedures were taught and discussed. The Licensee believes that, in any event, this could constitute a Severity Level IV violation.

NRC Evaluation of Licensee's Response to Example A.4 of the Violation

While Omnitron training may have covered emergency situations, License Condition 14 specifically requires that each operator/user of the HDR individually demonstrate emergency routine competence during "dry run" emergencies using several failure modes for each operator. At the transcribed enforcement conference, the Medical Director, recalling the portion of the Omnitron training that pertained to emergency situations, stated, "[t]o the best of my recollection, I believe they went through some of the descriptive terms on how to crank the machine manually, and I believe they showed us the knob. But I cannot say with any degree of recollection that we actually went through it." As noted in the inspection report, the dosimetrist stated to inspectors that she had not performed "dry run" emergencies using several failure modes. Therefore, the NRC concludes that this example of the violation occurred as stated in the Notice. The issue of severity level is addressed below under "NRC Evaluation of Licensee's Request for Mitigation."

Summary of Licensee Response to Example A.5 of the Violation

The Licensee admits this example of the violation, but states its belief that this would constitute a Severity Level IV violation.

NRC Evaluation of Licensee's Response to Example A.5 of the Violation

The issue of severity level is addressed below under "NRC Evaluation of Licensee's Request for Mitigation."

Summary of Licensee Response to Example B of the Violation

The Licensee denies this example. The Licensee states that failure to answer all questions posed by the inspector does not necessarily constitute evidence that employees were not adequately trained in accordance with the commitments in the application or in the regulations. The Licensee believes that at all times personnel were trained as required under the license and under the applicable regulations. The Licensee states that 10 CFR 19.12 only requires that personnel be trained "commensurate with potential radiological health protection problems in the restricted area." The Licensee also states that "the NRC did not allege that the dosimetrist did not know how to operate a hand held survey meter or that she was not trained in its operation." The Licensee asserts that the dosimetrist was trained pursuant to license requirements. The Licensee believes that, in any event, this would constitute a Severity Level IV violation.

NRC Evaluation of Licensee's Response to Example B of the Violation

As documented in the inspection report, the dosimetrist was asked to demonstrate the operation and use of the radiation survey meter. The dosimetrist incorrectly set the instrument response dial to the X1000 scale, stating that this was the instrument's lowest strength scale. The inspectors asked the dosimetrist to repeat this demonstration and explanation a second time and the dosimetrist produced the same result. The dosimetrist is the individual who operated the HDR unit at Marlton. When the inspectors asked the dosimetrist to explain the meaning of the "error code" and "error class" messages on a printout of a treatment record, the dosimetrist stated that she did not know the meaning of the error messages.

The NRC staff finds that the dosimetrist's lack of understanding of the differences between the highest setting on the meter and the lowest setting on the meter, as well as the lack of understanding concerning response to HDR error messages are clear evidence that adequate training was not provided.

10 CFR 19.12 also requires that all individuals working in or frequenting any portion of a restricted area shall be instructed in precautions or procedures to minimize exposure, and in the purposes and function of protective devices employed. The extent of these instructions shall be commensurate with potential radiological health protection problems in the restricted area. The dosimetrist operated the HDR. In an emergency situation, the dosimetrist's duties could involve use of a survey meter to determine the status and location of the source in the restricted area as a means of protecting herself as well as other employees and patients. The Licensee clearly recognized that emergency situations could arise because it discussed "dry run" emergency procedures

in its license application. In addition, since the dosimetrist's duties included operation of the HDR, this individual should have been knowledgeable on the meaning of error messages and how to respond to error messages generated by the HDR unit. Error messages could indicate hazardous conditions in the restricted area. Therefore, this individual was required by 10 CFR 19.12 to be trained by the Licensee on the meaning of the error messages, how to respond to error messages, and the use of a hand-held survey meter. Based on the above, the NRC concludes that this example of the violation occurred as stated in the Notice. The issue of severity level is addressed below under "NRC Evaluation of Licensee's Request for Mitigation."

Summary of Licensee Response to Example C of the Violation

The Licensee states in its response that it admits in part and denies in part this example. The Licensee asserts that it did record certain changes and may not have recorded others. The Licensee further asserts that, in this case, there was no potential or actual impact on health and safety. The Licensee believes that, in any event, this would constitute a Severity Level V violation.

NRC Evaluation of Licensee's Response to Example C of the Violation

10 CFR 35.31 authorizes medical use licensees to make minor changes in radiation safety procedures that are not potentially important to safety. 10 CFR 35.31(b) requires that if these changes (ministerial changes) are made, the licensee must maintain a record as specified in the regulation. There is no exception granted to the Licensee to only record certain changes. Since the Licensee did not maintain a record of some changes, the NRC concludes that this example of the violation occurred as stated in the Notice. The issue of severity level is addressed below under "NRC Evaluation of Licensee's Request for Mitigation."

Summary of Licensee Response to Example D of the Violation

The Licensee states in its response that it denies this example. The Licensee asserts that it had a written quality management program (QMP) which was in effect at the relevant times. In addition, the Licensee states that it has modified its quality management plan pursuant to completion of a review of its HDR program, and that the modified plan has been submitted to the NRC.

NRC Evaluation of Licensee's Response to Example D of the Violation

The requirement is that the Licensee establish and maintain a written quality management program to provide high confidence that byproduct material or radiation from byproduct material will be administered as directed by the authorized user. The inspection report indicates that inspectors did find a copy of "Quality Management of Brachytherapy Patients High Dose Rate Techniques" authorized by David Cunningham of Oncology Services Corporation and dated January 16, 1992. This

document was in a notebook containing other HDR records. According to the inspection report, the facility Medical Director/RSO had no knowledge of the document. In addition, the Medical Director/RSO stated at the time of the inspection that no one at the facility had received training on the document. Further, at the time of the inspection, the Licensee had not submitted its quality management program (QMP) to NRC as required by 10 CFR 35.32(f)(2). Since the Medical Director/RSO had no knowledge of the QMP, had not trained the staff on the QMP, and had not submitted the QMP to NRC, it is clear that the QMP was neither established nor maintained so as to provide high confidence that radiation from byproduct material would be administered as directed by the authorized user. Therefore, the NRC concludes that this example of the violation did occur.

Summary of Licensee Response to Example E of the Violation

The Licensee admits this example, but states its belief that this would constitute a Severity Level V violation.

NRC Evaluation of Licensee's Response to Example E of the Violation

The issue of severity level is addressed below under "NRC Evaluation of Licensee's Request for Mitigation."

Summary of Licensee Response to Example G of the Violation

The Licensee states in its response that it denies this violation. The Licensee states that it believes that certain records were maintained and that Omnitron also kept records for the benefit of the Licensee. The Licensee, in its letter dated December 1, 1994, provided copies of shipping papers showing the transfer of sources back to Omnitron, and copies of leak test results performed on sources by Omnitron. The Licensee believes that, in any event, this would constitute a Severity Level V violation.

NRC Evaluation of Licensee's Response to Example G of the Violation

The NRC staff has reviewed the records submitted by the Licensee on December 1, 1994. The particular shipping records that the Licensee submitted, which include the transferee, isotope, activity, and date, meet the requirement for records of the transfer of byproduct material. The leak test records that the Licensee submitted meet in part the requirement for records of receipt of licensed material. The leak test records did identify the transferor, isotope, and activity; but not the date of receipt. However, because the Licensee has other records, such as source exchange records, that identify the date of receipt, the NRC is withdrawing this example of the violation. The withdrawal of this example of the violation does not change the fact that the violation occurred, nor does it affect the appropriateness of the amount of the civil penalty assessed for the violation in this case, given the nature of the violation and the numerous other examples of the violation that are not being retracted.

Summary of Licensee's Request for Mitigation

The Licensee states in its response that it has taken numerous corrective actions to strengthen and improve all aspects of its radiation safety program. The licensee also states that over the past eighteen months, it has attempted to continually review and update its HDR program and staff, and emphasize the importance of radiation safety and applicable regulations. In addition, the Licensee indicates that management has attended courses regarding RSO duties and responsibilities. The Licensee also notes that five patients were treated with the HDR unit between March 1992 and December 1992 and there were no misadministrations or incidents.

The Licensee states that it: (1) Immediately and voluntarily suspended all HDR treatments in order to review the entire HDR program; (2) fully and timely complied with any and all CALs; and (3) replaced its contract physicist with a full-time physicist who, as RSO under the license, would provide necessary onsite RSO continuity needed to assure Licensee management and the NRC that the HDR program could run safely and in accordance with all regulations at all times. The Licensee also states its belief that the replacement of the RSO constitutes required and necessary corrective action regarding the identified issues, noting that the new physicist has held quarterly meetings where radiation safety, and regulatory issues have been reviewed with the staff. According to the Licensee, staff members have attended additional outside training and the authorized users have attended a six hour Radiation Safety Officers Review Course. In addition, the Licensee states that it has hired a Certified Health Physicist to assist in the coordination and oversight of all aspects of the Licensee's radiation safety program.

The Licensee states its belief that by hiring a full-time physicist to serve as RSO and obtaining the assistance of the Certified Health Physicist, it has clearly demonstrated that it has committed the resources necessary to develop and implement an appropriate, comprehensive and long lasting commitment to address the root cause of the violations. The Licensee believes that its new program, which permits only the physicist and physician to be involved with actual HDR patient treatments, will assure the NRC that none of the examples of the violation will be repeated.

The Licensee contends that a fine of \$80,000 for what the Licensee terms "a number of Level IV and V violations" is arbitrary, capricious and unsupported by any of the NRC rules, regulations and/or legislative history. In support of this argument, the Licensee claims that similar enforcement actions involving similar violations by Part 35 licensees resulted in substantially smaller penalties. The Licensee further states that these citations collectively do not constitute a Severity Level II program and, in any case, the maximum penalty should be \$8,000 before any mitigation. The Licensee asserts that it has an exemplary record having had no previous violations or misadministration. The Licensee cites a number of NRC Enforcement sanctions which

the Licensee believes supports its claim that the sanction imposed on the Licensee is inappropriate.

NRC Evaluation of Licensee's Request for Mitigation

Pursuant to Section 234 of the Atomic Energy Act, as amended, the NRC is authorized to impose civil penalties of up to \$100,000 per violation per day for each day that a violation continues. Normally, proposed civil penalties are determined after application to the base civil penalty of the mitigating and escalating factors in Section VI of the Enforcement Policy, including corrective action and past licensee performance. Section VII.A of the Enforcement Policy provides, however, that notwithstanding the outcome of the normal civil penalty adjustment process, the NRC may exercise its full enforcement authority to ensure that the resulting enforcement action appropriately reflects the level of NRC concern regarding the violations at issue and conveys the appropriate message to the licensee, in order to provide an appropriate sanction when particularly serious violations or serious breakdowns in management controls have occurred. Given the seriousness of the violation in that the RSO failed to devote time or attention to the radiation safety program and that corporate management created the environment in which this was allowed to occur, a large civil penalty is warranted to emphasize the unacceptable performance of the Licensee, its RSO, and its corporate owner; and to emphasize the need for the Licensee and its corporate owner, as well as other licensees engaged in similar activities, to assure that controls are in place to avoid similar violations. The NRC appropriately exercised its statutory authority when it proposed an \$80,000 civil penalty for the violation.

As the Licensee's arguments that some of the examples are appropriately classified at Severity Level IV or V, the NRC did not categorize the individual examples of the violation in the Notice by severity level. Rather, the NRC categorized the single violation, including all of the listed examples, at Severity Level II. The violation is appropriately categorized at Severity Level II because it is of very significant regulatory concern and involved high potential impact on the public. Enforcement Policy Section IV. The guidance given by the examples in Supplements I-VII of the Enforcement Policy is neither exhaustive nor controlling in classifying the severity level of violations. The NRC reviews each enforcement action on its own merits to ensure that the severity level of a violation is characterized at the level best suited to the significance of the violation, which may warrant an adjustment to the severity level categorization. Enforcement Policy, Section IV. In this case, the violation represents a near total failure of the RSO to address her regulatory responsibilities and an equally serious failure of licensee management to exercise oversight over the radiation safety program in order to ensure that regulatory requirements were met, all of which created a high potential impact on the public for an incident similar to the November 1992 misadministration and

radiological event at the owner's facility in Indiana, Pennsylvania.

The NRC acknowledges that the Licensee has taken corrective actions and is aware of the Licensee's past performance. However, in this case, the NRC exercised discretion to escalate the civil penalties, which supersedes the normal application of the adjustment factors, as explained above. In addition, civil penalties are imposed, in part, to deter future violations by not only the involved licensee, but other licensees conducting similar activities. See Enforcement Policy, Section VI.B.

The civil penalties proposed in this case are within the authority of the NRC. The Licensee's comparison of the civil penalty in this case with civil penalties in other cases does not bring NRC's exercise of its lawful authority into question. Of decisive importance is the NRC's clear authority to exercise discretion in the choice of enforcement sanctions and the ordering of enforcement priorities. *Advanced Medical Systems, Inc.*, (CLI-94-6), 39 NRC 285, 320 (1994). A sanction is not rendered invalid because it is more severe than that issued in other cases. *Id.* As explained above, the NRC acted within its statutory authority and the bounds of the Enforcement Policy when NRC exercised its discretion to escalate the civil penalties in this case. A rigid uniformity is neither required nor possible in enforcement decisions, which inherently involve the exercise of informed judgement on a case-by-case basis. *Id.* See also, *Radiation Technology, Inc.*, (ALAB-567), 10 NRC 533, 541 (1979).

NRC Conclusion

The NRC has concluded that: (1) With the exceptions of Examples A.3 and G., the violation occurred as stated in the Notice; (2) Examples A.3 and G are being withdrawn; (3) the withdrawal of these two examples of the violation does not change the fact that the violation occurred nor does it affect the appropriateness of the amount of the civil penalty assessed for the violation; and (4) an adequate basis for mitigation of the civil penalty was not provided by the Licensee. Consequently, the proposed civil penalty in the amount of \$80,000 is being imposed.

[FR Doc. 95-10730 Filed 5-1-95; 8:45 am]

BILLING CODE 7590-01-M

[Docket No. 50-244]

Rochester Gas and Electric Company (R. E. Ginna Nuclear Power Plant); Exemption

I

Rochester Gas and Electric Corporation (RG&E) is the holder of Facility Operating License No. DPR-18, which authorizes operation of R. E. Ginna Nuclear Power Plant at steady-state power levels up to a maximum of 1520 megawatts thermal. The facility is a pressurized water reactor located at the licensee's site in Wayne County, State of New York. The license provides

among other things, that the facility is subject to all rules, regulations, and Orders of the Commission.

II

Appendix J of Part 50 of Title 10 of the Code of Federal Regulations, "Primary Reactor Containment Leakage Testing for Water-Cooled Reactors," Section III.D.3, requires that Type C leakage rate testing be performed each reactor shutdown for refueling, but in no case at intervals greater than 2 years.

By letter dated March 15, 1995, RG&E requested a one-time Exemption from two parts of 10 CFR Part 50, Appendix J, Section III.D.3. First, RG&E requests an Exemption from performing Type C tests during the 1995 refueling outage except for isolation valves which have maintenance performed on them or valves which have not demonstrated acceptable leakage during the previous two leakage rate tests. Second, RG&E requests an Exemption from performing Type C tests within a 2-year interval, as required by the regulation. RG&E requests up to a 1-month extension of the 2-year interval for 129 containment isolation valves.

The last Type C tests were performed during the 1994 refueling outage after March 10, 1994. RG&E stated in the March 15, 1995, letter that the 1996 refueling outage will commence on March 31, 1996, with Cold Shutdown reached on April 1, 1996. RG&E requested an Exemption from the 2 year test interval until April 10, 1996, an interval 1 month greater than the required 2 year test interval.

The R. E. Ginna Nuclear Power Plant has a total of 151 containment isolation valves. RG&E has proposed to exempt 129 of these valves from Type C testing during the 1995 refueling outage. The other valves would be tested during the 1995 refueling outage either because maintenance has been done on them or they have not passed the RG&E's criterion for exemption of two successful consecutive tests.

The NRC staff finds RG&E's proposal to be acceptable for several reasons. As discussed in RG&E's March 15, 1995 letter, the performance of the containment isolation valves and the R. E. Ginna Nuclear Power Plant overall containment integrity have been good. The as-left Type A test leakage rate is 35% of L_a . The current Type B and C as-left maximum path leakage rate is 61% of the 0.6 L_a Appendix J limit. Therefore, there is reasonable assurance that the 1-month extension of the 2-year interval will not result in exceeding the Appendix J limits.

In addition, RG&E has proposed to limit the Exemption only to those valves

on which no maintenance has been done and which have passed the last two consecutive Type C leakage rate tests. The NRC staff has granted similar requests in the past. On February 2, 1994, the NRC staff granted a similar Exemption to the River Bend Station licensee, and by letter dated April 29, 1987, the NRC staff granted a similar request to the Washington Public Power Supply System, Unit 2 licensee.

The NRC staff, therefore, grants the requested one-time Exemption to the R. E. Ginna Nuclear Power Plant licensee subject to the condition that the Exemption apply only to those valves on which no maintenance has been done and which have passed the last two consecutive Type C leakage rate tests. The Exemption is granted until plant shutdown for the 1996 refueling outage, not to extend beyond April 10, 1996.

III

Section 50.12 of the Commission's regulations permit granting an Exemption from the regulations when special circumstances are present. According to 50.12(a)(2)(ii), special circumstances are present whenever application of the regulation in question is not necessary to achieve the underlying purpose of the rule.

The underlying purpose of Appendix J, Section III.D.3, is to assure a leak tight containment to mitigate the consequences of an accident. The past leakage rate data and available margin to the allowed technical specifications, as discussed above, are sufficient to assure that the underlying purpose of Appendix J, Section III.D.3, is achieved.

Accordingly, the Commission has determined that, pursuant to 10 CFR 50.12, this Exemption is authorized by law, will not present an undue risk to the public health and safety, and is consistent with the common defense and security.

Accordingly, the Commission hereby grants an Exemption from 10 CFR Part 50, Appendix J, Section III.D.3.

Pursuant to 10 CFR 51.32, the Commission has determined that the granting of the Exemption will have no significant impact on the environment (60 FR 20513).

Dated at Rockville, Maryland, this 26th day of April 1995.

This Exemption is effective upon issuance. For the Nuclear Regulatory Commission.

Steven A. Varga,

*Director, Division of Reactor Projects—I/II,
Office of Nuclear Reactor Regulation.*

[FR Doc. 95-10734 Filed 5-1-95; 8:45 am]

BILLING CODE 7590-01-M

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-35649; File No. SR-DTC-94-19]

Self-Regulatory Organizations; The Depository Trust Company; Order Approving a Proposed Rule Change Regarding Implementation of New Guidelines Regarding Principal and Income Payments in a Same-Day Funds Environment

April 26, 1995.

On December 5, 1994, The Depository Trust Company ("DTC") filed with the Securities and Exchange Commission ("Commission") a proposed rule change (File No. SR-DTC-94-19) under Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act").¹ As filed, the proposal consisted of changes to the depository-eligibility requirements for securities issues to require that principal and income distributions be made in same-day funds and provided for the use of a "Blanket Letter of Representations" in lieu of individual letters of representations for each securities issue.² Notice of the proposal was published in the **Federal Register** on February 14, 1995.³ On April 3, 1995, DTC amended the proposed rule change by requesting that the Commission withdraw from consideration the portion of the proposed rule change that related to implementing the use of a Blanket Letter of Representations for making securities depository-eligible.⁴ The Commission received one comment letter opposing a part of DTC's proposal.⁵ For the reasons discussed

below, the Commission is approving the proposed rule change.

I. Description

A. Background

In 1988, the Group of Thirty⁶ determined that international agreement on a set of practices and standards for clearance and settlement systems was desirable. Accordingly, a Working Committee appointed by the Group of Thirty issued a report in March 1989 containing nine recommendations to reduce risk, improve efficiency, and reduce costs in the world's clearance and settlement systems.⁷ One recommendation called for making payments associated with the settlement of securities transactions consistent across instruments and markets by adopting a same-day funds payment convention. The U.S. Working Committee of the Group of Thirty⁸ concluded that payment for settlements among financial intermediaries and between financial intermediaries and their institutional customers should be made using same-day funds. In particular, the U.S. Working Committee concluded that payments for dividends, interest, redemptions, and reorganizations, commonly referred to as "principal and income payments," also should be made using same-day funds.

Thereafter, the U.S. Working Committee encouraged DTC and the National Securities Clearing Corporation ("NSCC") to focus on developing a same-day funds settlement system for U.S. trades in equity securities and corporate and municipal debt. Accordingly, in June 1992, DTC and NSCC published a memorandum entitled "A Same-Day Funds Settlement System Proposal for Industry Evaluation." In response to the memorandum, issues were raised regarding the appropriate handling of principal and income payments in a same-day funds settlement environment. Accordingly, a task force comprised of issuers, trustees, paying

agents, depositories, depository participants and their customers, and the respective representative organizations for these various groups was formed ("Same-Day Funds Task Force" or "Task Force") to explore ways that principal and income payments could be made to a depository for pass through to participants in same-day funds on payment date.⁹

The Task Force determined that converting to a same-day funds settlement system for principle and income payments would have a significant impact on industry participants, including a change in the timing of payments to depositories by paying agents. Paying agents will have to make payments to depositories earlier in the day so that depositories can settle with their participants before the Fedwire closes.

The Task Force recommended that several principles be adopted in order to convert to a same-day funds settlement system for principal and income payments. As discussed below, DTC proposes to incorporate the relevant provisions in its operational arrangements memorandum.

B. Proposed Rule Change

DTC's operational arrangements that are necessary for securities issues to be eligible for DTC services are designed to maximize the number of issues that can be made depository-eligible while ensuring orderly processing and timely payments to participants. DTC's experience demonstrates that when issuers, underwriters, and their counsel are aware of DTC's requirements those requirements can be met almost without exception.¹⁰ The purpose of the rule change is to incorporate in DTC's operational arrangements memorandum

⁹ In the current next-day funds settlement ("NDFS") system, paying agents make payments in same-day funds to depositories for corporate income payments (e.g., interest and dividends) and reorganization actions (e.g., tenders and exchanges) for the majority of issues. Although corporate and municipal redemption payments and municipal income payments may be paid in next-day funds, generally paying agents make these payments in same-day funds on payment date to ensure their timely arrival at the depositories. DTC invests these funds overnight and rebates to the paying agents interest on the deposits as compensation for holding the funds overnight.

¹⁰ During 1993, a total of 392,000 new issues were made eligible for DTC's services. This was 99.94% of all new issues submitted to DTC's Underwriting Department for eligibility determinations. These figures include equity, corporate debt, municipal debt, and U.S. Government and Agency securities. In the unusual circumstance where the processing characteristics of a new issue that is being structured would not meet DTC's operational arrangements, if contacted early enough in the planning process DTC staff often is able to assist in suggesting restructuring alternatives that would permit the issue to be made depository eligible.

¹ 15 U.S.C. 78s(b)(1) (1988).

² Same-day funds, which are also known as "Fed funds," are immediately available for redelivery on the day of receipt.

³ Securities Exchange Act Release No. 35342 (February 8, 1995), 60 FR 8434.

⁴ Letter from Piku Thakkar, Assistant Counsel, DTC, to Peter Geraghty, Senior Counsel, Division of Market Regulation, Commission (April 3, 1995).

⁵ Letter from Terrence Hassett, President, North East Securities Transfer Association, Inc. ("NESTA"), to Jonathan Katz, Secretary, Commission (March 16, 1995). NESTA opposes the part of DTC's proposal that would deny depository eligibility to issues brought to market by agents who fail to make principal and income payments in same-day funds. In response, DTC stated that agents will not be penalized for isolated incidents of a failure to pay DTC in same-day funds on payment date and that the sanction of denying depository eligibility to an issue would be a last resort mechanism used in very limited circumstances. Furthermore, DTC indicated that it will make efforts to accommodate the needs of issuers and agents and will work closely with them in converting to a same-day funds payment standard for principal and income payments. Telephone conversation between Piku Thakkar, Assistant Counsel, DTC and Katherine Horan, Attorney, Commission (April 11, 1995).

⁶ The Group of Thirty, established in 1978, is an international, nonprofit organization charged with broadening the understanding of international economic and financial issues, exploring the international repercussions of decisions taken in public and private sectors, and examining the choices available to policymakers.

⁷ Group of Thirty, *Clearance and Settlement Systems in the World's Securities Markets*, New York and London, March 1989.

⁸ The U.S. Working Committee of the Group of Thirty is an organization made up of representatives from broker-dealers, banks, and financial intermediaries charged with analyzing the existing clearance and settlement systems in the U.S. in light of the Group of Thirty's nine recommendations.

principles for the processing of principal and income payments in same-day funds.¹¹ Towards this end, the operational arrangements memorandum incorporates the relevant provisions of the "Standards for Principal and Income Payments Guidelines" established by the U.S. Working Committee of the Group of Thirty. Pursuant to this rule change, the relevant provisions of these principles, as set forth below, will become a part of DTC's income and reorganization/redemption payments standards.

First, all new issues are required to meet depository-eligibility requirements and must be structured so that all payments to depositories of principal and income are made in same-day funds on payment date by 2:30 p.m. Eastern Standard time.

Second, for all depository-eligible issues already outstanding, paying agents must remit to DTC all principal and income payments in same-day funds on payment date by 2:30 p.m. Eastern Standard time according to existing arrangements between the paying agent and DTC. Recognizing that paying agents for certain issues may need to modify their current business arrangements to account for this change, DTC will continue through July 31, 1996, to pay the same rebates it now pays to paying agents that pay municipal interest and municipal and corporate redemptions to DTC in same-day funds on payment date.¹²

However, once DTC converts to same-day funds settlement for all security transactions, DTC will make all payments to its participants on payment date in same-day funds. As a result, DTC will not have funds resulting from overnight investing available to rebate to paying agents. Recognizing that participants will benefit by receiving all their expected payments in same-day funds on payment date DTC will charge participants in proportion to their holdings in each issue for which a rebate applies the funds needed to pay the rebate from the date of the conversion to same-day funds settlement for all security transactions until July 31, 1996. With respect to

payments made on or after August 1, 1996, these charges to participants will no longer be required. The rebate will not be applied to payments of corporate interest, dividends, and reorganizations for which the paying agents already pay DTC in same-day funds on payment date and which currently are not subject to interest earnings rebates. However, DTC will require that 100% of corporate interest, dividend, and reorganization payments to paid to DTC in same-day funds on payment date by 2:30 p.m. Eastern Standard time.

Third, DTC will require paying agents to provide DTC with the CUSIP numbers for each issue for which payment is being sent as well as the dollar amount of the payment for each issue no later than noon Eastern Standard time on the payment date. Notification of payment details should be made using automated communications.

Finally, if an issuer or agent continually fails to make payment as called for in DTC's guidelines, DTC may decide to systematically prevent the allocation of such payments to participants on the payable date. Eventually, DTC also may elect to deny depository-eligibility to issues brought to market by noncomplying issuers or agents.

II. Discussion

Section 17A(b)(3)(F) of the Act requires that the rules of a clearing agency be designed to promote the prompt and accurate clearance and settlement of securities transactions and to foster cooperation and coordination with persons engaged in the clearance and settlement of securities transactions. The Commission believes that the proposed rule change is consistent with Section 17A(b)(3)(F) because it provides a framework for the conversion of principal and income payments to same-day funds. Making principal and income payments in same-day funds is consistent with the goal of prompt and accurate clearance and settlement because it will give participants same-day access to their funds. Requiring paying agents to provide DTC with the corresponding CUSIP numbers for each issue for which payment is being made will make the processing of such payments more accurate. The Commission also believes that the guidelines for converting to a same-day funds payment standard for principal and interest payments are consistent with the goal of fostering cooperation and coordination among persons engaged in the clearance and settlement of securities transactions. Specifically, in order to allow paying

agents time to modify their current business practices, DTC will continue to pay rebates through July 31, 1996, to those paying agents currently making payments to DTC in same-day funds on payment date for municipal interest and municipal and corporate redemption payments.

III. Conclusion

On the basis of the foregoing, the Commission finds that the proposed rule change is consistent with the requirements of the Act and in particular with Section 17A of the Act and the rules and regulations thereunder.

It Is Therefore Ordered, pursuant to Section 19(b)(2) of the Act,¹³ that the proposed rule change (File No. SR-DTC-94-19) be, and hereby is, approved.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.¹⁴

Margaret H. McFarland,
Deputy Secretary.

[FR Doc. 95-10790 Filed 5-1-95; 8:45 am]

BILLING CODE 8010-01-M

[Release No. 34-35647; File No. SR-MSTC-94-12]

Self-Regulatory Organization; Midwest Securities Trust Company; Order Granting Temporary Approval of Proposed Rule Change Enabling Midwest Securities Trust Company To Enter Into Contracts With Participants To Provide Custodial, Transactional, and Related Services

April 25, 1995.

On October 11, 1994, the Midwest Securities Trust Company ("MSTC") filed with the Securities and Exchange Commission ("Commission") a proposed rule change (File No. SR-MSTC-94-12) pursuant to Section 19(b) of the Securities Exchange Act of 1934 ("Act").¹ Notice of the proposal appeared in the **Federal Register** on October 19, 1994, to solicit comment from interested persons.² For the reasons discussed below, the Commission is approving the proposed rule change through October 1, 1995.

I. Description of the Proposal

The purpose of the proposed rule change is to permit MSTC to enter into contracts with any of its participants whereby MSTC will provide certain

¹¹ DTC's operational arrangements were published in a June 1987 memorandum and were updated in both June 1988 and February 1992. For a complete description of the operational arrangements memorandum, refer to Securities Exchange Act Release No. 24818 (August 19, 1987), 52 FR 31833 [File No. SR-DTC-87-10] (order approving the implementation of DTC's operational arrangements for the eligibility of security issues), and Securities Exchange Act Release No. 30625 (April 30, 1992), 57 FR 18534 [File No. SR-DTC-92-06] (order approving modifications to DTC's operational arrangements).

¹² *Supra* note 9.

¹³ 15 U.S.C. 78s(b)(2) (1988).

¹⁴ 17 CFR 200.30-3(a)(12) (1994).

¹ 15 U.S.C. 78s(b) (1988).

² Securities Exchange Act Release No. 34835 (October 13, 1994), 59 FR 52851.

custodial and transactional processing services for the participant with respect to the participant's certificated securities. The proposed services will consist, among other things, of processing and accepting physical deposits of certificates, processing the physical withdrawal of certificates, and providing incidental services in connection thereto. Book-entry movements of deposited securities will not be permitted.³

Under the proposal, MSTC will provide all custodial and transactional processing services on a negotiated basis with its participants. MSTC will not be obligated to enter into such contracts with any participant, and if it chooses to enter into such a contract with any participant, it will not be obligated to enter into a contract with similar terms with any other participant.

II. Discussion

The Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder and more specifically with the requirements of Section 17A(b)(3)(F).⁴ Section 17A(b)(3)(F) requires that the rules of a clearing agency be designed to remove impediments to and perfect the mechanism of a national system for the prompt and accurate clearance and settlement of securities transactions. The Commission believes that MSTC's service is consistent with this obligation.

MSTC's new service will provide custodian, transaction processing, and related data-entry services with respect to participants' certificated securities. Participants have been experiencing a continual decline in their activity associated with the processing of physical securities primarily due to the increase in book-entry eligibility of securities at the clearing agency level. Many participants no longer find it desirable to maintain their own custodial operations. As a result, MSTC has been requested to provide such custodial and processing services as part of MSTC's operations.

The Commission believes that MSTC's proposed rule change should help to minimize inefficient procedures employed by individual participants by concentrating these operations in one centralized facility. As a result, the individual participants will be able to eliminate their own custodial operations and the high fixed costs associated with

them while maintaining the required safeguarding of these securities.

III. Conclusion

For the reasons stated above, the Commission finds that MSTC's proposal is consistent with Section 17A of the Act⁵ and the rules and regulations thereunder.

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,⁶ that the proposed rule change (File No. SR-MSTC-94-12) be, and hereby is, approved until October 1, 1995.

For the Commission of the Division of Market Regulation, pursuant to delegated authority.⁷

Margaret H. McFarland,
Deputy Secretary.

[FR Doc. 95-10788 Filed 5-1-95; 8:45 am]

BILLING CODE 8010-01-M

[Release No. 34-35650; File No. SR-NYSE-95-08]

Self-Regulatory Organizations; Notice of Filing of Proposed Rule Change by the New York Stock Exchange, Inc., Relating to Listed Company Relations Proceedings

April 26, 1995.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"), 15 U.S.C. 78s(b)(1), notice is hereby given that on March 3, 1995, the New York Stock Exchange, Inc. ("NYSE" 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 self-regulatory organization. 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 proposed rule change consists of new Rule 103C concerning procedures relating to initiation and conduct of a review of the relationship between a listed company and its specialist organization. The text of the proposed Rule 103C is attached as Exhibit A.

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 self-regulatory organization 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 self-regulatory organization 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 proposes to adopt new Rule 103C (Listed Company Relations Proceedings) to provide its listed companies and specialist units with a procedure for resolving non-regulatory issues that may arise between them. The Exchange believes that the relationship between a listed company and its specialist unit is a significant one.

Specialist units work to foster and promote sound mutual understanding and effective communications with their listed companies, but situations may occasionally arise in which one or both sides cannot easily resolve differences with respect to non-regulatory issues. Such issues might include, for example, misunderstandings with respect to the frequency and adequacy of communications between a company and its specialist unit. Proposed new Rule 103C contains a formal procedure by which a listed company could make a written notification (known as an "Issuer Notice") to the Exchange's New Listings and Client Services Division of its desire to commence a proceeding to mediate and resolve such issues. The Exchange's Quality of Markets Committee ("QOMC"), a Board of Directors level committee, would be responsible for oversight of the Listed Company Relations Proceeding ("LCRP") through a subcommittee consisting of the two Exchange vice-chairmen, a senior Exchange official, and two listed company representatives, all of whom would be appointed from the QOMC membership. This subcommittee would work with the listed company and the specialist unit through written submissions and meetings designed to produce an action plan with specific steps for resolution of the matter. At regular intervals of three, six and nine months, the subcommittee would work with the parties to resolve their issues. The listed company could conclude the LCRP at any time during the process if it believed that matters had been satisfactorily addressed.

³ Letter from George T. Simon, Foley & Lardner, to Jonathan Kallman, Associate Director, Division of Market Regulation, Commission (January 23, 1995).

⁴ 15 U.S.C. 78q-1(b)(3)(F) (1988).

⁵ 15 U.S.C. 78q-1 (1988).

⁶ 15 U.S.C. 78s(b)(2) (1988).

⁷ 17 CFR 200.30-3(a)(12) (1994).

If matters were not resolved at the end of one year from the commencement of the LCRP, the listed company could formally request a reassignment of its stock to another specialist unit. The subcommittee would prepare a recommendation to the QOMC as to whether it is appropriate to reassign the stock. The QOMC would review the recommendation and give the parties an additional opportunity to present their views in writing. It would then make a recommendation to the Exchange's Board of Directors. The Board could also afford the parties an opportunity to present their views in writing. The Board would then determine whether the stock should be reassigned. If the stock were to be reassigned, the Board would direct the Exchange's Allocation Committee to reallocate it. The then current specialist unit and the unit of any specialist member of the Board would not be permitted to apply for allocation of the stock. Proposed Rule 103C also provides that no reference to the LCRP or the Board's action would be retained in the information maintained by the Allocation Committee regarding the then current specialist unit. The rule further provides that the specialist unit subject to a reallocation would not be afforded any preferential treatment in subsequent allocations as a result of a reallocation pursuant to the rule.

2. Statutory Basis

The basis under the Act for the proposed rule change is the requirement under Section 6(b)(5) that an Exchange have rules that are designed to promote just and equitable principles of trade, to remove impediments to, and perfect the mechanism of a free and open market and, in general, to protect investors and the public interest. The adoption of Rule 103C is consistent with these objectives in that it would enhance the Exchange's ability to foster closer relationships between its specialists and their listed companies.

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 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

Within 35 days of the publication of this notice in the **Federal Register** or within such other 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 the proposed rule change, or

(B) Institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, N.W., Washington, D.C. 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying at the Commission's Public Reference Section, 450 Fifth Street, N.W., Washington, D.C. 20549. Copies of such filing will also be available for inspection and copying at the principal office of the NYSE. All submissions should refer to File No. SR-NYSE-95-08 and should be submitted by May 23, 1995.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

Margaret H. McFarland,

Deputy Secretary.

Exhibit A—New Rule 103C: Listed Company Relations Proceedings

(a) A listed company may file with the New Listings & Client Service Division a written notification ("Issuer Notice"), signed by the company's chief executive officer, that it wishes to commence a proceeding whereby the Quality of Markets Committee ("QOMC") shall attempt to mediate and resolve non-regulatory issues that have arisen between the company and its assigned specialist unit. The Issuer Notice shall indicate the specific issues sought to be mediated and resolved, and what steps, if any, have been taken to try to address them before the filing of the Issuer Notice.

(b) The QOMC shall refer the Issuer Notice to its Listed Company Relations Subcommittee (the "Subcommittee") which shall consist of two listed company members of the QOMC, as well as a senior officer and two vice-chairmen of the Exchange, provided these individuals are also members of the QOMC. The Subcommittee shall review the Issuer Notice and shall notify the subject specialist unit that a Listed Company Relations Proceeding ("LCRP") is being commenced pursuant to this rule, and that the LCRP shall run for one year from the date of notice to the specialist unit, unless concluded earlier by the listed company. The specialist unit shall be provided with a copy of the Issuer Notice, and shall be given two weeks within which to submit a written response to the Subcommittee.

(c) After the two-week period for a response from the subject specialist unit, the Subcommittee shall meet with representatives of the listed company and the specialist unit that are parties to the LCRP, and shall identify specific steps that may be taken to mediate and resolve matters indicated in the Issuer Notice.

(d) The parties to the LCRP shall each submit a written report to the Subcommittee no later than three months from the date the LCRP is commenced with respect to all matters indicated in the Issuer Notice, and any other matter that either party believes may have a bearing on the LCRP. The listed company may give written notice that it is concluding the LCRP at any time if it believes matters have been satisfactorily addressed. If the listed company wishes the LCRP to continue, it must so state. After receiving the written reports from the parties to the LCRP, the Subcommittee shall then advise the QOMC, as appropriate. The Subcommittee may meet further with the parties to the LCRP, and identify such other specific steps that may be taken to resolve matters, as it deems appropriate. The same process shall be followed at six and nine month intervals from the date the LCRP is commenced, unless the listed company has chosen to conclude the LCRP.

(e) At the end of one year from the commencement of the LCRP, the listed company shall, in writing, either (i) inform the Subcommittee that it wishes to conclude the LCRP; or (ii) inform the Subcommittee that matters between it and its specialist unit remain unresolved, and that it wishes that its stock be assigned to a different specialist unit. The Subcommittee shall prepare a report to the QOMC recommending either that (i) the LCRP should be concluded; or (ii) that the listed company's stock should be assigned to a different specialist unit.

(f) The QOMC shall review the report prepared by the Subcommittee and shall give the parties to the LCRP an opportunity to present their views in writing. The QOMC shall then make a recommendation to the Exchange's Board of Directors as to the disposition of the LCRP, including a recommendation as to whether the listed company's stock should be assigned to a different specialist unit.

(g) The Exchange's Board of Directors shall review the QOMC's recommendation and may give the parties to the LCRP an

opportunity to present their views in writing. The Board of Directors shall then determine the appropriate disposition of the LCRP, and may, if it deems such action to be in the best interests of the Exchange, direct that the Allocation Committee reallocate the listed company's stock to a different specialist unit. The currently-assigned specialist unit and the member organization of any specialist member of the Board of Directors shall be precluded from applying to be allocated the stock. No reference to the LCRP or the Board's action shall be retained in the information maintained by the Allocation Committee with respect to the currently-assigned specialist unit, and the currently-assigned specialist unit shall not be afforded preferential treatment in subsequent allocations as a result of a reallocation pursuant to this rule.

[FR Doc. 95-10789 Filed 5-1-95; 8:45 am]

BILLING CODE 8010-01-M

DEPARTMENT OF STATE

[Public Notice 2195]

Advisory Committee on International Law; Meeting

A meeting of the Advisory Committee on International Law will take place on Thursday, May 18, 1995, from 2:00 to approximately 5:00 p.m., as necessary, in room 1207 of the United States Department of State, 2201 C Street, N.W., Washington, D.C. The meeting will be chaired by the Legal Adviser of the Department of State, Conrad K. Harper, and will be open to the public up to the capacity of the meeting room. The meeting will focus on the establishment of an international criminal court and possible United States Government involvement in genocide cases before the International Court of Justice, as well as review of other current developments in international law.

Entry to the building is controlled and will be facilitated by advance arrangements. Members of the public desiring access to the session should, prior to May 17, 1995, notify the Office of the Assistant Legal Adviser for United Nations Affairs (telephone (202) 647-6771) of their name, Social Security number, date of birth, professional affiliation, address and telephone number in order to arrange admittance. The above includes government and non-government attendees. All attendees must use the "C" entrance. One of the following valid IDs will be required for admittance: any U.S. driver's license with photo, a passport, or a U.S. Government agency ID.

Dated: April 20, 1995.

Bruce C. Rashkow,

Assistant Legal Adviser for United Nations Affairs; Executive Director, Advisory Committee on International Law.

[FR Doc. 95-10689 Filed 5-1-95; 8:45 am]

BILLING CODE 4710-08-M

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

Final Order Amending Certain Tentative Findings Contained in an Earlier Order to Show Cause Order 94-10-5, Dated October 6, 1994

We are publishing the order in its entirety as an appendix to this document.

DATES: Issued in Washington, D.C. April 26, 1995.

EFFECTIVE DATE: April 26, 1995.

FOR FURTHER INFORMATION CONTACT:

Dennis DeVany, U.S. Department of Transportation, Office of Aviation Analysis, X-53, Room 6407C, 400 7th Street, S.W., Washington, DC 20590 (202) 366-1061.

Patrick V. Murphy,

Acting Assistant Secretary for Aviation and International Affairs.

Appendix

[Order 95-4-38; Docket 49814]

Waivers for Regional/Commuter Carriers from Certain Service Termination Notice Requirements; Final Order Granting Waiver

By Order 94-10-5, October 6, 1994, the Department tentatively established criteria for granting waivers to regional/commuter carriers from the notice provision of the Federal Aviation Administration Authorization Act of 1994 (Public Law 103-305). That law requires carriers to file a 45-day notice of their intention to suspend service at FAA-designated nonhub communities. However, it also instructed the Department to establish terms and conditions under which regional/commuter carriers were to be exempted from the notice requirement.¹

Order 94-10-5 proposed that the notice requirement should be waived for regional/commuter carriers under either of two scenarios: first, if the affected community would continue to receive scheduled service with jet aircraft; or second, if the affected community would continue to receive scheduled service from at least two other regional/commuter carriers. Thus, in

¹ P.L. 103-305 defines "regional/commuter carriers" as (a) all Part 135 carriers, and (b) Part 121 carriers whose operations consist entirely of service with aircraft with 70 or fewer passenger seats. An FAA-designated "nonhub" is a community that accounts for less than 0.05 percent of all revenue enplanements in the nation—less than 234,157 enplanements during calendar year 1993, the most recent year for which data are available.

situations where reasonable levels of capacity would remain in the form of at least one jet operator or at least two regional/commuter carriers, no 45-day notice would have been required.

The Regional Airline Association (RAA) has responded to Order 94-10-5 on behalf of its members. According to the RAA, the legislative history of Public Law 103-305 clearly suggests that the notice requirement is aimed at jet service, particularly at the 27 nonhubs for which the Department has not established essential air service determinations.² The RAA contends that, if the Department's proposed waiver criteria were finalized, the effect would be the creation of notice obligations at many nonhubs that are served exclusively by regional/commuter carriers. The RAA concludes that our proposed criteria would thus shift the main burden of the requirement from major carriers providing jet service at a small number of nonhubs, as intended by Congress, to many regional/commuter carriers serving numerous small communities throughout the country.

We agree with the RAA that our proposed criteria were unnecessarily narrow. The legislative history of Public Law 103-305 indicates that the focus of Congress's concern was the abrupt loss of jet service at nonhubs for which we have not established essential air service determinations. Moreover, communities for which we have established determinations already enjoy the protections of the more stringent 90-day notice requirement and hold-in provisions contained in 49 U.S.C. 41734; application of the new 45-day notice in such cases would therefore be superfluous.

Under these circumstances, we conclude that regional/commuter carriers should be subject to the 45-day notice requirement of Public Law 101-305 only at communities for which the Department has not established an essential air service determination. We will therefore grant a waiver from the notice requirement to regional/commuter carriers serving nonhubs for which the Department has established a determination. In the latter cases, however, carriers should be mindful that they remain subject to the more stringent essential air service provisions contained in 49 U.S.C. 41734.

The appendix to this order contains the nonhubs to which the 45-day notice requirement continues to apply. We would stress, however, that this list is likely to change over time. Some communities may grow from nonhubs to small hubs while others shrink from small hubs to nonhubs, or we could ultimately establish determinations for some communities that currently have none.

Accordingly,

1. We grant a waiver from the 45-day notice requirement contained in the Federal Aviation Administration Authorization Act of 1994, Public Law 103-305, to all regional/commuter carriers insofar as it would apply to service at nonhub communities for which the Department has established essential air service determinations;

² The Appendix lists the 27 nonhubs at issue.

2. We grant the motion for leave to file an otherwise unauthorized document by the Regional Airline Association in Docket 49184; and

3. We will publish a copy of this order in the **Federal Register** and serve a copy on the Regional Airline Association.

Patrick V. Murphy,
Acting Assistant Secretary for Aviation and International Affairs.

Nonhubs for Which a 45-Day Notice Is Required

Ashland, Kentucky/Huntington, West Virginia
Bismarck/Mandan, North Dakota
Bristol/Kingsport/Johnson City, Tennessee
Bozeman, Montana
Butte, Montana
Caspar, Wyoming
Charleston/Dunbar, West Virginia
Evansville, Indiana
 Fargo, North Dakota
Grand Forks, North Dakota
Grand Junction, Colorado
Great Falls, Montana
Helena, Montana
Idaho Falls, Idaho
Kalispell, Montana
Lincoln, Nebraska
Minot, North Dakota
Missoula, Montana
Monroe, Louisiana
Montgomery, Alabama
Peoria, Illinois
Rapid City, South Dakota
Rochester, Minnesota
Saginaw/Bay City/Midland, Michigan
Scranton/Wilkes-Barre, Pennsylvania
Sioux City, Iowa
Sioux Falls, South Dakota

[FR Doc. 95-10760 Filed 5-1-95; 8:45 am]

BILLING CODE 4910-62-P

Federal Aviation Administration

Airworthiness Standards; Fiscal Year 1998, Small Airplane Directorate's Research, Engineering and Development Initiatives, Program Identification

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Request for small airplane directorate's research, engineering and development program proposals.

SUMMARY: This notice announces a request for proposals that will define the Federal Aviation Administration (FAA), Aircraft Certification Service, Small Airplane Directorate, Research, Engineering and Development (R,E&D) initiatives for Fiscal Year (FY) 1998 by defining and documenting specific, potential R,E&D program proposals. The request for proposals will focus on Aircraft Certification R,E&D programs related to the Small Airplane Directorate's activities. The Small Airplane Directorate is responsible for

airworthiness areas related to the normal, utility, acrobatic, and commuter category airplanes, gliders, balloons, and airships. Other FAA requirements such as flight standards, air traffic, or airway facilities will not be addressed. The FAA is soliciting the public sector to ensure that the proposed Small Airplane Directorate's R,E&D requirements will have relevant, practical applications and will be cost effective.

DATES: The request for proposals will be open until close of business May 31, 1995.

ADDRESSES: Submit comments in triplicate to: Ervin E. Dvorak, Standards Staff (ACE-110), Small Airplane Directorate, Aircraft Certification Service, Federal Aviation Administration, 601 East 12th Street, Kansas City, Missouri 64106.

FOR FURTHER INFORMATION CONTACT: Ervin E. Dvorak, Aerospace Engineer, Standards Staff (ACE-110), Small Airplane Directorate, Aircraft Certification Service, Federal Aviation Administration; telephone number (816) 426-6941.

SUPPLEMENTARY INFORMATION: Each FY the FAA prepares an R,E&D program plan that include new (and amended) R,E&D proposals. The Aircraft Certification Service's Small Airplane Directorate is responsible for preparing its part of the overall FAA submittal.

The philosophy of the R,E&D process is to create an atmosphere that will promote the identification of requirements by any person or organization in the government or private sector. This makes the R,E&D process more responsive to public sector needs. Within the Aircraft Certification Service's Small Airplane Directorate, the R,E&D process places increased emphasis on outside participation in identifying new requirements and in sponsoring and monitoring the resulting R,E&D projects. Therefore, as part of the overall FAA and Aircraft Certification initiatives, the FAA's Small Airplane Directorate is undertaking a directly-related initiative specifically for airworthiness areas related to the normal, utility, acrobatic, and commuter category airplanes, gliders, balloons, and airships. Requirements should support issues critical to our regulatory and policy development. Also, the requirements could support certification issues for new and innovative designs and technology, and/or support correcting deficiencies in continued airworthiness. It has the same basic mission, goals, and procedures as the agency-wide initiative.

The Small Airplane Directorate will implement its segment of the FY-98 submittal by identifying, describing, evaluating, and cataloguing potential R,E&D requirements (i.e., proposals) for potential sponsorship and incorporation into the overall FAA FY-98 R,E&D submittal. This will result in a coordinated FY-98 requirements package that will be assigned to the appropriate FAA R,E&D provider organizations when approved and when funds are allocated by the budget process.

It should be stressed that the proposals that are evaluated as a result of this notice, if accepted, will not be funded until the overall FAA FY-98 R,E&D submittal is funded, (i.e., at least two years after their original submittal on October 15, 1995) and that reprogramming of limited R,E&D resources before than is highly unlikely. Also, the accepted proposals will have to complete for resources with other requirements identified for R,E&D by other FAA activities. Nonetheless, the need clearly exists to identify Small Airplane Directorate's Certification R,E&D needs to complete for the agency's R,E&D resources.

As a matter of information, there are four primary FAA R,E&D supplier organizations: (1) the FAA Technical Center (FAATC) in Atlantic City, New Jersey; (2) the Research and Development Service (ARD) in Washington, D.C.; (3) the Office of Environment and Energy (AEE) in Washington, D.C.; and (4) the Civil Aeromedical Institute (CAMI) in Oklahoma City, Oklahoma, of the Office of Aviation Medicine (AAM). These organizations perform the R,E&D on programs that are approved and funded through the process.

Although not mandatory, the format of Figure 1 for R,E&D proposals is preferred:

Figure 1—FY-98 Small Airplane Director's R,E&D Program Description Form I.D. No. (FAA will fill in)

Originator

(Insert Name, Address, Phone Number, and Fax Number)

Proposed R,E&D Program Description & Objectives

(Insert Brief Description of the proposal program and its major goals and objectives)

Note: A more detailed description may be attached in addition to this summary but is not mandatory at this time.

How Would You Accomplish This Program?

(Insert Brief Description of your recommended method of accomplishing the proposed R,E&D program)

Justification/History

(If appropriate, furnish data such as a concise accident/incident history and any other relevant statistics or information that would show that the proposed research is needed, cost-effective, and applicable to developing a solution to the proposed R,E&D project. This history/justification input data will be used to aid in assessing the relative value of the proposed R,E&D project.)

Anticipated Benefits/Products and Beneficiaries

(Insert Brief Description of anticipated benefits/products, who would benefit, and how)

If an R,E&D proposal has been submitted previously, then (unless a major change or update has been made) it is on file and need not be resubmitted.

Copies of this notice are being mailed to all known interested parties. Any interested party who desires but has not received a copy of this notice by May 19, 1995, should request a copy from Terre Flynn, Standards Staff (ACE-110), Small Airplane Directorate, Aircraft Certification Service, Federal Aviation Administration, 601 East 12th Street, Kansas City, Missouri 64106; telephone number (816) 426-6941.

Issued in Kansas City, Missouri, on April 25, 1995.

Henry A. Armstrong,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 95-10769 Filed 5-1-95; 8:45 am]

BILLING CODE 4910-13-M

Aviation Rulemaking Advisory Committee; Airport Certification Issues—New Task

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of new task assignment for the Aviation Rulemaking Advisory Committee (ARAC).

SUMMARY: Notice is given of a new task assigned to and accepted by the Aviation Rulemaking Advisory Committee (ARAC). This notice informs the public of the activities of ARAC.

FOR FURTHER INFORMATION CONTACT: Robert E. David, Assistant Executive Director for Airport Certification Issues, Office of Airport and Safety Standards

(AAS-300), 800 Independence Avenue, SW., Washington, DC 20591; telephone (202) 267-3085; fax (202) 267-5383.

SUPPLEMENTARY INFORMATION:

Background

The FAA has established an Aviation Rulemaking Advisory Committee to provide advice and recommendations to the FAA Administrator, through the Associate Administrator for Regulation and Certification, on the full range of the FAA's rulemaking activities with respect to aviation-related issues. This includes obtaining advice and recommendations on the FAA's commitment to harmonize its Federal Aviation Regulations (FAR) and practices with its trading partners in Europe and Canada.

One area ARAC deals with is Airport Certification issues. These issues involve the certification and operation of airports that service air carriers in 14 CFR part 139.

The Task

This notice is to inform the public that the FAA has asked ARAC to provide advice and recommendations on the following task.

Review Title 14, Code of Federal Regulations (CFR) part 139 and develop recommendations concerning what requirements are applicable to airports that have scheduled service with aircraft having a seating capacity of 10 to 30 seats. In developing these recommendations, consideration should be given to accepted industry practices regarding airport safety, personnel available at these airports, costs associated with meeting these requirements (e.g., capital, operating, and maintenance costs) and the types of accidents/incidents that occur at these airports. Where it appears that it is not reasonable to apply a part 139 requirement at these airports, the ARAC shall examine alternatives to the requirement to determine if there is another means to assure a comparable level of safety.

In conducting this review, ARAC should (1) Consider categorizing the requirements applicable to these airports by the size of the airport, or some other means to achieve specific safety objectives, while minimizing the operational burden; (2) consider alternatives to providing aircraft rescue and firefighting services for operations at these airports; (3) consider conducting a survey of the airports that would be affected by this rule; and (4) recommend applicable requirements, including a reasonable compliance period, taking into account economic and operational factors.

The recommendations from ARAC could serve as the basis for a notice of proposed rulemaking, if the FAA is granted the legislative authority to certificate these airports.

ARAC Acceptance of Task

ARAC has accepted the task and has chosen to establish a new Commuter Airport Certification Working Group. The working group will serve as staff to ARAC to assist ARAC in the analysis of the assigned task. Working group recommendations must be reviewed and approved by ARAC. If ARAC accepts the working group's recommendations, it forwards them to the FAA as ARAC recommendations.

Working Group Activity

The Commuter Airport Certification Working Group is expected to comply with the procedures adopted by ARAC. As part of the procedures, the working group is expected to:

1. Recommend a work plan for completion of the tasks, including the rationale supporting such a plan, for consideration at the meeting of ARAC to consider airport certification issues held following publication of this notice.

2. Give a detailed conceptual presentation of the proposed recommendations, prior to proceeding with the work stated in item 3 below.

3. Provide a status report at each meeting of ARAC held to consider airport certification issues. Participation in the Working Group.

The Commuter Airport Certification Working Group will be composed of experts having an interest in the assigned task. A working group member need not be a representative of a member of the full committee.

An individual who has expertise in the subject matter and wishes to become a member of the working group should write to the person listed under the caption **FOR FURTHER INFORMATION CONTACT** expressing that desire, describing his or her interest in the task, and stating the expertise he or she would bring to the working group. The request will be reviewed by the assistant chair, the assistant executive director, and the working group chair, and the individual will be advised whether or not the request can be accommodated.

The Secretary of Transportation has determined that the formation and use of ARAC are necessary and in the public interest in connection with the performance of duties imposed on the FAA by law.

Meetings of ARAC will be open to the public, except as authorized by section 10(d) of the Federal Advisory Committee Act. Meetings of the Commuter Airport Certification Working Group will not be open to the public, except to the extent that individuals with an interest and expertise are selected to participate. No

public announcement of working group meetings will be made.

Issued in Washington, DC, on April 25, 1995.

Robert E. David,

Assistant Executive Director for Airport Certification Issues, Aviation Rulemaking Advisory Committee.

[FR Doc. 95-10771 Filed 5-1-95; 8:45 am]

BILLING CODE 4910-13-M

Notice of Intent To Rule on Application To Impose and Use the Revenue From a Passenger Facility Charge (PFC) at Fort Collins-Loveland Municipal Airport, Submitted by the Cities of Fort Collins and Loveland, CO

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of intent to rule on application.

SUMMARY: The FAA proposes to rule and invites public comment on the application to impose and use PFC revenue at Fort Collins-Loveland Municipal Airport under the provisions of 49 U.S.C. 40117 and Part 158 of the Federal Aviation Regulations (14 CFR 158).

DATES: Comments must be received on or before June 1, 1995.

ADDRESSES: Comments on this application may be mailed or delivered in triplicate to the FAA at the following address: Alan E. Wiechmann, Manager; Denver Airports District Office, DEN-ADO; Federal Aviation Administration; 5440 Roslyn, Suite 300; Denver, CO 80216-6026.

In addition, one copy of any comments submitted to the FAA must be mailed or delivered to Mr. Fred Anderton, Airport Manager, at the following address: Cities of Ft. Collins & Loveland, 4824 Earhart Road, Fort Collins, CO 80538.

Air Carriers and foreign air carriers may submit copies of written comments previously provided to Ft. Collins-Loveland Municipal Airport, under section 158.23 of Part 158.

FOR FURTHER INFORMATION CONTACT: Mr. Chris Schaffer, (303) 286-5525; Denver Airports District Office, DEN-ADO; Federal Aviation Administration; 5440 Roslyn, Suite 300; Denver, Colorado 80216-6026. The application may be reviewed in person at this same location.

SUPPLEMENTARY INFORMATION: The FAA proposes to rule and invites public comment on the application to impose and use PFC revenue at Ft. Collins-Loveland Municipal Airport, under the provisions of 49 U.S.C. 40117 and Part

158 of the Federal Aviation Regulations (14 CFR Part 158).

On April 24, 1995, the FAA determined that the application to impose and use the revenue from a PFC submitted by the Cities of Fort Collins & Loveland was substantially complete within the requirements of section 158.25 of Part 158. The FAA will approve or disapprove the application, in whole or in part, no later than July 28, 1995.

The following is a brief overview of the application. Level of the proposed PFC: \$3.00; Proposed charge effective date: October 1, 1995; Proposed charge expiration date: September 30, 1999; Total estimated PFC revenues: \$385,201.00

Brief description of proposed project: Acquire Index "A" aircraft/rescue fire fighting (ARFF) vehicle; extend Taxiway "D"; rehabilitate Runway 15/33; and acquire passenger lift device.

Class or classes of air carriers which the public agency has requested not be required to collect PFC's: None.

Any person may inspect the application in person at the FAA office listed above under **FOR FURTHER INFORMATION CONTACT** and at the FAA Regional Airports Office located at: Federal Aviation Administration, Northwest Mountain Region, Airports Division, ANM-600, 1601 Lind Avenue S.W., Suite 540, Renton, WA 98055-4056.

In addition, any person may, upon request, inspect the application, notice and other documents germane to the application in person at the Fort Collins-Loveland Municipal Airport.

Issued in Renton, Washington on April 25, 1995.

David A. Field,

Manager, Planning, Programming and Capacity Branch, Northwest Mountain Region.

[FR Doc. 95-10767 Filed 5-1-95; 8:45 am]

BILLING CODE 4910-13-M

Notice of Intent To Rule on Application To Impose and Use the Revenue From a Passenger Facility Charge (PFC) at Medford-Jackson County Airport, Submitted by Jackson County, Medford, OR

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of intent to rule on application.

SUMMARY: The FAA proposes to rule and invites public comment on the application to impose and use PFC revenue at Medford-Jackson County Airport under the provisions of 49

U.S.C. 40117 and Part 158 of the Federal Aviation Regulations (14 CFR 158).

DATES: Comments must be received on or before June 1, 1995.

ADDRESSES: Comments on this application may be mailed or delivered in triplicate to the FAA at the following address: J. Wade Bryant, Manager; Seattle Airports District Office, SEA-ADO; Federal Aviation Administration; 1601 Lind Avenue SW, Suite 250; Renton, WA 98055-4056.

In addition, one copy of any comments submitted to the FAA must be mailed or delivered to Mr. Bern E. Case, Airport Director, at the following address: Medford-Jackson County Airport, 3650 Biddle Road, Medford, OR 97504.

Air Carriers and foreign air carriers may submit copies of written comments previously provided to Medford-Jackson County Airport, under section 158.23 of Part 158.

FOR FURTHER INFORMATION CONTACT: Mr. Jerry Trujillo, (206) 227-2629; Seattle Airports District Office, SEA-ADO; Federal Aviation Administration; 1601 Lind Avenue SW; Suite 250; Renton, Washington 98055-4056. The application may be reviewed in person at this same location.

SUPPLEMENTARY INFORMATION: The FAA proposes to rule and invites public comment on the application to impose and use PFC revenue at Medford-Jackson County Airport, under the provisions of 49 U.S.C. 40117 and Part 158 of the Federal Aviation Regulations (14 CFR Part 158).

On April 24, 1995, the FAA determined that the application to impose and use the revenue from a PFC submitted by Jackson County was substantially complete within the requirements of section 158.25 of Part 158. The FAA will approve or disapprove the application, in whole or in part, no later than August 1, 1995.

The following is a brief overview of the application.

Level of the proposed PFC: \$3.00.

Proposed charge effective date: November 1, 1995.

Proposed charge expiration date: October 31, 2000.

Total estimated PFC revenues: \$1,810,000.00.

Brief description of proposed project: Acquire passenger life device; ground level loading bridge/mobile covered walkway; and air carrier ramp rehabilitation.

Class or classes of air carriers which the public agency has requested not be required to collect PFC's: Operations by Air Taxi/Commercial Operators when enplaning revenue passengers in

limited, irregular, special service air taxi/commercial operations such as air ambulance services, student instruction, non-stop sightseeing flights that begin and end at the airport and are concluded [conducted] within a 25 mile radius of the airport, and other similar limited, irregular, special service operations by such Air Taxi/Commercial Operators.

Any person may inspect the application in person at the FAA office listed above under **FOR FURTHER INFORMATION CONTACT** and at the FAA Regional Airports Office located at: Federal Aviation Administration, Northwest Mountain Region, Airports Division, ANM-600, 1601 Lind Avenue S.W., Suite 540, Renton, WA 98055-4056.

In addition, any person may, upon request, inspect the application, notice and other documents germane to the application in person at the Medford-Jackson County Airport.

Issued in Renton, Washington on April 24, 1995.

David A. Field,

Manager, Planning, Programming and Capacity Branch, Northwest Mountain Region.

[FR Doc. 95-10768 Filed 5-1-95; 8:45 am]

BILLING CODE 4910-13-M

Federal Highway Administration

Environmental Impact Statement; Lapeer County, MI

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice of Intent.

SUMMARY: The FHWA is issuing this notice to advise the public that an Environmental Impact Statement will be prepared for the proposed improvement of M-24 from 1.6 kilometers (one mile) north of the Oakland County line to the I-69 interchange south of Lapeer in Lapeer County, Michigan.

FOR FURTHER INFORMATION CONTACT: Mr. Norman Stoner, Program Operations Engineer, Federal Highway Administration, 315 West Allegan St., Room 211, Lansing, Michigan 48933, Telephone (517) 377-1880 or Mr. Ron Kinney, Manager, Environmental Section, Bureau of Transportation Planning, Michigan Department of Transportation, PO Box 30050, Lansing, Michigan 48909, Telephone (517) 335-2621.

SUPPLEMENTARY INFORMATION: The FHWA, in cooperation with the Michigan Department of Transportation, (MDOT), is preparing an Environmental Impact Statement (EIS) for the proposed

improvement of M-24 from 1.6 kilometers (one mile) north of the Oakland County line to the I-69 interchange south of Lapeer in Lapeer County, Michigan. The proposed project is approximately 14.5 kilometers (9 miles) in length and is needed to accommodate current and future traffic volumes and to improve operating conditions and the safety of the traveling public. The present facility is two lanes.

The alternatives under consideration include (1) No Action; (2) a Low Capital Investment Improvement Alternative which would include intersection improvements and other minor traffic safety modifications; and (3) Improvements Along the Existing Alignment which include a five-lane roadway or a four-lane divided highway. The five-lane alternative consists of five 3.6 meter (12-foot) lanes, shoulders and open drainage. The four-lane divided highway alternative consists of two 7.3 meter (24 foot) paved roadways with an 25.6 meter (84-foot) median, valley ditch type design and paved shoulders constructed within a predominant 91.4 meter (300 foot) right-of-way. Minor corrections of the vertical alignment would be implemented where possible. It has not yet been determined whether improvements are more likely on the east side or the west or if there are areas where the alignments need to cross over or narrow. Consequently, the alternatives are centered on the existing roadway with the widening either all west or all east. The existing right-of-way varies but is predominantly 36.6 meters (120 feet).

Early coordination with a number of Federal, State, and local agencies has identified the more significant issues to be addressed in the EIS. Accordingly, no agency scoping meeting is planned at this time. A scoping report has been prepared identifying the alternatives and the social, economic, and environmental issues involved and is available to all interested agencies, organizations and individuals on request. A public meeting was held on March 25, 1993 to provide the public an opportunity to discuss the proposed action. Comment on the scoping report and issues identified are invited from all interested parties. Requests for a copy of the scoping document or any comments submitted should be addressed to the above contact persons.

The Draft EIS is scheduled for completion in 1996 and will be made available for public and agency review and comment.

(Catalog of Federal Domestic Assistance Program Number 20.205, Highway Planning

and Construction. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program.)

Issued on: April 12, 1995.

Donald Cameron,

Planning & Program Development Engineer, Lansing, Michigan.

[FR Doc. 95-10664 Filed 5-1-95; 8:45 am]

BILLING CODE 4910-22-M

DEPARTMENT OF TREASURY

Internal Revenue Service

Announcement of Open Membership Application Period for the Information Reporting Program Advisory Committee

AGENCY: Internal Revenue Service, Treasury.

SUMMARY: In 1991 the Internal Revenue Service (IRS) established the Information Reporting Program Advisory Committee (IRPAC). The primary purpose of IRPAC is to provide an organized public forum for discussion of relevant information reporting issues between the officials of the IRS and representatives of the payer community. IRPAC offers constructive observations about current or proposed policies, programs, and procedures, and when necessary, suggests ways to improve the operation of the Information Reporting Program. IRPAC is currently comprised of 20 representatives from various segments of the private sector payer community. Ten of these appointments to IRPAC will expire at the end of 1995. Additional members will be selected for two-year terms beginning in January 1996. National business, technical, and professional associations are encouraged to submit multiple nominees.

SUPPLEMENTARY INFORMATION: IRPAC reports to the National Director, Service Center Compliance, who is the executive responsible for information reporting and is charged with its system-wide planning and improvement. IRPAC is instrumental in providing advice to enhance the IRP Program. Increasing participation by external stakeholders in the planning and improvement of the tax system will help achieve the goals of increasing voluntary compliance and reduction of burden.

IRPAC members are not paid for their time or services, but consistent with Federal regulations, they will be reimbursed for their travel and lodging expenses to attend two two-day public meetings each year. IRPAC members are

expected to attend and pay their own way to four subcommittee meetings each year; these meetings are generally held in Washington, DC or New York, NY.

The IRS is interested in representation from different areas of the payer community (e.g., banking, data processing, mutual funds, securities, life insurance, public accounting, payroll, and state & local government, etc.). Anyone wishing to be considered for membership on IRPAC should so advise the IRS. Please complete the following application questionnaire (or a facsimile thereof prepared on a word processor), and forward it to Ms. Kate LaBuda of the Office Payer Compliance, at the address below.

ADDRESSES: Internal Revenue Service, CP:CO:SC:P, 1111 Constitution Avenue, NW., room 1013, Washington, DC 20224.

DATES: Completed questionnaires (or facsimiles) should be received by IRS no later than June 30, 1995. Questionnaires received after this date will not be considered. An acknowledgment letter will be sent upon receipt.

FOR FURTHER INFORMATION CONTACT: Kate LaBuda at 202-622-3404 (not a toll-free number).

Dated: April 19, 1995.

Larry Faulkner,

Director, Office of Payer Compliance, Service Center Compliance.

Information Reporting Program Advisory Committee Membership Application Questionnaire

The following questions must be answered by anyone interested in becoming a member of the Information Reporting Program Advisory Committee (IRPAC). Applications (or facsimiles produced on a word processor) must be received at the address listed below by June 30, 1995. Those received after this date will not be considered. All applications received will be acknowledged. Questions may be directed to Kate LaBuda at 202-622-3404.

Ms. Kate LaBuda, CP:CO:SC:P, Service Center Compliance, Internal Revenue Service, Room 1013, 1111 Constitution Avenue NW., Washington, DC 20224.

1. Name:
2. Title:
3. Company or Organization Name:
4. Business Address:
5. Business Phone:
6. Fax Number:
7. Home Address:
8. Home Phone:
9. If you are applying on behalf of an organization or association other than

your employer, please state the name, and address of that organization. Also, provide a letter of reference from that organization stating that you are nominated on their behalf. This letter should contain the name of a contact and this contact's phone number.

10. List professional credentials (e.g., Ph.D., CPA, Enrolled Agent, Attorney, Accountant, etc.)

11. Check the *one* segment of the Information Reporting Program (IRP) payer community to which the organization that you represent, and your experience, most closely relate:

- | | |
|-------------|---------------------------|
| _____ | Real Estate |
| _____ | Transmitter/Forms |
| Developer | _____ |
| _____ | Software Developer |
| _____ | Insurance: Property & |
| Casualty | _____ |
| _____ | Insurance: Life |
| _____ | Securities |
| _____ | Mutual Funds |
| _____ | Payroll |
| _____ | State & Local Government |
| _____ | Corporate Compliance |
| _____ | Small Business |
| Compliance | _____ |
| _____ | Public Accounting |
| _____ | Employee Plans |
| _____ | Trust Company |
| _____ | Corporate Transfer Agent/ |
| Utilities | _____ |
| _____ | Large Financial |
| Institution | _____ |
| _____ | Small Financial |
| Institution | _____ |
| _____ | Other (Please specify. |
| _____) | |

12. List the number of years of IRP-related experience you have, and specific sources of this IRP experience. (Account for all years of IRP experience claimed.)

13. Identify organizations to which you belong and any relevant leadership positions you have held.

14. List any previous IRS employment (please state position/s, title/s, and length of time in each position):

15. Please propose two topic ideas that you feel would be appropriate for discussion by IRPAC. Include a short description (two sentences) of each topic.

THE FOLLOWING THREE ITEMS ARE REQUIRED FOR AN FBI NAME CHECK.

16. Date of Birth:

17. Place of Birth:

18. Other names ever used:

THE FOLLOWING ITEMS ARE REQUIRED FOR AN IRS TAX CHECK. (PLEASE NOTE THAT A TAX CHECK IS NOT A TAX AUDIT.)

I hereby authorize the Internal Revenue Service to perform the

standard Federal Advisory Committee member tax check, (pursuant to 26 U.S.C. 6103; 5 U.S.C. 1303; Executive Orders 9397, 11222, 10450; CFR 5.2; 31 CFR Part O, Treasury Department Order Nos. 82 (Revised) and 150-87) and to provide this information to the Assistant Secretary (Administration) of the Treasury Department.

I understand that the purpose of such tax check and income tax filing record check is to promote public confidence in the integrity of the Treasury Department and its administration of the Federal tax system. I have been advised that my Social Security Number is required to identify my tax records accurately. I also understand that this tax check must be completed prior to my appointment to this Federal Advisory Committee and I hereby voluntarily provide the following information:

19. Social Security Number:

20. Spouse's name and SSN (if married and filing jointly):

21. Name(s) and address(es) under which tax returns were filed for the past three years.

THE FOLLOWING ITEM IS REQUIRED BECAUSE OF THE FOREIGN AGENTS REGISTRATION ACT (FARA), AS AMENDED.

22. I presently _____ am / _____ am not required to register as an agent of a foreign principal under FARA, as amended.

Note: Pursuant to 18 U.S.C. sec. 219, an individual who is required to register as an agent of a foreign principal under FARA is prohibited from serving on IRPAC. By executing this questionnaire, you agree that (1) if you are required to register as an agent of a foreign principal under the FARA before your term commences on IRPAC, you will terminate any and all such agencies prior to beginning your tenure and will provide appropriate verification therefor; and (2) you will immediately resign from IRPAC if you become such an agent at any time during your term.

Certification

23. I certify that, to the best of my knowledge and belief, all of my statements are true, correct, complete, and made in good faith. I also agree to the background checks set forth herein.

Signature _____
Date _____

[FR Doc. 95-10764 Filed 5-1-95; 8:45 am]

BILLING CODE 4830-01-U

DEPARTMENT OF VETERANS AFFAIRS**Information Collections Under OMB Review**

AGENCY: Department of Veterans Affairs.
ACTION: None.

The Department of Veterans Affairs has submitted to OMB the following proposals for the collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35). This document lists the type of information collection and the following: (1) The title of the information collection, and the Department form number(s), if applicable; (2) a description of the need and its use; (3) who will be required or asked to respond; (4) an estimate of the total annual reporting hours, and recordkeeping burden, if applicable; (5) the estimated average burden hours per respondent; (6) the frequency of response; and (7) an estimated number of respondents.

ADDRESSES: Copies of the proposed information collections and supporting documents may be obtained from Trish Fineran, Veterans Benefits Administration (20M30), Department of Veterans Affairs, 810 Vermont Avenue NW., Washington, DC 20420, (202) 273-6886.

Comments and questions about the items on the list should be directed to VA's OMB Desk Officer, Joseph Lackey, NEOB, Room 10102, Washington, DC 20503, (202) 395-7316. Do not send requests for benefits to this address.

DATES: Comments on the information collections should be directed to the OMB Desk Officer on or before June 1, 1995.

Dated: April 24, 1995.

By direction of the Secretary.

Donald L. Neilson,
Director, Information Management Service.

Extension

1. Application for Reimbursement from Accrued Amounts Due a Deceased Beneficiary, VA form 21-601.

2. The form is used to file a claim for accrued benefits available at the time of the veteran's death. The information is used by Veterans Benefits Administration to determine the appropriate claimant eligible for accrued benefits.

3. Individuals or households.
4. 1,875 hours.
5. 30 minutes.
6. On occasion.
7. 3,750 respondents.

Extension

1. Report and Certification of Loan Disbursement, VA Form 26-1820.
2. This form is completed by lenders closing VA loans under the automatic or prior approval procedure subsequent to issuance of guaranty.
3. Individuals or households.
4. 150,000 hours.
5. 30 minutes.
6. On occasion.
7. 300,000 respondents.

Reinstatement

1. Application for Conversion, VA Form 29-0152.
2. The form is used by the insured to apply for conversion of a term policy to a permanent plan of insurance. The information is used by Veterans Benefits Administration to initiate the processing of the insured's request to convert his/her term insurance.
3. Individuals or households.
4. 1,125 hours.
5. 15 minutes.
6. On occasion.
7. 4,500 respondents.

Reinstatement

1. Designation of Beneficiary, VA Form 29-336.
2. The form is used by the insured to designate a beneficiary and select an optional settlement to be used when the insurance matures by death. The information is requested to determine the claimants eligibility to receive the proceeds.
3. Individuals or households.
4. 13,917 hours.
5. 10 minutes.
6. On occasion.
7. 83,500 respondents.

Reinstatement

1. Application of Surviving Spouse or Child for REPS Benefits (Restored Entitlement Program for Survivors), VA Form 21-8924.
2. The form is used by dependents of deceased veterans for the sole purpose of making a claim for REPS benefits. The information is used by Veterans Benefits Administration to determine whether the claimant is eligible for REPS benefits.
3. Individuals or households.
4. 2,500 hours.
5. 20 minutes.
6. On occasion.
7. 7,000 respondents.

[FR Doc. 95-10691 Filed 5-1-95; 8:45 am]

BILLING CODE 8320-01-M

Privacy Act of 1974; Report of Matching Programs

AGENCY: Department of Veterans Affairs (VA).

ACTION: Notice of renewal—VA/IRS Match Program.

SUMMARY: Notice is hereby given that the Department of Veterans Affairs (VA), Veterans Health Administration (VHA), intends to renew the computer matching program comparing Internal Revenue Service (IRS) and Social Security Administration (SSA) income records with VA patient income data which is contained in the patient medical records.

The goal of these matches is to compare income, social security number, and employment status as reported to VHA with income records maintained by IRS and SSA. For the information of all concerned, a summary report of the VHA matching program describing the computer matches follows. In accordance with 5 U.S.C. 552a(o)(2), copies of the computer matching report are being sent to both houses of Congress. These matches are expected to commence on or about May 1, 1995, but start no sooner than 30 days after publication of this notice in the **Federal Register**, or 40 days after copies of this notice and the agreement are submitted to Congress and the Office of Management and Budget. These matches may be extended by the involved Data Integrity Boards for a twelve month period provided all agencies involved certify to the Data Integrity Boards, within three months of the termination date of the original match, that the matching program will be conducted without change and the matching programs have been conducted in compliance with the original matching agreements. The matches will not continue past the legislative authorized date to obtain this information. However, expiration of this agreement is December 31, 1995.

ADDRESSES: Interested individuals may comment on the matches by writing to the Associate Chief Medical Director for Administration (161D), Veterans Health Administration, Department of Veterans Affairs, 810 Vermont Avenue NW., Washington, DC 20420.

FOR FURTHER INFORMATION CONTACT: Janice E. Wheeler (202) 273-6276, Program Analyst, Income Verification Match Policy Service.

SUPPLEMENTARY INFORMATION: Further information regarding the matching program is provided below. This information is required by Title 5 U.S.C. 552a(e)(12), the Privacy Act of 1974, as

amended. A copy of this notice has been provided to both houses of Congress and the Office of Management and Budget.

Approved: April 25, 1995.

Jesse Brown,

Secretary of Veterans Affairs.

Report of Matching Program

Department of Veterans Affairs Patient Medical Records With Income Records Maintained by the Internal Revenue Service and the Social Security Administration

a. *Authority:* Title 38, U.S.C. 5106 and 5317; Pub. L. 101-508 as amended by Pub. L. 102-568.

b. *Program Description:*

(1) Purpose: (a) the Department of Veterans Affairs (VA), Veterans Health Administration (VHA) plans to match the household income information contained in the medical records of certain nonservice-connected veterans, with the income records for those persons maintained by the Internal Revenue Service (IRS) and the Social Security Administration (SSA). Those nonservice-connected veterans subject to income verification matching are those veterans who are receiving VA medical care in a mandatory eligibility category due to a finding of low income subsequent to means testing.

(b) Currently, information about a veterans household income (i.e., veterans and spouses receipt of wage, self-employment and other income as well as employment status, health insurance coverage and number of dependents) is obtained when the veteran makes application for medical care at a VA medical care facility. The household income and dependent data is evaluated in a "means test" which takes into account deductions of certain income not counted as such for Veterans Health Administration eligibility purposes. Once a net income for the veteran is established, it is applied against means test thresholds, or levels of income establishing mandatory or discretionary eligibility for medical care. If the veteran's net income falls

below the applicable means test threshold, he or she is eligible for mandatory care (i.e., no-cost care); however, if the net income falls over the applicable threshold, the veteran is given a discretionary eligibility. Veterans who are eligible for discretionary care are provided care if the VA medical facility has the resources to treat discretionary veterans, and if the veteran agrees to make a co-payment for such care. The proposed matching programs will enable VA to verify the accuracy of reported income and employment status and therefore more accurately determine eligibility for medical care.

(2) *Procedures:* VA's Veterans Health Administration has established an Income Verification Match (IVM) Center. The IVM Center will electronically extract demographic and income data from each VA medical care facility's database on nonservice-connected veterans found eligible for mandatory care based solely on low income. The VHA IVM extract file will be matched against IRS and SSA income records. If a VHA record and SSA or IRS record match on social security number and name, the IVM Center will begin an extensive case development and verification process. This process will assure the validity of the matched cases by verifying the IRS/SSA reported income amount with the payer(s) and recipients of the income. Each veteran and/or spouse identified by the match will be contacted in order to notify the veteran and/or spouse of any income discrepancy identified by the match, to verify the discrepancy, and to advise him or her of potential changes to the veteran's medical care eligibility at the VA medical center, and the potential billing action for co-payments. Before any adverse action is taken, the individual(s) identified by the match will be given the opportunity to contest the findings. Where there are reasonable grounds to believe that there has been a violation of criminal laws, the matter will be referred for prosecution

consideration in accordance with existing VA policies.

c. *Records to be Matched:* The VA records involved in the match are patient medical records maintained in the "Patient Medical Record-VA (24VA136)" published at 40 FR 38095 (8/26/75) and amended at 40 FR 52125 (11/7/75), 41 FR 2881 (1/20/76), 41 FR 11631 (3/19/76), 42 FR 30557 (6/15/72), 44 FR 31058 (5/30/79), 45 FR 77220 (11/21/80), 46 FR 2766 (1/12/81), 47 FR 28522 (6/30/82), 47 FR 51841 (11/17/82), 50 FR 11610 (3/22/85), 51 FR 25968 (7/17/86), 51 FR 44406 (12/9/86), 52 FR 381 (1/5/87), 53 FR 49818 (12/13/90), 55 FR 5112 (2/13/90), 55 FR 37604 (9/12/90), 55 FR 42534 (10/19/90), 56 FR 1054 (1/10/91), 57 FR 28003 (6/23/92), 57 FR 4519 (10/1/92), 58 FR 29853 (5/24/93), 58 FR 40852 (7/30/93) and 58 FR 57674 (10/26/93). The IRS records are from the Wage and Information Returns (IRP) Master File, Privacy Act system Treas/IRS 22.061. The SSA records are from the Earnings Recording and Self-Employment Income system, HHS/SSA/OSR 09-60-0059.

d. *Period of Match:* The initial date exchanges are expected to begin 40 days after the matching agreements are signed by the Data Integrity Boards (DIB's) and Congressional Offices and OMB have been notified, and 30 days from the date of publication of notice in the **Federal Register** or 40 days from the date this notice is approved, whichever is later. These matches may be extended by the involved DIB's for a twelve-month period provided the agencies participating in the match certify to the DIB's, within three months of the termination date of the original match, that the matching program will be conducted without change and the matching programs have been conducted in compliance with the original matching agreements. The matches will not continue past the date legislative authority to obtain this information expires.

[FR Doc. 95-10692 Filed 5-1-95; 8:45 am]

BILLING CODE 8320-01-M

Sunshine Act Meetings

Federal Register

Vol. 60, No. 84

Tuesday, May 2, 1995

This section of the FEDERAL REGISTER contains notices of meetings published under the "Government in the Sunshine Act" (Pub. L. 94-409) 5 U.S.C. 552b(e)(3).

FEDERAL COMMUNICATIONS COMMISSION

FCC to Hold Open Commission Meeting Thursday, May 4, 1995

The Federal Communications Commission will hold an Open Meeting on the subjects listed below on Thursday, May 4, 1995, which is scheduled to commence at 9:30 a.m., in Room 856, at 1919 M Street, N.W., Washington, D.C.

Item No., Bureau, and Subject

- 1—Mass Media—Title: Review of the Commission's Regulations Regarding Network Control of Station Rates and Network Advertising Representation Rules. Summary: The Commission will consider action concerning Sections 73.658(h) and (i) of the Commission's Rules, which regulate a broadcast television network's relationship with its affiliates with regard to the affiliates' advertising rates and sales representation.
- 2—Cable Services—Title: Implementation of Section 19 of the Cable Television Consumer Protection and Competition Act of 1992—Annual Assessment of the Status of Competition in the Market for the Delivery of Video Programming. Summary: The Commission will consider whether to solicit information, data and comment from the public for its 1995 report to Congress on the status of competition in the market for the delivery of video programming.
- 3—Common Carrier—Title: The NYNEX Telephone Companies Petition for Waiver, Transition Plan to Preserve Universal Service in a Competitive Environment. Summary: The Commission will consider the NYNEX petition for waiver of Parts 61 and 69 of the Commission's Rules.
- 4—Common Carrier—Title: Rules and Policies Regarding Calling Number Identification Service—Caller ID (CC Docket No. 91-281). Summary: The Commission will consider action concerning policies for interstate caller ID.
- 5—Mass Media and General Counsel—Title: Application for Renewal of License of Station WNYW-TV, New York, New York. Summary: The Commission will consider the Application of Fox Television Stations, Inc., for renewal of License for Station WNYW-TV, New York, New York.

Additional information concerning this meeting may be obtained from Audrey Spivack or Maureen Peratino, Office of Public Affairs, telephone number (202) 418-0500.

Federal Communications Commission.

William F. Caton,

Acting Secretary.

[FR Doc. 95-10849 Filed 4-28-95; 11:01 am]

BILLING CODE 6712-01-M

BOARD OF GOVERNORS OF THE FEDERAL RESERVE SYSTEM

TIME AND DATE: 11:00 a.m., Monday, May 8, 1995.

PLACE: Marriner S. Eccles Federal Reserve Board Building, C Street entrance between 20th and 21st Streets, N.W., Washington, D.C. 20551.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

1. Personnel actions (appointments, promotions, assignments, reassignments, and salary actions) involving individual Federal Reserve System employees.

2. Any items carried forward from a previously announced meeting.

CONTACT PERSON FOR MORE INFORMATION:

Mr. Joseph R. Coyne, Assistant to the Board; (202) 452-3204. You may call (202) 452-3207, beginning at approximately 5 p.m. two business days before this meeting, for a recorded announcement of bank and bank holding company applications scheduled for the meeting.

Dated: April 28, 1995.

Jennifer J. Johnson,

Deputy Secretary of the Board.

[FR Doc. 95-10915 Filed 4-28-95; 3:02 pm]

BILLING CODE 6210-01-P

FEDERAL TRADE COMMISSION

TIME AND DATE: 4:00 p.m., Wednesday, May 3, 1995.

PLACE: Room 432, Federal Trade Commission Building, 6th Street and Pennsylvania Avenue, N.W., Washington, DC 20580.

STATUS: Open.

MATTER TO BE CONSIDERED: Discussion of status of Telemarketing Rulemaking.

CONTACT PERSON FOR MORE INFORMATION:

Bonnie Jansen, Office of Public Affairs: (202) 326-2180, Recorded Message: (202) 326-2711.

Donald S. Clark,

Secretary.

[FR Doc. 95-10930 Filed 4-28-95; 3:54 pm]

BILLING CODE 6750-01-M

INTERSTATE COMMERCE COMMISSION

TIME AND DATE: 10:00 a.m., Tuesday, May 9, 1995.

PLACE: Hearing Room A, Interstate Commerce Commission, 12th and Constitution Avenue, N.W., Washington, DC 20423.

STATUS: The Commission will meet to discuss among themselves the following agenda items. Although the conference is open for the public observation, no public participation is permitted.

MATTERS TO BE DISCUSSED: Ex Parte No. 346 (Sub-No. 34), *Rail General Exemption Authority—Exemption Of Hydraulic Cement*. Finance Docket No. 32352, *Chevron U.S.A., Inc.—Lease And Operation Exemption—Richmond Belt Railway*. Docket No. AB-362 (Sub-No. 2X), *Texas And Oklahoma R.R. Company—Abandonment—Between The Oklahoma-Texas State Line And Orient Junction (Sweetwater), Texas*. Ex Parte No. MC-37 (Sub-No. 41), *Petition To Establish A Commercial Zone Of El Paso County, Texas And Dona Ana And Luna Counties, New Mexico*.

CONTACT PERSONS FOR MORE INFORMATION:

Alvin H. Brown or A. Dennis Watson, Office of Congressional and Press Services, Telephone: (202) 927-5350, TDD: (202) 927-5721.

Vernon A. Williams,

Secretary.

[FR Doc. 95-10892 Filed 4-28-95; 3:02 pm]

BILLING CODE 7035-01-P

NUCLEAR REGULATORY COMMISSION

DATE: Weeks of May 1, 8, 15, and 22, 1995.

PLACE: Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland.

STATUS: Public and Closed.

MATTERS TO BE CONSIDERED:

Week of May 1

Wednesday, May 3

2:00 p.m.

Briefing on NRR Licensing Actions Program (Public Meeting)

(Contact: Roy Zimmerman, 301-415-1284)

3:30 p.m.

Affirmation/Discussion and Vote (Public Meeting) (if needed)

Week of May 8—Tentative

Thursday, May 11

10:00 a.m.

Briefing on Business Process Reengineering for Materials Licensing Area (Public Meeting)
(Contact: Pat Rathbun, 301-415-7178)
11:30 a.m.
Affirmation/Discussion and Vote (Public Meeting) (if needed)

Friday, May 12

10:00 a.m.
Briefing by DOE on HLW Licensing Support System (LSS) (Public Meeting)

Week of May 15—Tentative

Friday, May 19

10:00 a.m.
Briefing on Site Decommissioning Management Plan (SDMP) Program and Policy Issues (Public Meeting)
(Contact: Mike Weber, 301-415-7298)

Week of May 22—Tentative

Wednesday, May 24

10:00 a.m.
Briefing on Part 1 Recommendations for National Performance Review Phase II (Public Meeting)
(Contact: Jack Roe, 301-415-1354)
11:30 a.m.
Affirmation/Discussion and Vote (Public Meeting) (if needed)

Friday, May 26

10:00 a.m.

Briefing on Steam Generator Issues (Public Meeting)

ADDITIONAL INFORMATION: By a vote of 3-0 on April 25, the Commission determined pursuant to U.S.C. 552b(e) and § 9.107(a) of the Commission's rules that "Affirmation of Babcock and Wilcox Company (Pennsylvania Nuclear Service Operations, Parks Township, PA), Initial Decision (License Renewal), LBP-95-1, Docket No. 70-364-ML-Ren" (Public Meeting) be held on April 26, and on less than one week's notice to the public.

Note: Affirmation sessions are initially scheduled and announced to the public on a time-reserved basis. Supplementary notice is provided in accordance with the Sunshine Act as specific items are identified and added to the meeting agenda. If there is no specific subject listed for affirmation, this means that no item has as yet been identified as requiring any Commission vote on this date.

The schedule for Commission meetings is subject to change on short notice.

TO VERIFY THE STATUS OF MEETINGS CALL (RECORDING): (301) 415-1292.

CONTACT PERSON FOR MORE INFORMATION: William Hill (301) 415-1661.

* * * * *

This notice is distributed by mail to several hundred subscribers; if you no longer wish to receive it, or would like to be added to it, please contact the Office of the Secretary, Attn: Operations Branch, Washington, D.C. 20555 (301-415-1963).

In addition, distribution of this meeting notice over the internet system will also become available in the near future. If you are interested in receiving this Commission meeting schedule electronically, please send an electronic message to alb@nrc.gov or gkt@nrc.gov.

* * * * *

William M. Hill, Jr.,

SECY Tracking Officer, Office of the Secretary.

[FR Doc. 95-10908 Filed 4-28-95; 2:16 pm]

BILLING CODE 7590-01-M

Corrections

Federal Register

Vol. 60, No. 84

Tuesday, May 2, 1995

This section of the FEDERAL REGISTER contains editorial corrections of previously published Presidential, Rule, Proposed Rule, and Notice documents. These corrections are prepared by the Office of the Federal Register. Agency prepared corrections are issued as signed documents and appear in the appropriate document categories elsewhere in the issue.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 310

Drug Products Containing Quinine for the Treatment and/or Prevention of Malaria for Over-the-Counter Human Use

Correction

In proposed rule document 95-9701 beginning on page 19650 in the issue of

Wednesday, April 19, 1995, make the following correction:

§ 310.547 [Corrected]

On page 19655, in the third column, in § 310.547(d), in the first line, “May 19, 1995” should read “(insert date 30 days after date of publication of the final rule in the Federal Register)”.

BILLING CODE 1505-01-D

OFFICE OF PERSONNEL MANAGEMENT

5 CFR Part 890

RIN 3206-AF18

Federal Employees Health Benefits Program: Filing Claims; Disputed Claims Procedures and Court Actions

Correction

In rule document 95-7793 beginning on page 16037, in the issue of

Wednesday, March 29, 1995, make the following corrections:

1. On page 16037, in the third column, under **SUPPLEMENTARY INFORMATION:**, in the first full paragraph, in the second line, “15 CFR 890.105,” should read “5 CFR 890.105,”.

§890.107 [Corrected]

2. On page 16039, in the first column, in §890.107 (c), in the third line, “State” should read “Federal”.

BILLING CODE 1505-01-D

Final Rule

Tuesday
May 2, 1995

Part II

Environmental Protection Agency

40 CFR Part 439

Effluent Limitations Guidelines,
Pretreatment Standards, and New Source
Performance Standards: Pharmaceutical
Manufacturing Category; Proposed Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 439

[FRL-5165-2]

RIN 2060-AC49

Effluent Limitations Guidelines, Pretreatment Standards, and New Source Performance Standards: Pharmaceutical Manufacturing Category

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: This proposed rule would limit the discharge of pollutants into waters of the United States and the introduction of pollutants into publicly owned treatment works by existing and new facilities that manufacture pharmaceuticals. The proposed rule establishes limitations on pollutants, but does not specify the technology to be employed to achieve compliance. The Agency intends that this proposed rule will have a common technology basis with a rule yet to be proposed to control air emissions to allow coordinated and cost effective compliance planning by the industry.

This proposed rule would annually reduce priority pollutant discharges from this industry by an estimated 15.7 million pounds and total pollutant discharges by 139 million pounds at an estimated annual cost of \$80 million (1994 \$). The benefits include reductions in both carcinogenic and non-carcinogenic risk, ecological and recreational benefits due to improved water quality, and benefits to publicly owned treatment works such as improved worker health and safety.

As a result of consultation with stakeholders, the preamble solicits comments and data not only on issues raised by EPA, but also on those issues raised by State and local governments who will be implementing these regulations and by industry representatives who will be affected by them.

DATES: Comments on the proposed rule must be received by July 31, 1995 at the address noted below. EPA will conduct a public hearing on the effluent pretreatment standards included in the proposed rule. EPA will publish in the **Federal Register** an announcement of the public hearing.

ADDRESSES: Send written comments on this proposal in triplicate and in electronic form if possible to Mr. David Hoadley, Engineering and Analysis Division (4303), U.S. EPA, 401 M Street

SW., Washington, DC 20460. The public record supporting the proposed effluent limitations guidelines and standards is in the Water Docket located in the basement of the EPA Headquarters building, Room L102, 401 M Street SW., Washington, DC 20460, telephone number (202) 260-3027. EPA regulations at 40 CFR part 2 provide that a reasonable fee may be charged for copying.

FOR FURTHER INFORMATION CONTACT:

Background documents supporting the proposed regulations are described in the "Background Documents" section below. Contact the Office of Water Resource Center, RC-4100, at the U.S. EPA, Washington, DC address shown above, telephone (202) 260-7786, for the voice mail publication request line. For additional information on the engineering aspects of the regulation, contact Dr. Frank H. Hund, Engineering and Analysis Division (4303), U.S. EPA, 401 M Street SW., Washington, DC 20460, at (202) 260-7182. For additional information on the economic and statistical aspects of the regulation, contact Mr. Neil Patel at the address above at (202) 260-5405. For additional engineering information on the preliminary air emissions control aspects of this rule, contact Mr. Randy McDonald, Office of Air Quality Planning and Standards (MD-13), Research Triangle Park, NC 27711, at (919) 541-5402.

SUPPLEMENTARY INFORMATION:

Overview

The preamble describes the definitions, acronyms, and abbreviations used in this notice; the background documents that support these proposed regulations; the legal authority of this rule; a summary of the proposal; background information; and the technical and economic methodologies used by the Agency to develop these proposed regulations. This preamble also solicits comment and data on all aspects of this rulemaking, including on specific areas of interest.

Confidential Business Information

EPA notes that many documents in the record supporting this proposed rule have been claimed as confidential business information and, therefore, are not included in the record that is available to the public in the Water Docket. To support the rulemaking, EPA is presenting certain information in aggregated form or is masking plant identities to preserve confidentiality claims. Further, the Agency has withheld from disclosure some data not

claimed as confidential business information because release of this information could indirectly reveal information claimed to be confidential.

Plant-specific data that have been claimed as confidential business information are available to the company that submitted the information. To ensure that all CBI is protected in accordance with EPA regulations, any requests for company-specific data should be submitted on that company's letterhead and signed by a responsible official authorized to receive such data. The request must list the specific data requested and include the following statement, "I certify that EPA is authorized to transfer confidential business information submitted by my company, and that I am authorized to receive it." Organization of this document:

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I. Definitions, Acronyms, and Abbreviations

1989 Pharmaceutical Screener Questionnaire—A short questionnaire distributed by EPA to all known pharmaceutical facilities in June 1989 in order to identify plants which manufacture pharmaceutical products.

1990 Detailed Questionnaire—The 1990 Pharmaceutical Manufacturing Survey. A questionnaire sent by EPA to certain facilities in the pharmaceutical manufacturing industry in September 1991 to gather technical and financial information. The questionnaire was sent to those facilities likely to be affected by promulgation of revised effluent limitations guidelines, pretreatment standards, and new source performance standards for this industry.

Administrator—The Administrator of the U.S. Environmental Protection Agency.

Agency—The U.S. Environmental Protection Agency.

Annual average—The mean concentration, mass loading or production-normalized mass loading of a pollutant over a period of 365 consecutive days (or such other period of time determined by the permitting authority to be sufficiently long to encompass expected variability of the concentration, mass loading or production-normalized mass loading at the relevant point of measurement).

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 a calendar month divided by the number of "daily discharges" measured during that month.

BAT—The best available technology economically achievable, as described in section 304(b)(2) of the Clean Water Act.

Bench-scale operation—Laboratory testing of materials, methods, or processes on a small scale, such as on a laboratory worktable.

BCT—The best conventional pollutant control technology, as described in section 304(b)(4) of the Clean Water Act.

BID—Background Information Document, which presents the technical basis for air pollution controls under the Clean Air Act.

Biological and Natural Extraction—The chemical and physical extraction of pharmaceutically active ingredients from natural sources such as plant roots and leaves, animal glands, and parasitic fungi. The process operations involving biological and natural extraction define subcategory B (40 CFR 439, subpart B).

BMP or BMPs—Best management practices, as described in section 304(e) of the Clean Water Act.

BOD₅—Five-Day Biochemical Oxygen Demand. A measure of biochemical decomposition of organic matter in a water sample. It is determined by measuring the dissolved oxygen consumed by microorganisms to oxidize the organic contaminants in a water sample under standard laboratory conditions of five days and 20 °C. BOD₅ is not related to the oxygen requirements in chemical combustion.

Boiler—Any enclosed combustion device that extracts useful energy in the form of steam and is not an incinerator.

BPT—The best practicable control technology currently available, as described in section 304(b)(1) of the Clean Water Act.

CAA—Clean Air Act. The Air Pollution Prevention and Control Act (42 U.S.C. 7401 et seq.), as amended, *inter alia*, by the Clean Air Act Amendments of 1990 (Pub. L. 101-549, 104 Stat. 2399).

Chemical Synthesis—The process(es) of using a chemical reaction or a series of chemical reactions to manufacture pharmaceutically active ingredients. The chemical synthesis process operations define subcategory C (40 CFR 439, subpart C).

Clarifier—A treatment unit designed to remove suspended materials from wastewater, typically by sedimentation.

Closed vent system—A system that is not open to the atmosphere and is composed of piping, ductwork,

connections, and, if necessary, flow-inducing devices that transport gas or vapor from an emission point to a control device or back into the process.

CN—Abbreviation for total cyanide.

COD—Chemical oxygen demand (COD)—A nonconventional bulk parameter that measures the total oxygen-consuming capacity of wastewater. This parameter is a measure of materials in water or wastewater that are biodegradable and materials that are resistant (refractory) to biodegradation. Refractory compounds slowly exert demand on downstream receiving water resources. Certain of the compounds measured by this parameter have been found to have carcinogenic, mutagenic, and similar adverse effects, either singly or in combination. It is expressed as the amount of oxygen consumed by a chemical oxidant in a specific test.

Combustion device—An individual unit of equipment, including but not limited to, an incinerator or boiler, used for the thermal oxidation of organic hazardous air pollutant vapors.

Condensate—Any material that has condensed from a gaseous phase into a liquid phase.

Continuous discharge—Discharge that occurs without interruption throughout the operating hours of the facility.

Control Techniques Guidance (CTG)—A document prepared to provide State and local air pollution authorities with an information base for proceeding with analysis of Reasonably Available Control Technology (RACT) to meet Clean Air Act statutory requirements.

Controlled-release discharge—A discharge that occurs at a rate that is intentionally varied to accommodate fluctuations in receiving stream assimilative capacity or for other reasons.

Conventional pollutants—The pollutants identified in section 304(a)(4) of the Clean Water Act and the regulations thereunder (i.e., biochemical oxygen demand (BOD₅), total suspended solids (TSS), oil and grease, fecal coliform and pH).

CWA—Clean Water Act. The Federal Water Pollution Control Act Amendments of 1972 (33 U.S.C. 1251 et seq.), as amended, *inter alia*, by the Clean Water Act of 1977 (Pub. L. 95–217) and the Water Quality Act of 1987 (Pub. L. 100–4).

Daily discharge—The discharge of a pollutant measured during any calendar day or any 24-hour period that reasonably represents a calendar day for purposes of sampling. For pollutants with limitations expressed in units of mass, the daily discharge is calculated as the total mass of the pollutant

discharged over the day. For pollutants with limitations expressed in other units of measurement, the daily discharge is calculated as the average measurement of the pollutant over the day.

Direct discharger—A facility that discharges or may discharge treated or untreated process wastewaters, non-contact cooling waters, or non-process wastewaters (including stormwater runoff) into waters of the United States. Effluent—Wastewater discharges.

Effluent limitation—Any restriction, including schedules of compliance, established by a State or the Administrator on quantities, rates, and concentrations of chemical, physical, biological, and other constituents which are discharged from point sources into waters of the United States, the waters of the contiguous zone, or the ocean.

Emission—Passage of air pollutants into the atmosphere via a gas stream or other means.

Emission point—Any location within a source from which air pollutants are emitted, including an individual process vent, an opening within a wastewater collection and treatment system, or an open piece of process equipment.

EOP effluent—Final plant effluent discharged to waters of the United States or to a POTW.

EOP treatment—End-of-pipe treatment facilities or systems used to treat process wastewaters, non-process wastewaters (including stormwater runoff) after the wastewaters have left the process area of the facility and prior to discharge. End-of-pipe treatment generally does not include facilities or systems where products or by-products are separated from process wastewaters and returned to the process or directed to air emission control devices.

EPA—The U.S. Environmental Protection Agency.

General Provisions—General Provisions for national emission standards for hazardous air pollutants and other regulatory requirements pursuant to section 112 of the Clean Air Act, as amended November 15, 1990. The General Provisions, located in subpart A of part 63 of title 40 of the Code of Federal Regulations, codify procedures and criteria to implement emission standards for stationary sources that emit (or have the potential to emit) one or more of the 189 chemicals listed as hazardous air pollutants in section 112(b) of the Clean Air Act as amended in 1990. EPA published the NESHAP General Provisions in the **Federal Register** on March 16, 1993 (59 FR 12408). The term General Provisions also refers to the

General Provisions for the effluent limitations guidelines and standards proposed today, to be located at 40 CFR part 439.

Fermentation—A chemical change induced by a living organism or enzyme, specifically bacteria or the microorganisms occurring in unicellular plants such as yeast, molds, or fungi. Process operations that utilize fermentation to manufacture pharmaceutically active ingredients define subcategory A (40 CFR 439, subpart A).

HAP—Hazardous Air Pollutant. Any of the 189 chemicals listed under section 112(b) of the Clean Air Act.

HON—Hazardous Organic NESHAP. As used in this notice, it refers to the standard published by EPA for the Synthetic Organic Chemical Manufacturing Industry (SOCMI) on April 22, 1994 (59 FR 19402).

Incinerator—An enclosed combustion device that is used for destroying organic compounds. Auxiliary fuel may be used to heat waste gas to combustion temperatures. Any energy recovery section present is not physically formed into one manufactured or assembled unit with the combustion section; rather, the energy recovery section is a separate section following the combustion section and the two are joined by ducts or connections carrying flue gas.

Indirect discharger—A facility that discharges or may discharge wastewaters into a publicly owned treatment works.

Individual drain system—The system used to convey process wastewater streams away from the pharmaceutical manufacturing process equipment or tank, or process wastewater collection and treatment system unit. The term includes all process drains and junction boxes, together with their associated sewer lines and other junction boxes, manholes, sumps and lift stations. The individual drain system is designed to segregate the vapors within the system from other drain systems. A separate storm sewer system, which is a drain and collection system designed and operated for the purpose of collecting storm runoff at a facility, and which is segregated from all other individual drain systems, is excluded from this definition.

In-plant Control Technologies—These include controls or measures applied within the manufacturing process to reduce or eliminate pollutant and hydraulic loadings; these also include technologies, such as steam stripping and cyanide destruction, applied directly to wastewater generated by manufacturing processes.

IU—Industrial User. Synonym for “Indirect Discharger.”

Junction box—A manhole access point to a wastewater sewer system or a lift station.

LTA—Long-term average. For purposes of proposed effluent limitations guidelines and standards, average pollutant levels achieved over a period of time by a plant, subcategory, or technology option. LTAs were used in developing the limitations and standards in today’s proposed regulation.

MACT—Maximum Achievable Control Technology. Technology basis for the national emission standards for hazardous air pollutants.

Major source—As defined in section 112(a) of the Clean Air Act, major source is any stationary source or group of stationary sources located within a contiguous area and under common control that emits or has the potential to emit, considering controls, in the aggregate 10 tons per year or more of any hazardous air pollutant or 25 tons per year or more of any combination of hazardous air pollutants.

Maximum daily discharge limitation—The highest allowable daily discharge of a pollutant measured during a calendar day or any 24 hour period that reasonably represents a calendar day for purposes of sampling.

Mg—Megagram. One million (10⁶) grams, or one metric ton.

Metric ton—One thousand (10³) kilograms (abbreviated as kkg), or one megagram. A metric ton is equal to 2,204.5 pounds.

Minimum level—The level at which an analytical system gives recognizable signals and an acceptable calibration point.

Mixing/Compounding/Formulating—Processes through which pharmaceutically active ingredients are put in dosage forms. Processes involving mixing/compounding/formulating define subcategory D (40 CFR 439, subpart D).

Modification—As defined in section 112(a) of the Clean Air Act, modification is any physical change in, or change in the method of operation of, a major source which increases the actual emissions of any hazardous air pollutant emitted by such source by more than a de minimis amount or which results in the emission of any hazardous air pollutant not previously emitted by more than a de minimis amount.

NESHAP—National Emission Standard for Hazardous Air Pollutants. Emission standard promulgated that has been or will be promulgated under section 112(d) of the Clean Air Act for

hazardous air pollutants listed in section 112(b) of the Clean Air Act.

New Source—As defined in 40 CFR 122.2, 122.29, and 403.3(k), a new source is any building, structure, facility, or installation from which there is or may be a discharge of pollutants, the construction of which commenced (1) For purposes of compliance with New Source Performance Standards, after the promulgation of such standards being proposed today under CWA section 306; or (2) for the purposes of compliance with Pretreatment Standards for New Sources, after the publication of proposed standards under CWA section 307(c), if such standards are thereafter promulgated in accordance with that section.

Nonconventional pollutants—Pollutants that are neither conventional pollutants nor toxic pollutants.

Non-detect value—A concentration-based measurement reported below the minimum level that can reliably be measured by the analytical method for the pollutant.

Non-water quality environmental impact—An environmental impact of a control or treatment technology, other than to surface waters.

NPDES—The National Pollutant Discharge Elimination System authorized under section 402 of the CWA. The Clean Water Act requires NPDES permits for discharge of pollutants from any point source into waters of the United States.

NRDC—Natural Resources Defense Council.

NSPS—New Source Performance Standards. As used in this notice, this term refers to standards for new sources under section 306 of the CWA.

OMB—Office of Management and Budget.

Outfall—The mouth of conduit drains and other conduits from which a plant discharges effluent into receiving waters.

Pharmaceutically active ingredient—Any substance considered to be an active ingredient by Food and Drug Administration regulations (21 CFR 210.3(6)(7)).

Pilot-scale operation—The trial operation of processing equipment, which is the intermediate stage between laboratory experimentation and full-scale operation in the development of a new process or product.

Point of Generation—The location where the process wastewater stream exits the pharmaceutical process equipment.

Point source category—A category of sources of water pollutants that are included within the definition of “point

source” in section 502(14) of the Clean Water Act.

Pollutant (to water)—Dredged spoil, solid waste, incinerator residue, filter backwash, sewage, garbage, sewage sludge, munitions, chemical wastes, biological materials, certain radioactive materials, heat, wrecked or discarded equipment, rock, sand, cellar dirt, and industrial, municipal, and agricultural waste discharged into water. See CWA section 502(6); 40 CFR 122.2.

POTW or POTWs—Publicly owned treatment works, as defined at 40 CFR 403.3(o).

Pretreatment standard—A regulation specifying industrial wastewater effluent quality required for discharge to a POTW.

Primary fuel—The fuel that provides the principal heat input to a combustion device. To be considered primary, the fuel must be able to sustain operation of the combustion device without the addition of other fuels.

Priority pollutants—The toxic pollutants listed in 40 CFR part 403, Appendix A (printed immediately following 40 CFR 423.17).

Process changes—Alterations in process operating conditions, equipment, or chemical use that reduce the formation of chemical compounds that are pollutants and/or pollutant precursors.

Process emission point—A gas stream that contains hazardous air pollutants discharged during operation of process equipment. Process emission points include gas streams that are discharged directly to the atmosphere, discharged to the atmosphere via vents or open process equipment, or discharged after diversion through a product recovery device.

Process unit—A piece of equipment, such as a chemical reactor or fermentation tank, associated with pharmaceutical manufacturing operations.

Process wastewater—Any water that, during manufacturing or processing, comes into direct contact with or results from the production or use of any raw material, intermediate product, finished product, byproduct, or waste product. Process wastewater includes surface runoff from the immediate process area that has the potential to become contaminated.

(1) For purposes of this part, the following materials are excluded from the definition of process wastewater:

1. Trimethyl silanol;
2. Any active anti-microbial materials;
3. Wastewater from imperfect fermentation batches; and
4. Process area spills.

(2) For purposes of this part, the following waters and wastewaters are excluded from the definition of process wastewater: noncontact cooling water, utility wastewaters, general site surface runoff, groundwater (e.g., contaminated groundwaters from on-site or off-site groundwater remediation projects), and other water generated on site that are not process wastewaters.

The discharge of such waters and wastewaters must be regulated separately.

Process wastewater collection system—A piece of equipment, structure, or transport mechanism used in conveying or storing a process wastewater stream. Examples of process wastewater collection system equipment include individual drain systems, wastewater tanks, surface impoundments, and containers.

Process wastewater stream—When used in connection with CAA obligations, any HAP-containing liquid that results from either direct or indirect contact of water with organic compounds.

Process water—Water used to dilute, wash, or carry raw materials or any other materials used in pharmaceutical manufacturing processes.

PSes—Pretreatment standards for existing sources of indirect discharges, under section 307(b) of the CWA.

PSNs—Pretreatment standards for new sources of indirect discharges, under sections 307(c) of the CWA.

RCRA—Resource Conservation and Recovery Act of 1976, as amended (42 U.S.C. 6901, et seq.).

Research—Bench-scale activities or operations used in research and/or product development of a pharmaceutical product. The Research operations define subcategory E (40 CFR 439, Subpart E).

SIC—Standard Industrial Classification. A numerical categorization system used by the U.S. Department of Commerce to denote segments of industry. An SIC code refers to the principal product, or group of products, produced or distributed, or to services rendered by an operating establishment. SIC codes are used to group establishments by the primary activity in which they are engaged.

Source Category—A category of major or area sources of hazardous air pollutants.

Source Reduction—The reduction or elimination of waste generation at the source, usually within a process. A source reduction practice is any practice that (1) Reduces the amount of any hazardous substance, pollutant, or contaminant entering any waste stream or otherwise released into the

environment (including fugitive emissions) prior to recycling, treatment, or disposal; and (2) reduces the hazards to public health and the environment associated with the release of such substances, pollutants, or contaminants.

Stationary source—Any building, structure, facility, or installation that emits or may emit any air pollutant. See CAA section 111(a)(3).

Support Document(s)—see section II for titles.

TDD—Technical Development Document

TEQ—Toxic Equivalent.

TSCA—Toxic Substances Control Act (15 U.S.C. 2601, et seq.).

TSS—Total Suspended Solids.

Toxic pollutants—the pollutants designated by EPA as toxic in 40 CFR 401.15.

Variability factor—The daily variability factor is the ratio of the estimated 99th percentile of the distribution of daily values divided by the expected value, or mean, of the distribution of the daily data. The monthly variability factor is the estimated 95th percentile of the monthly averages of the data divided by the expected value of the monthly averages.

VOC—Volatile Organic Compound—means any organic compound, excluding carbon monoxide, carbon dioxide, carbonic acid, metallic carbides or carbonates, and ammonium carbonate, which participates in atmospheric photochemical reactions other than those that the Administrator designates as having negligible photochemical reactivity. The Administrator has designated the following organic compounds as negligibly reactive: methane; ethane; methylene chloride; methyl chloroform; CFC-113; CFC-111; CFC-12; CFC-22; CFC-23; CFC-114; CFC-115; HCFC-123; HFC-134a; HCFC-141b; HCFC-142b; HCFC-124; HFC-125; HFC-134; HFC-143a; HFC-152a; and perfluorocarbon compounds which fall into these classes: (i) Cyclic, branched, or linear, completely fluorinated alkanes; (ii) cyclic, branched, or linear, completely fluorinated ethers with no unsaturations; cyclic, branched, or linear, completely fluorinated tertiary amines with no unsaturations; and (iv) sulfur containing perfluorocarbons with no unsaturations and with sulfur bonds only to carbon and fluorine. 40 CFR 51.100(s)(1).

Waters of the United States—the same meaning set forth in 40 CFR 122.2.

Zero discharge (ZD)—No discharge of wastewater to waters of the United States or to a POTW.

II. Background Documents

The rule proposed today is supported by several major documents: (1) EPA's technical conclusions concerning the wastewater regulations are detailed in the "Development Document for Proposed Effluent Limitations Guidelines and Standards for the Pharmaceutical Manufacturing Point Source Category," hereafter referred to as the Technical Development Document (TDD) (EPA 821-R-95-019), (2) the Agency's economic analysis is found in the "Economic Impact and Regulatory Flexibility Analysis of Proposed Effluent Guidelines for the Pharmaceutical Manufacturing Industry," hereafter called the Economic Impact Analysis (EPA 821-R-95-018), (3) the regulatory impact analysis (including the Agency's assessment of environmental benefits) is detailed in the "Regulatory Impact Assessment of Proposed Effluent Guidelines for the Pharmaceutical Manufacturing Industry," hereafter called the Regulatory Impact Assessment (EPA 821-R-95-017), (4) an analysis of the incremental costs and pollutant removals for the proposed effluent limitations guidelines and standards is presented in "Cost-effectiveness Analysis of Proposed Effluent Limitations Guidelines for the Pharmaceutical Manufacturing Industry," (EPA 821-R-95-015), (5) analytical methods used in the development of the proposed effluent limitations guidelines and standards are found in "Analytical Methods for the Determination of Pollutants in Pharmaceutical Manufacturing Industry Wastewater," a compendium of analytical methods (EPA 821-R-95-014), and (6) the statistical (EPA 821-R-95-016) support for today's proposed effluent limitations guidelines and standards is found in "Statistical Support Document for the Proposed Effluent Limitations Guidelines for the Pharmaceutical Manufacturing Industry."

III. Legal Authority

This regulation is being proposed under the authority of sections 301, 304, 306, 307, 308, and 501 of the Clean Water Act, 33 U.S.C. 1311, 1314, 1316, 1317, 1318, and 1361.

IV. Summary and Scope of the Proposed Rule

In today's notice, EPA proposes effluent limitations guidelines and standards for process wastewater generated by the pharmaceutical manufacturing industry. Section IX of this notice discusses the rationale for

the proposed guidelines and standards. This summary section highlights the technology bases and other key aspects of the proposed rule. The technology descriptions in this section are presented in abbreviated form; more detailed descriptions are included in the TDD.

Today's notice presents the Agency's proposed regulatory approach and several others that EPA considered. The Agency's proposal is based on comments received from interested parties during the development of this proposed rule, and on detailed evaluation of the available data. As indicated below in the discussion of the specifics of the proposal, the Agency welcomes comment on all options, issues, rationale, and proposed decisions and encourages commenters to submit additional data during the comment period (see section XIV of this preamble). In particular, the Agency welcomes comments on the treatment technologies that EPA has selected as the basis for the limitations and standards being proposed today. For example, EPA bases its proposed standards for new sources primarily on steam stripping with distillation technology. For most existing sources, EPA bases the proposed limitations and standards primarily on steam stripping technology, which is less costly and less energy intensive than distillation technology.

EPA expects a variety of human health, environmental, and economic benefits to result from these reductions in effluent loadings and, in some cases, air emissions. In particular, the benefits include: human health and agricultural benefits due to reductions in emissions of ozone precursors (i.e., reductions in VOC emissions); human health benefits due to reductions in excess cancer risk; human health benefits due to reductions in non-carcinogenic risk; ecological and recreational benefits due to improved water quality; and benefits to publicly owned treatment works (POTWs) from reductions in interference, passthrough, and sludge contamination problems and improvements in worker health and safety. EPA monetized the estimated benefits for reductions in air emissions of ozone precursors and cancer risk reductions, but is unable to quantify the dollar magnitude of benefits from the other benefit categories. Therefore, the reported benefit estimate understates the total benefits of the proposed rule. EPA estimates that the annual benefits resulting from the proposed rule will range from \$231,000 to \$7.6 million (\$1994).

EPA has internally coordinated among relevant program offices in

developing this rule. Section X of this preamble describes close coordination between the Office of Water and the Office of Air and Radiation on this proposed water rule and an air rule that will be proposed at a later date for the pharmaceutical manufacturing industry. As explained in detail in Section X, the Agency intends that direct and indirect dischargers will be able to employ a single steam stripper design to achieve the requirements of both final rules. It is also the Agency's intent, upon promulgation, that both rules will apply to essentially the same high concentration, low volume process wastewater streams in which the bulk of the volatile organic pollutants are contained (see Section X for details). The practical effect of this approach will be that only a relatively small portion (i.e., substantially less than half) of all process wastewaters will require control of volatile organic pollutants (e.g., by steam stripping) to achieve compliance with both rules. In the air rule, EPA also will develop air emission standards for other emission points (e.g., process vents, process area fugitive emissions, etc.). Also, Section XII of this preamble describes coordination between the Office of Water and the Office of Solid Waste and Emergency Response regarding the hazardous waste implications of this proposed water rule, including recovering ignitable nonhalogenated organics and reusing them as "clean fuels."

The Agency has worked with the Food and Drug Administration (FDA) to explore pollution prevention opportunities to the maximum extent feasible. EPA shared with FDA information and data gathered from the industry in responses to EPA's detailed Section 308 questionnaire. This was done to assist FDA in evaluating the environmental impacts of revised drug manufacturing processes (as described in "supplement" applications) and of new drug manufacturing processes. These reviews will ensure that opportunities for solvent use minimization/elimination and water-based manufacturing processes (e.g., water-based tablet coating) are considered and adopted within the constraints of maintaining the efficacy of both existing and new pharmaceutical products.

EPA has involved stakeholders and interested parties, including state and local governments, in the process of developing this rule. Since the inception of the project in 1986, there have been periodic meetings with the industry and its trade association, the Pharmaceutical Research and Manufacturers of America (PhRMA), to

discuss progress on the rulemaking. The Agency also has met with the Natural Resources Defense Council (NRDC) to discuss progress on this rulemaking. Because most of the facilities affected by this proposal are indirect dischargers, the Agency conducted an outreach survey in 1990 to a limited number of POTWs substantially affected by one or more pharmaceutical manufacturing facilities to solicit their input on the need for this proposed rule and pertinent technical issues.

The Agency also held a public meeting on May 23, 1994. EPA representatives of the Office of Water and the Office of Air and Radiation outlined the underlying technical basis and options being considered for this proposal, the efforts to coordinate the future air rule and this proposed water rule, and took comments and questions from the audience. The Agency also consulted recently with representatives of selected POTWs regarding underlying technical aspects of this proposal.

The Agency plans to have additional discussions with stakeholders and interested parties during the comment period to minimize the potential for unfunded mandates and to help ensure that the Agency has the views of such parties and the best possible data upon which to base a decision for the final rule. EPA's final rule may be based upon any technologies, rationale or approaches that are a logical outgrowth of this proposal, including any options discussed in this or subsequent **Federal Register** documents.

A. Effluent Limitations Guidelines and Standards

1. Subcategorization

EPA is proposing to maintain the subcategorization scheme under the existing effluent limitations guidelines and standards for this industry (in part 439). The rationale for maintaining the existing subcategorization scheme is detailed in section IX.A.

2. Best Practicable Control Technology Currently Available (BPT)

EPA is proposing to revise the BPT effluent limitations guidelines for biochemical oxygen demand (BOD₅), COD, and total suspended solids (TSS) for four subcategories of the pharmaceutical manufacturing industry. These proposed revisions are based on the application of advanced biological treatment. EPA also is proposing to revise the BPT effluent limitations guidelines for CN (Total Cyanide) for facilities with subcategory A and/or C operations, based on in-plant cyanide destruction technology. As discussed in

Section IX.E., below, EPA also is proposing to repeal the existing BPT cyanide limitations for facilities with subcategory B and/or D operations. The proposed BPT effluent limitations are defined by the performance of the average of the best plants in the subcategory. The development of proposed BPT effluent limitations is discussed in section IX.E.1 of this notice and in Section 8 of the TDD.

3. Best Conventional Pollutant Control Technology (BCT)

EPA is proposing to revise the BCT effluent limitations guidelines for BOD₅ and TSS for four subcategories of the pharmaceutical manufacturing industry. In all cases, the proposed BCT effluent limitations are equal to the proposed BPT effluent limitations. The development of proposed BCT effluent limitations is further explained in section IX.E.2.

4. Best Available Technology Economically Achievable (BAT)

The Agency is proposing to revise the BAT effluent limitations guidelines for four subcategories of the pharmaceutical manufacturing industry to control priority and nonconventional pollutants. Table IV.A-1 is a summary of the technology basis for the proposed BAT effluent limitations for each subcategory.

TABLE IV.A-1.—PROPOSED TECHNOLOGY BASIS FOR BAT EFFLUENT LIMITATIONS

Proposed subpart	Name of subcategory	Proposed technology basis
A	Fermentation	In-plant steam stripping and cyanide destruction followed by advanced biological treatment.
B	Natural Extraction	Advanced biological treatment.
C	Chemical Synthesis	In-plant steam stripping and cyanide destruction followed by advanced biological treatment.
D	Mixing/Compounding/Formulating	Advanced biological treatment. ¹

¹ Same technology basis as for proposed BPT limitations.

The pollutants that EPA proposes to regulate and the points of monitoring to establish compliance with the limitations vary for each subcategory and are described in sections IX.C and IX.E.3.

5. New Source Performance Standards (NSPS)

a. Priority and Nonconventional Pollutants. EPA is proposing revised NSPS for four subcategories of the pharmaceutical manufacturing industry. For facilities with subcategory A and/or C and B and/or D operations, EPA is proposing NSPS to be more stringent than the proposed BAT effluent

limitations and is basing those standards primarily on steam stripping with distillation technology. The development of proposed NSPS for priority and nonconventional pollutants is discussed in section IX.E.4.

b. Conventional Pollutants. EPA is proposing to revise NSPS pertaining to discharges of BOD₅, COD and TSS for four subcategories of the pharmaceutical manufacturing industry at a level equal to the discharge characteristics of the best performing plant. A summary of the pollutants and subcategories proposed to be regulated is presented in section IX.C. The development of proposed

NSPS for conventional pollutants and COD is discussed in section IX.E.4.

6. Pretreatment Standards for Existing Sources (PSES)

EPA is proposing to revise PSES for four subcategories of the pharmaceutical manufacturing industry for the priority and nonconventional pollutants to be controlled by technologies summarized in Table IV.A-2. EPA also co-proposes two different pass-through determinations for 33 less strippable volatile organic pollutants. PSES are further discussed in section IX.E.5.

TABLE IV.A-2.—PROPOSED TECHNOLOGY BASIS FOR PSES EFFLUENT LIMITATIONS

Proposed subpart	Name of subcategory	Proposed technology basis
A	Fermentation	In-plant cyanide destruction; in-plant steam stripping.
B	Natural Extraction	In-plant steam stripping.
C	Chemical Synthesis	In-plant cyanide destruction; in-plant steam stripping.
D	Mixing/Compounding/Formulating	In-plant steam stripping.

7. Pretreatment Standards for New Sources (PSNS)

EPA is proposing to revise PSNS for four subcategories of the pharmaceutical manufacturing industry for the same priority and nonconventional pollutants controlled by the proposed PSES, but based on steam stripping with distillation technology. As under PSES, EPA co-proposes two different pass-through determinations for 33 less strippable volatile organic pollutants.

PSNS are further discussed in section IX.E.6.

8. Best Management Practices (BMPs)

The Agency is not proposing today BMPs for the pharmaceutical manufacturing point source category. However, the Agency is soliciting comment on whether BMPs are applicable to pharmaceutical manufacturing facilities and, if so, what they should be. See Section XIV of this preamble, solicitation number 31.

B. Scope of the Proposed Rule

The rule proposed today covers four subcategories of the pharmaceutical manufacturing point source category. As discussed in Section IX.A.4, below, EPA does not propose to revise the effluent limitations guidelines applicable to Subcategory E (Pharmaceutical Research) facilities and subcategory E operations at facilities with subcategory A through D operations. These activities will be covered by the existing BPT effluent limitations regulations for this

subcategory and subject to BAT and BCT limitations, where appropriate, set on a case-by-case basis using best professional judgment (BPJ).

Pharmaceutical manufacturers use many different raw materials and manufacturing processes to create a wide range of products. These products include medicinal and feed grades of all organic chemicals having therapeutic value, whether obtained by chemical synthesis, fermentation, extraction from naturally occurring plant or animal substances, or by refining a technical grade product.

The pharmaceutical products, processes and activities covered by this proposal include:

a. Biological products covered by the U.S. Department of Commerce, Bureau of the Census Standard Industrial Classification (SIC) Code No. 2836, with the exception of diagnostic substances. (Products covered by SIC Code No. 2836 were formerly covered under the 1977 SIC Code No. 2831.)

b. Medicinal chemicals and botanical products covered by SIC Code No. 2833;

c. Pharmaceutical products covered by SIC Code No. 2834;

d. All fermentation, biological and natural extraction, chemical synthesis and formulation products considered to be pharmaceutically active ingredients by the Food and Drug Administration that are not covered by SIC Code Nos. 2833, 2834, and 2836;

e. Multiple end-use products derived from pharmaceutical manufacturing operations (e.g., components of formulations, intermediates, or final products, provided that the primary use of the product is intended for pharmaceutical purposes);

f. Products not covered by SIC Code Nos. 2833, 2834, and 2836 if they are manufactured by a pharmaceutical manufacturer by processes that generate wastewaters that in turn closely correspond to those of pharmaceutical products;

g. Cosmetic preparations covered by SIC Code No. 2844 that function as a skin treatment. (This group of preparations does not include products such as lipsticks or perfumes that serve to enhance appearance or to provide a pleasing odor, but do not provide skin care. In general, this also excludes deodorants, manicure preparations, and shaving preparations that do not function primarily as a skin treatment.); and

h. Pharmaceutical research that includes biological, microbiological, and chemical research, product development, clinical and pilot-scale activities. (This does not include farms that breed, raise, and/or hold animals

for research at another site. This also does not include ordinary feedlot or farm operations utilizing feed that contains pharmaceutically active ingredients.) Pilot-scale and product development operations conducted at research facilities would be subject to the specific manufacturing subcategory limitations and standards corresponding to the subcategory wastewater that the research facility's wastewater resembles. For example, a pilot chemical synthesis operation that generates wastewater that is similar to wastewater generated by chemical synthesis manufacturing would be subject to the subcategory C limitations and standards.

A number of products and/or activities such as surgical and medical manufacturing and medical laboratory activity are not part of the pharmaceutical manufacturing category. A descriptive listing of the products and activities that are specifically excluded from the pharmaceuticals manufacturing category may be found in section 2 of the TDD.

V. Background

A. Clean Water Act

1. Statutory Requirements of Regulations

The objective of the Clean Water Act (CWA) is to "restore and maintain the chemical, physical, and biological integrity of the Nation's waters".

Section 101(a) of the CWA. To assist in achieving this objective, EPA issues effluent limitations guidelines, pretreatment standards, and new source performance standards for industrial dischargers. These guidelines and standards are summarized below:

a. *Best Practicable Control Technology Currently Available (BPT)*—section 304(b)(1) of the CWA. BPT effluent limitations guidelines apply to all discharges from existing direct dischargers. BPT guidelines are based on the average of the best performance achieved by plants in a category or subcategory utilizing currently available technology. In establishing BPT, EPA considers the cost of achieving effluent reductions in relation to the effluent reduction benefits, the age of equipment and facilities, the processes employed, process changes required, engineering aspects of the control technologies, non-water quality environmental impacts (including energy requirements), and other factors as the EPA Administrator deems appropriate. Section 304(b)(1)(B) of the CWA. Where existing performance is uniformly inadequate within a category or subcategory, BPT may be transferred from a different subcategory or category.

b. *Best Conventional Pollutant Control Technology (BCT)*—section 304(b)(4) of the CWA. The 1977 amendments to the CWA established BCT as an additional level of control for discharges of conventional pollutants from existing industrial point sources. Section 304(a)(4) designates the following as conventional pollutants: biochemical oxygen demanding pollutants (measured as 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). See 40 CFR 401.16. In addition to other factors specified in section 304(b)(4)(B), the CWA requires that BCT limitations be established in light of a two part "cost-reasonableness" test. EPA issued a methodology for the development of BCT limitations on July 9, 1986 (51 FR 24974).

c. *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, based on available technology. The CWA establishes BAT as a principal means of controlling the direct discharge of toxic and nonconventional pollutants to waters of the United States. The factors considered in assessing BAT include 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. As with BPT, where existing performance is uniformly inadequate within a category or subcategory, BAT may be transferred from a different category or subcategory. BAT may be based upon process changes or internal controls, even when these technologies are not common industry practice.

d. *New Source Performance Standards (NSPS)*—section 306 of the CWA. NSPS are based on the best available demonstrated treatment technology. New plants 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, nonconventional, and toxic 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.

e. 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 (POTWs). 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 are technology-based and are analogous to BAT effluent limitations guidelines. See Section IX.E.5.(ii) for discussion of EPA's pass-through methodology.

The General Pretreatment Regulations, which set forth the framework for the implementation of categorical pretreatment 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 nondomestic dischargers. For national instances of pass-through, EPA performs an analysis based on the procedures set forth at 52 FR 1586 (January 14, 1987).

f. Pretreatment Standards for New Sources (PSNS)—section 307(b) of the CWA. Like PSES, PSNS are designed to prevent the discharge of pollutants that pass through, interfere with, or are otherwise incompatible with the operation of a POTW. 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.

g. Best Management Practices (BMPs). Section 304(e) of the CWA gives the Administrator the authority to publish regulations, in addition to the effluent limitations guidelines and standards listed above, to control plant site runoff, spillage or leaks, sludge or waste disposal, and drainage from raw material storage that the Administrator determines are associated with or ancillary to the industrial manufacturing or treatment process of the regulated point source category and that she (he) determines may contribute significant amounts of pollutants to waters of the United States.

2. Prior Regulations

EPA promulgated interim final BPT regulations for the pharmaceutical manufacturing point source category on November 17, 1976 (41 FR 50676; 40 CFR part 439, Subparts A–E). The five subcategories of the pharmaceutical manufacturing industry (40 CFR 439) are:

- Subpart A—Fermentation Products Subcategory.
- Subpart B—Extraction Products Subcategory.
- Subpart C—Chemical Synthesis Subcategory.
- Subpart D—Mixing, Compounding, and Formulating Subcategory.
- Subpart E—Research Subcategory.

The 1976 BPT regulations set monthly limitations for BOD₅ and COD based on percent removal for all subcategories. No daily maximum effluent limitations were established for these parameters. The pH was set within the range of 6.0 to 9.0 standard units. The regulations also set maximum 30 day average total suspended solids (TSS) limitations for subcategories B, D, and E. No TSS limitations were established for subcategories A and C. Subpart A was amended (42 FR 6813) on February 4, 1977, to improve the language referring to separable mycelia and solvent recovery. The amendment also allowed the inclusion of spent beers (broths) in the calculation of raw waste loads for Subpart A in those instances where the spent beer is actually treated in the wastewater treatment system.

On October 27, 1983, at 48 FR 49808, EPA promulgated revised BPT and BAT, PSES, and PSNS regulations for Subparts A–D covering the toxic pollutant cyanide and the conventional pollutants BOD₅, TSS and pH and the nonconventional pollutant COD. The 1983 regulations kept intact the percent reduction regulations for BOD₅ and COD established in 1976 but added floor concentration-based limitations for these parameters applicable to subcategories B and D. In addition, limitations for TSS based on each plant's BOD₅ discharge were promulgated for subcategories A–D. EPA also promulgated BPT, BAT, PSES and PSNS for pH (6.0–9.0) and BAT concentration-based limitations controlling the discharge of cyanide from subcategory A–D plants. The Agency also proposed NSPS for BOD₅, TSS and pH in the October 1983 notice, but did not publish final NSPS for these parameters. That proposal is being replaced by today's NSPS proposal.

On December 16, 1986, at 51 FR 45094, EPA promulgated BCT effluent limitations for BOD₅, TSS and pH for

subcategories A–D. That final rule set BCT effluent limitations equal to the existing BPT effluent limitations for BOD₅, TSS, and pH.

3. Litigation History

The effluent limitations guidelines and standards for the pharmaceutical manufacturing industry have never been the subject of litigation.

4. Section 304(m) Requirements

Section 304(m) of the Clean Water Act (33 U.S.C. 1314(m)), added by the Water Quality Act of 1987, requires EPA to establish schedules for (i) reviewing and revising existing effluent limitations guidelines and standards and (ii) promulgating new effluent guidelines. On January 2, 1990, EPA published an Effluent Guidelines Plan (55 FR 80), in which schedules were established for developing new and revised effluent guidelines for several industry categories. One of the industries for which the Agency established a schedule was the pharmaceutical manufacturing point source category.

Natural Resources Defense Council, Inc. (NRDC) and Public Citizen, Inc. challenged the Effluent Guidelines Plan in a suit filed in U.S. District Court for the District of Columbia (*NRDC et al. v. Reilly*, Civ. No. 89–2980 (D.D.C.)). (The suit originally challenged EPA's failure to publish the plan by the statutory deadline.) The plaintiffs charged that EPA's plan did not meet the requirements of section 304(m). On January 31, 1992, EPA entered into a consent decree (the "304(m) Decree"), which established schedules for, among other things, EPA's proposal and promulgation of approximately 20 effluent guidelines including those for the pharmaceutical manufacturing point source category.

On May 18, 1994, the Agency published a second plan (see 59 FR 25859). The plan projected proposal and promulgation dates for several industrial categories including the pharmaceutical manufacturing category.

B. Clean Air Act

Title III of the 1990 Clean Air Act Amendments was enacted to reduce the amount of nationwide emissions of hazardous air pollutants. It comprehensively amended section 112 of the Clean Air Act (CAA).

Section 112(b) lists the 189 chemicals, compounds, or groups of chemicals deemed by Congress to be hazardous air pollutants (HAPs). These toxic air pollutants are to be regulated by national emission standards for hazardous air pollutants (NESHAP). Section 112(c) requires the

Administrator to use this list of HAPs to develop and publish a list of source categories for which NESHAP will be developed. EPA must list all known categories and subcategories of "major sources."

The term major source is defined in paragraph 112(a)(1) to mean any stationary source or group of stationary sources located within a contiguous area and under common control that emits or has the potential to emit, considering controls, in the aggregate 10 tons per year (tons/yr) or more of any HAP or 25 tons/yr or more of any combination of HAPs. The term stationary source, from section 111 of the CAA, means any building, structure, facility, or installation that emits or may emit any air pollutant. The term area source, as defined in section 112(a)(2), means any stationary source of HAPs that is not a major source.

Notice of the initial list of categories of major and area sources of HAPs was published on July 16, 1992 (57 FR 31576), under authority of section 112(c). This notice listed pharmaceutical manufacturing as a category of major sources of HAPs. Notice of the schedule for the promulgation of emission standards for the listed categories, under authority of section 112(e), was given on December 3, 1993 (58 FR 63941). Under this notice, emission standards for the pharmaceutical production industry would be promulgated no later than November 15, 1997.

Section 112(d) of the CAA directs the Administrator to promulgate emission standards for each category of HAP sources listed under section 112(c). Such standards are applicable to both new and existing sources and must require the maximum degree of reduction in emissions of the hazardous air pollutants subject to this section (including a prohibition on such emissions, where achievable) that the Administrator, taking into consideration the cost of achieving such emission reduction, and any non-air quality health and environmental impacts and energy requirements, determines is achievable for new and existing sources in the category or subcategory to which such emission standard applies. See 42 U.S.C. 7412(d)(2).

Section 112(d)(3) provides that the maximum degree of reduction in emissions that is deemed achievable for new sources shall not be any less stringent than the emission control that is achieved in practice by the best controlled similar source. For existing sources, the standards may not be less stringent than the average emission limitation achieved by the best

performing 12 percent of existing sources in each category of 30 or more sources.

Once this minimum control level (referred to as the floor) has been determined for new or existing sources for a category, the Administrator must set a standard based on maximum achievable control technology (MACT) that is no less stringent than the floor. The Administrator may set MACT standards that are more stringent than the floor if such standards are achievable considering the cost, environmental, and other impacts listed in section 112(d)(2). Such standards must then be met by all sources within the category.

C. Resource Conservation and Recovery Act (RCRA)

Subtitle C of RCRA, 42 U.S.C. 6921–39b, directs EPA to establish a comprehensive "cradle to grave" system regulating the generation, transport, storage, treatment and disposal of hazardous wastes. The hazardous wastes subject to this comprehensive management scheme include any solid waste, or combination of solid wastes, that because of its quantity, concentration, or physical, chemical, or infectious characteristics may cause or significantly contribute to an increase in mortality or an increase in serious irreversible, or incapacitating reversible, illness; or pose a substantial present or potential hazard to human health or the environment when improperly treated, stored, transported, or disposed of, or otherwise managed. 42 U.S.C. 6903(5).

RCRA defines "solid waste" to include any garbage, refuse, sludge from a waste treatment plant, water supply treatment plant, or air pollution control facility and other discarded material. 42 U.S.C. 6903(27). The Act does not specify what characteristics of a waste render it hazardous to human health or the environment; instead, it directs EPA to develop and promulgate criteria for identifying the characteristics of hazardous waste and for listing hazardous waste, taking into account toxicity, persistence, and degradability in nature, potential for accumulation in tissue, and other related factors such as flammability, corrosiveness, and other hazardous characteristics. 42 U.S.C. 6921. Pursuant to this directive, EPA has adopted a two track scheme for identifying hazardous wastes. So-called "characteristic wastes," regulated under 40 CFR 261.20–24, exhibit at least one of four specified characteristics: ignitability, corrosivity, reactivity, or toxicity. Such wastes are deemed automatically subject to regulation under RCRA subtitle C, and retain the

designation of hazardous waste until they cease to exhibit any of the characteristics. See 40 CFR 261.3(d)(1).

The other type of hazardous wastes, "listed wastes," comprises wastes specifically classified as hazardous by EPA rule. See 40 CFR 261.11 (setting out criteria EPA considers in determining whether a solid waste should be a listed hazardous waste). Under EPA regulations, a listed hazardous waste retains that classification, even if has been treated in some fashion, until the waste has been demonstrated to be no longer hazardous. See 40 CFR 261.3(c)–(d) (the "derived-from" rule).

Once a waste has been identified or listed by EPA, RCRA permits its disposal on the land if the waste has been treated to meet standards established by EPA pursuant to 42 U.S.C. 6924(m). Section 6924(m)(1) instructs EPA to specify those levels or methods of treatment, if any, that 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. EPA has concluded that requiring hazardous wastes to be treated in accordance with the best demonstrated available technology ("BDAT") is sufficient to satisfy this criterion. See 51 FR 40,572, 40,578 (1986). These standards can apply even after a characteristic waste no longer exhibits a characteristic. 40 CFR 261.3(d)(1).

In addition to meeting treatment standards before land disposal, hazardous wastes are also subject to cradle-to-grave control from point of generation to point of final disposition. Generators prepare manifests to assure proper tracking of all hazardous wastes. Facilities treating, storing or disposing of such wastes are subject to design and operating standards established by EPA. Such standards ordinarily are embodied in an operating permit issued by EPA to the facility. In addition to meeting design and operating standards, facilities must commit sufficient money to assure that the facility will be properly closed, or that proper post-closure care of the wastes will occur.

D. Pollution Prevention Act of 1990

In the Pollution Prevention Act of 1990 (42 U.S.C. 13101 *et seq.*), Congress declared pollution prevention the national policy of the United States. The Pollution Prevention Act declares that pollution should be prevented or reduced whenever feasible; pollution that cannot be prevented should be recycled or reused in an

environmentally safe manner whenever feasible; pollution that cannot be prevented or recycled should be treated in an environmentally safe manner whenever feasible; and disposal or other release into the environment should be chosen only as a last resort and should be conducted in an environmentally safe manner. See 42 U.S.C. 13101(b).

Today's proposed rule is consistent with this policy. The technology basis for the proposed NSPS and PSNS for facilities with subcategory A, B, C and/or D operations includes steam stripping with distillation. Today's proposed PSES for facilities with subcategory A, B, C and/or D operations, as well as today's proposed BAT limitations for facilities with subcategory A and/or C operations, are based on steam stripping. Both technologies allow for the recovery from wastewaters and possible reuse of organic solvents. As part of today's proposal, the Agency also investigated whether solvent use could be minimized and/or eliminated through process changes but concluded that such opportunities may be limited to specific process operations at some facilities. The Agency encourages research regarding solvent use reduction and/or elimination procedures for existing as well as future pharmaceutical manufacturing operations. The Agency solicits comment on process change (source reduction) opportunities for pharmaceutical manufacturing and products. See section XIV, solicitation number 12.0.

E. Common Sense Initiative

On August 19, 1994, the Administrator established the Common Sense Initiative (CSI) Council in accordance with the Federal Advisory Committee Act (U.S.C. App. 2, Section 9(c)) requirements. A principal goal of the CSI includes developing recommendations for optimal approaches to multi-media controls for six industrial sectors including Metal Plating and Finishing, Electronics and Computers, Auto Manufacturing, and Iron and Steel Manufacturing. The following are the six overall objectives of the CSI program, as stated in the "Advisory Committee Charter."

1. Regulation. Review existing regulations for opportunities to get better environmental results at less cost. Improve new rules through increased coordination.

2. Pollution Prevention. Actively promote pollution prevention as the standard business practice and a central ethic of environmental protection.

3. Recordkeeping and Reporting. Make it easier to provide, use, and

publicly disseminate relevant pollution and environmental information.

4. Compliance and Enforcement. Find innovative ways to assist companies that seek to comply and exceed legal requirements while consistently enforcing the law for those that do not achieve compliance.

5. Permitting. Improve permitting so that it works more efficiently, encourages innovation, and creates more opportunities for public participation.

6. Environmental Technology. Give industry the incentives and flexibility to develop innovative technologies that meet and exceed environmental standards while cutting costs.

The pharmaceutical manufacturing rulemaking effort was not among those included in the Common Sense Initiative. However, the Agency believes that the CSI objectives already have been incorporated into the pharmaceutical manufacturing industry rulemaking. Nonetheless, given the multimedia considerations affecting this rulemaking, the Agency will continue to pursue these objectives. The Agency particularly will focus on avenues for giving state and local authorities flexibility in implementing this rule, and giving the industry flexibility to develop innovative and cost-effective compliance strategies. In developing this rule, EPA took advantage of several opportunities to gain the involvement of various stakeholders. Section XIII.F of this preamble describes consultations with state, local, and tribal governments and other parties including the industry. EPA has internally coordinated among relevant program offices in developing this rule. Section X of this preamble describes coordination between the Office of Water and the Office of Air and Radiation concerning this proposed water and a related air rule that will be proposed at a later date. Also, Section XII of this preamble describes coordination between the Office of Water and the Office of Solid Waste and Emergency Response regarding the hazardous waste implications of this proposed water rule. See Section XIV of this preamble for pertinent comment and data solicitations. The effluent guideline development process for the pharmaceutical manufacturing industry will continue to implement the principles of the Common Sense Initiative.

VI. Regulatory Development Under the Clean Water Act

This section describes the Agency's approach for developing proposed effluent limitations guidelines and standards applicable to the

pharmaceutical manufacturing industry under the CWA. In developing this rule, EPA first collected information about the industry, next identified potential control and treatment technology bases for the effluent limitations and standards EPA proposes to establish, and then, using methodologies, assumptions, and data described in the economic and regulatory impact analyses (See Section XI of this preamble), estimated and analyzed the total environmental and economic impacts of basing limitations and standards on various combinations of these control technologies. Finally, EPA selected the control technologies upon which it based the proposed effluent limitations and standards.

A. Background

The pharmaceutical manufacturing industry releases significant amounts of pollutants to surface waters, and POTWs, and ambient air. Section V of this notice discusses in greater detail the legal authorities available to EPA to address these pollutant releases.

B. Goals

EPA has several technical and policy goals regarding the development of the proposed effluent limitations guidelines and standards. These goals include: (1) Protecting the public health and the environment by attaining significant reductions in pharmaceutical manufacturing industry pollutant releases to water and other media; (2) minimizing the cost of complying with the rule; (3) promoting and facilitating coordinated compliance planning within the industry; (4) promoting and facilitating pollution prevention; and (5) taking into account the multimedia nature of pollution control.

In light of the multimedia nature of the environmental releases from this industry, the Agency has closely coordinated this effluent guidelines rulemaking with the rulemaking and related activities of the Office of Air and Radiation (OAR) and the Office of Solid Waste and Emergency Response (OSWER).

C. Technical Approach

1. Information Collection

EPA's first step in developing these proposed regulations was to develop a plant-specific database, using information gathered under section 308 of the CWA, of all facilities potentially subject to the limitations and standards. See Section VIII below. Information and data were gathered by EPA from a number of sources, including EPA's wastewater sampling program, the 1989

screener questionnaire, and the 1990 survey questionnaire. The information collected includes the processes and control technologies in use, current control levels, and pollutant releases. EPA also updated survey data through telephone calls and letters to specific facilities in an attempt to ensure that the database reasonably reflects the current status of the industry. The Agency recognizes that the industry is dynamic, and that processes and equipment change over time. Accordingly, EPA will consider information and data submitted in a timely manner by interested parties in response to this proposal for the purpose of updating the database prior to promulgation.

EPA placed information collected about the industry into plant-specific databases. These databases consist mainly of the 1990 survey responses provided by 244 plants but also contain information from EPA's sampling program. EPA then estimated costs of implementing the proposed technology bases in order to analyze the economic impacts of achieving the proposed effluent limitations guidelines and standards. The Agency used the plant-specific databases and other components to calculate wastewater discharges and the costs of complying with the proposed effluent limitations and standards. This comprehensive information provides a strong basis for ensuring that the proposed regulations meet the statutory requirements, and allows consideration of other factors such as multimedia pollutant reduction.

2. Summary of Public Participation

Beginning in 1989, EPA met on at least a biennial basis with industry representatives from the Pharmaceutical Research and Manufacturers of America (PhRMA) to discuss the development of the screener and detailed questionnaires that EPA intended to distribute under section 308 of the CWA. The Agency received input from the industry representatives that was invaluable in the development of these information collection instruments. Following the completion of the screener and detailed questionnaires, EPA has continued to meet informally with PhRMA representatives to discuss progress in the rulemaking effort. EPA has also met informally with the Natural Resources Defense Council regarding this rulemaking and has made available to environmental groups and other members of the public the information that was provided to the industry.

On May 23, 1994, EPA held a public meeting on the pharmaceutical rulemaking (see 59 FR 21740, April 26, 1994). Following the meeting EPA sent

copies of revised meeting handout materials to all attendees and to interested parties who could not attend. In addition, by letter dated August 12, 1994, EPA provided written responses to questions submitted by PhRMA concerning issues raised at the public meeting. These documents are in the rulemaking docket.

3. Development of Effluent Limitations Control Technology Options

After evaluating a variety of control and treatment technologies and their use in the industry, EPA selected BPT, BAT, BCT, PSES, NSPS, and PSNS control technology options upon which it bases this proposed rule. This process is described in Section IX of this notice.

4. Analyses of Regulatory Alternatives

EPA conducted a series of analyses to assess the economic and environmental impacts of various combinations of BPT, BCT, BAT, NSPS, PSES, and PSNS control options. EPA then compared the projected effluent loadings and air emissions resulting from each regulatory alternative to baseline pollutant releases estimated as of January 1, 1991, based on the 1990 survey data. EPA also estimated the costs of implementing the various control options and other environmental and economic impacts for each alternative above the baseline level of control which EPA determined as treatment technologies in place in 1990. EPA evaluated each alternative in order to determine the effectiveness of the control technologies represented and to ascertain the reductions in effluent loadings and air emissions below the baseline that each control technology option could attain. The Agency also determined the environmental effects of these technologies with a goal toward minimizing the cross-media transfer of pollutants between water and air.

EPA also evaluated the possibility of basing BAT and PSES on process changes involving solvent use minimization or elimination. After evaluating information provided in response to the section 308 detailed questionnaire survey regarding pollution prevention measures on-going at pharmaceutical manufacturing facilities, the Agency concluded that no option involving solvent use elimination or minimization is technically available at this time. Nonetheless, the Agency is encouraging the industry to conduct research into eliminating or minimizing the use of solvents for existing processes and to design future manufacturing processes that eliminate or minimize the use of

volatile solvents. See Section XIV, solicitation number 12.0.

VII. Description of the Industry

A. Pharmaceutical Manufacturing Facilities

Presented below is a brief description of the pharmaceutical manufacturing industry. Other characteristics of the industry are detailed in Sections IX.B., IX.C., IX.D., and IX.E. of this notice and in Section 3 of the TDD. Based upon responses to EPA's 1989 Screener Survey of Pharmaceutical Manufacturing Facilities, the Agency estimates that there are 566 manufacturing facilities located in 39 States, Puerto Rico, and the Virgin Islands. The major pharmaceutical manufacturing areas in the U.S. are the Northeast, the Midwest, and Puerto Rico.

B. Manufacturing Processes

1. Fermentation

Fermentation is the usual method for producing most steroids and antibiotics. The fermentation process involves three basic steps: inoculum and seed preparation, fermentation or growth, and product recovery. Production of a pharmaceutically active ingredient begins with spores from the plant master stock. The spores are activated with water, nutrients, and warmth and are then propagated through the use of agar plates, test tubes, and flasks until enough mass is produced for transfer to the seed tank. Following adequate propagation in the seed tank, microorganisms from the seed tank are transferred to a fermenter tank along with the sterilized nutrients and the tank is then sparged with air to begin the fermentation or growth process. After a period ranging from 12 hours to a week, depending on the specific process, the fermenter batch whole broth is ready for filtration, which removes mycelia (i.e., the remains of the microorganisms). The filtered aqueous broth containing product and residual nutrients is then ready to enter the product recovery phase.

There are three common methods of product recovery: solvent extraction, direct precipitation, and ion exchange or adsorption. The most common method, solvent extraction, involves the use of an organic solvent to remove or extract the pharmaceutically active ingredient or product from the aqueous broth. Numerous solvent extractions are usually necessary to remove an acceptable yield of product from the contaminant mixture. Another common recovery method, direct precipitation, involves the use of aqueous solutions of

heavy metals such as copper and zinc to precipitate the product as a metal salt from the aqueous broth, after which the broth is filtered and the product is extracted from the solid residue. Ion exchange or adsorption involves removal of the product from the broth using solid materials such as ion exchange resin, adsorptive resin or activated carbon to bond with the product. The product is extracted from the solid phase material using solvent extraction followed by solvent evaporation.

2. Biological and Natural Extraction

Biological and natural extraction is used to manufacture pharmaceutically active ingredients whose molecular structure is too complex for chemical synthesis or fermentation methods. Extraction involves the collection and processing of large volumes of plant or animal matter to produce small quantities of product. Initially, this large volume material is subject to a large, usually organic solvent-based, extraction procedure to obtain a first product cut or extraction. This cut is purified in many successive extraction operations. At each stage of the extraction process, the volume of material used becomes smaller. In the end, the volume of product may be only a few thousandths of the mass of material handled in the earlier procedures. Generally, the yield from extraction procedures is very small and pharmaceutical companies use extraction only when they have no other alternative.

Recently, pharmaceutical manufacturers have been developing bioengineered microorganisms that can produce pharmaceutically active ingredients. Pharmaceutical manufacturers sometimes use extraction procedures to obtain and purify these ingredients, but EPA understands generally that the amounts of water and solvents used in these procedures at this time are minimal. Nonetheless, EPA is soliciting information and data to better characterize wastewaters from these operations (see Section XIV at solicitation number 11.0).

3. Chemical Synthesis

Chemical synthesis involves the use of a series of chemical reactions to produce pharmaceutically active ingredients, usually starting with common feedstock chemicals as raw materials. The product of each successive chemical reaction then becomes the reactant in the next chemical reaction until the final reaction step of the synthesis is reached when the pharmaceutically active

ingredient product is generated. More pharmaceutically active ingredients are manufactured by chemical synthesis than by any other process.

4. Mixing/Compounding/Formulating

Before active ingredients can be used as pharmaceuticals, they must be prepared in dosage forms. The primary dosage forms utilized by the industry include tablets, capsules, liquids and ointments. For example, in tablet-making, manufacturers blend pharmaceutically inactive materials filler (e.g., starch) and binder (e.g., corn starch) with the active ingredient(s) and form tablets using a tablet press machine. Mixing, compounding, and formulating operations are utilized by more plants than any other process operation.

VIII. Summary of Data Gathering Efforts

A. Technical and Economic Data

1. 1989 Screener Survey of the Pharmaceutical Industry

In 1988, the Agency developed a short questionnaire for distribution to all known or suspected pharmaceutical manufacturers. The purpose of the questionnaire was to identify facilities that could be affected by future effluent limitations guidelines and standards applicable to the pharmaceutical manufacturing industry. The Information Collection Review (ICR) package for this questionnaire was sent to OMB in May 1989 and approved in June 1989. The questionnaire was sent to 1163 facilities in July of 1989. The Agency received 962 responses.

2. 1990 Pharmaceutical Manufacturing Industry Survey

In early 1989, EPA began to develop a questionnaire to gather the technical and financial information necessary for this rulemaking. EPA met with industry representatives during the questionnaire development process in an effort to keep the industry informed of the Agency's plans and to solicit informed comments on questionnaire design. Before pretesting the questionnaire, EPA sent a preliminary version of the questionnaire to the Pharmaceutical Manufacturers Association (now known as the Pharmaceutical Research and Manufacturers of America) for distribution and review by representatives of member companies. The Agency then incorporated all appropriate comments of the industry representatives into a pretest version of the questionnaire. In 1990, EPA sent pretest versions of the questionnaire to eight facilities for response and

comment. Along with their responses, the pretest candidates provided information on the amount of time required to complete the questionnaire and suggestions for improving the questionnaire as an information gathering instrument.

The pretest suggestions were used to develop a final version of the questionnaire, which was part of an ICR package that was sent to OMB for approval in May 1990. In August of that year, OMB cleared part A (technical section) of the questionnaire and some questions in part B (economic and financial) but denied clearance for most of the part B plant-specific financial and economic questions. In order to accommodate OMB's and industry's concerns about the need for responses to plant-specific economic and financial questions, the Agency developed a certification procedure. This procedure allowed industry respondents to certify that future pharmaceutical category regulations would not impact their facility above a certain dollar amount. A respondent making the certification was not required to respond to most of the part B questions.

In May 1991, the Agency submitted a revised ICR package to OMB, including the certification option discussed above. OMB approved the questionnaire and EPA sent the final questionnaire to 280 facilities in September 1991. EPA received responses from 244 of the 304 facilities still engaged in pharmaceutical manufacturing with solvent use.

3. Sampling and Analytical Program

Between 1986 and 1991, EPA conducted a sampling program at 13 pharmaceutical manufacturing facilities to: (1) Characterize the pollutants in the wastewater being discharged directly to surface waters and indirectly to POTWs; (2) generate pollutant treatment system performance data from facilities with well-operated advanced biological treatment systems (those systems attaining better than BPT annual average effluent quality); and (3) obtain treatability data from steam stripping units.

Prior to 1986, the Agency had focused on five conventional pollutants and 126 priority pollutants in the pharmaceutical manufacturing industry's wastewater. Beginning in 1986, the Agency expanded the analysis of pharmaceutical wastewater and wastewater treatment plant sludges to determine the presence and levels of all the pollutants on the "Industrial Technology Division (ITD) List of Analytes" (hereinafter, the "List of Analytes").

During the sampling program, EPA gathered analytical data to characterize the wastewater from five direct dischargers and eight indirect dischargers. Treatment system performance data were gathered from three advanced biological treatment systems and two biological pretreatment systems. Treatment unit performance data documenting the performance of five steam stripping columns were also gathered. The performance of one resin adsorption column and one cyanide destruction unit was also documented.

a. Bench-, Pilot-, and Full-Scale Studies. Between October and December 1991, EPA conducted bench-scale and pilot-scale tests to study: (1) Air stripping technology (with ammonia capture) for ammonia removal from pharmaceutical plant final effluent; and (2) steam stripping technology for removal of volatile organic pollutants from pharmaceutical plant process wastewaters.

EPA conducted the air stripping and steam stripping pilot studies at a pharmaceutical manufacturing facility with fermentation, chemical synthesis, formulation, and research operations. The objective of the air stripping study was to examine the feasibility of obtaining at least 90 percent ammonia removal using air stripping technology. A portion of the total facility effluent was used as the feed to the pilot-scale air stripping study.

The objectives of the steam stripping study were to demonstrate the achievement of the lowest practical concentrations of volatile organic pollutants in the treated effluent, using the available bench- and pilot-scale steam stripping test equipment, and to collect sufficient data to document these concentrations using the available bench- and pilot-scale data. On-site pilot-scale testing was conducted for two of the three streams. EPA elected not to run pilot-scale tests on one of the streams because the stream flow from that process area was insufficient for pilot-scale testing during the study time period. Performance data for this third process wastewater stream were collected using bench-scale equipment.

In September 1993, EPA conducted an on-site treatment performance study using a pharmaceutical manufacturing facility's existing distillation column that treated wastewaters containing methanol. The objective of the study was to achieve the lowest practical concentrations of methanol (within the operating constraints of the facility) in the treated effluent and to collect sufficient data to document these concentrations. All of the studies are

discussed in more detail in sections 5 and 8 of the TDD.

B. Air Emission Data

In July 1993, pursuant to section 114 of the Clean Air Act, EPA distributed questionnaires seeking data on air emissions to 396 pharmaceutical manufacturing facilities. The scope of the survey included all manufacturing operations that were covered by the SIC Code Nos. 2833, 2834, and 2836 and that also emitted hazardous air pollutants. Research facilities were not included. The questionnaire requested production data, process flow diagrams, emissions data, emission control technology data, and information on source reduction measures. EPA will use this data and information in developing standards to be promulgated under the Clean Air Act for the pharmaceutical manufacturing industry. EPA will compare these data and information, to the extent it is appropriate, to the data and information collected under the Clean Water Act to ensure that the best and most consistent data are used in both rulemaking efforts. See Section X below.

IX. Development of Effluent Limitations Guidelines and Standards

A. Industry Subcategorization

1. Introduction

In developing today's proposed rule, EPA considered whether different effluent limitations and standards were appropriate for different groups of plants or subcategories within the pharmaceutical manufacturing industry. Factors considered included: processes employed, effluent characteristics, costs, age of equipment and facilities, size, location, engineering aspects of the application of various types of control techniques, process changes, and non-water quality environmental impacts. In determining which subcategories were appropriate for this proposed rule, EPA, using recently available data, evaluated the scheme for establishing subcategories regulated under the current effluent limitations guidelines and standards applicable to this industry.

2. Current Subcategorization

The current subcategorization of this industry dates back to 1976 and was developed using data from the mid-1970s. The current subcategories are as follows:

- Subpart A Fermentation
- Subpart B Biological and Natural Extraction
- Subpart C Chemical Synthesis
- Subpart D Mixing/Compounding/
Formulating

Subpart E Pharmaceutical Research

3. Rationale for Maintaining the Current Subcategorization

Prior to finalizing the 1983 regulation, the Agency evaluated the original subcategorization scheme developed for the 1976 interim final regulations. This evaluation is discussed in section 4 of the 1983 technical development document and in the preamble to the final regulation at 48 FR 49808 (October 27, 1983). The Agency concluded at that time that the original subcategorization scheme based on manufacturing process type was the most appropriate one for the Pharmaceutical Manufacturing Point Source Category. In determining whether this scheme is appropriate for the rule being proposed today, the Agency evaluated the wastewater and production data obtained from the detailed questionnaire responses as well as plant sampling data in light of the current scheme. The Agency compared the wastewater flow and pollutant characteristics data (influent and effluent BOD₅, TSS, and COD) obtained from the 1990 detailed questionnaire responses with the data presented in Section 4 of the 1983 TDD. EPA concluded that the similarities and data trends reported for both subcategory A and C and subcategory B and D facilities were identical to those reported in 1983 for analogous data. Consequently, the Agency concluded that the current subcategorization scheme continues to be appropriate for today's proposed rule. As was the case with the 1983 final regulation, the limitations and standards being proposed today for subcategory A are identical to those proposed for subcategory C and those limitations and standards being proposed for subcategory B are identical to those being proposed for subcategory D. The Agency invites comments regarding this regulatory scheme. The subcategorization analysis is discussed in more detail in section 4 of the TDD for this rulemaking. See Section XIV, solicitation number 4.0.

4. Subcategory Regulation Not Revised

EPA is not proposing new or revised effluent limitations and standards for the Pharmaceutical Research Subcategory (Subcategory E). Rather, research activities falling within this subcategory will continue to be subject to the BPT regulations established for that subcategory in the 1983 regulations for this industry. The 1983 regulations did not establish BCT, BAT, NSPS, PSES, or PSNS effluent limitations and standards for the research subcategory, and today's proposed revisions to 40

CFR part 439 will not change this. However, process wastewater generated by research activities falling within this subcategory will continue to be subject to BCT and BAT limitations, as appropriate, established on a best professional judgment (BPJ) basis. In addition, indirect dischargers will be subject to local limits, as appropriate.

In its preamble to the 1983 regulations, EPA explained that it was specifically excluding subcategory E pharmaceutical research from all limitations and standards in the regulation other than BPT limitations because these operations do not involve production and wastewater generation in appreciable quantities on a regular basis. See 48 FR 49808, 49816 (Oct. 27, 1983). EPA also noted that research activities conducted at mixed and single subcategory plants (A, B, C, and D only) would be covered by that regulation. In today's Notice, EPA proposes to exclude subcategory E research operations from all limitations and standards in the proposed rule, other than the existing BPT limitations, at both stand alone and mixed subcategory plants. However, in order to clarify the scope of Subcategory E as described in the 1983 preamble, EPA proposes to define Subcategory E research operations specifically as bench-scale activities related to the development of pharmaceutical products. Bench-scale activities, in contrast to pilot-scale operations, do not involve production or wastewater generation in appreciable quantities on a regular basis and therefore describe the activities historically encompassed within Subcategory E, Pharmaceutical Research.

Consequently, under this proposal, bench-scale research activities that generate process wastewater at manufacturing facilities or at stand-alone Subcategory E facilities will be covered by the current subcategory E BPT limitations on BOD₅, COD, TSS and pH. This means that if a facility engaging in bench-scale research operations also engages in pharmaceutical manufacturing operations covered by subcategories A, B, C, or D, the process wastewater from the bench-scale research operations would be subject only to subcategory E regulations (and on a case-by-case basis BCT and BAT limitations based on BPJ, as appropriate). Conversely, if a facility engages in research operations on a pilot-scale level, then the wastewater generated by those operations would be subject to the standards and limitations applicable to the manufacturing subcategory (A, B, C, or D) that the wastewater most resembles. See 40 CFR 439.50 et seq.

The proposal that subcategory E applies to all bench-scale research operations irrespective of their proximity to pharmaceutical manufacturing process operations represents a change from the interpretation expressed by EPA in the preamble to the 1983 rule. In that preamble, EPA indicated that research activities conducted at mixed and single subcategory plants (A, B, C, and D only) would be covered by the regulations corresponding to the particular subcategory. Accordingly, the Agency is soliciting comment on whether facilities with both subcategory E and subcategory A, B, C, or D process operations should be subject to the standards and limitations corresponding to the manufacturing subcategory (A, B, C, or D) and not to subcategory E BPT limitations as proposed here. See Section XIV, solicitation number 5.2.

B. Water Use, Wastewater Discharge and Characterization

This section describes current water use and wastewater recycling practices, discharge practices and the general characteristics of wastewater at the plants that manufacture pharmaceuticals in the United States. A more detailed presentation can be found in Section 5 of the TDD. Almost all pharmaceutical manufacturing processes require the use of water, although use and discharge practices and the characteristics of the wastewater will vary depending on the process operations at individual facilities.

1. Water Use and Wastewater Generation

a. Water Use. EPA estimates the average daily wastewater generation by the pharmaceutical manufacturing industry to be 266 million gallons, based on the responses to questions in part A section 4 of the 1990 Pharmaceutical Manufacturing Survey. Pharmaceutical manufacturers use water for process operations and for other nonprocess purposes such as noncontact cooling and sanitation.

The water is used or generated in pharmaceutical manufacturing process operations in several ways, thereby generating process wastewater:

- *Water of reaction:* Water formed during the chemical reaction.
- *Process solvent:* Water used to transport or support the chemicals involved in the reaction process; this water is usually removed from the process through a separation step, such as centrifugation, decantation, drying, or stripping.
- *Process stream washes:* Water added to a process stream (i.e., the

carrier, spent acid, or spent base) that has been separated from the reaction mixture, in order to purify the stream by washing away impurities in the stream.

- *Product washes:* Water added to the reaction medium to purify an intermediate or final product by washing away the impurities (this water is subsequently removed through a separations step); or water used to wash the crude product after it has been removed from the reaction medium.

- *Spent Acid/Caustic:* Spent acid and caustic streams, which may consist primarily of water, that are discharged from the process during the separation steps following the reaction step in which acid and basic reagents are used to facilitate, catalyze, or participate in the reactions.

- *Condensed steam:* Steam used as a sterilizing medium and in steam strippers for solvent recovery and wastewater treatment.

Other sources of process wastewater associated with pharmaceutical manufacturing operations include:

- *Air pollution control scrubber blowdown:* Water or acidic or basic compounds used in air emission control scrubbers to control fumes from reaction vessels, storage tanks, incinerators, and other process equipment.

- *Equipment and floor washes:* Water used to clean process equipment during unit shutdowns and floors during general housekeeping or for spill cleanup.

- *Pump seal water:* Direct contact water used to cool packing material and lubricate pumps.

In addition to process wastewater, non-process wastewater may be generated during pharmaceutical manufacturing. This non-process wastewater may include noncontact cooling water (used in heat exchangers), noncontact ancillary water (e.g., boiler blowdown, bottle washing), sanitary wastewater, and wastewater from other sources such as stormwater.

b. Water Conservation. In response to the 1990 detailed survey questionnaire, 137 of the 244 responding pharmaceutical manufacturers reported implementing water conservation measures with regard to process wastewater. Such water conservation measures include: careful monitoring of water use, installation of automatic monitoring and alarm systems on in-plant discharges, implementation of alternative production processes requiring less water, conversion from barometric to surface condensers, reuse of wastewater from other manufacturing processes, reuse of noncontact water as process makeup water, and treatment of contact cooling water to allow reuse.

2. Wastewater Discharge

Based on the responses to the screener and detailed survey questionnaires and other information, EPA has learned that of the 304 potentially affected facilities, 35 facilities discharge their wastewater directly to surface waters of the United States, 259 discharge to a POTW, three discharge directly to surface water as well as to a POTW, and seven do not discharge to a POTW or to surface waters. EPA estimates that the average daily volume of pharmaceutical process wastewater discharged via a POTW or directly from the manufacturing facility to surface waters of the U.S. is 84 and 20 million gallons, respectively.

3. Wastewater Characterization

The pharmaceutical manufacturing industry generates process wastewaters containing a variety of pollutants. Most of this process wastewater receives some treatment, either in-plant at the process unit prior to commingling with other facility wastewaters or in an end-of-pipe wastewater treatment system. Pharmaceutical manufacturers discharge wastewater containing conventional, priority, and nonconventional pollutants. These pollutants are discussed in Section IX.C below.

a. Conventional Pollutants: BOD₅, TSS, and pH. BOD₅, the quantity of oxygen used in the aerobic stabilization of wastewater streams, is the most widely used measure of general organic pollution in wastewater. BOD₅ discharges from facilities with subcategory A and/or C operations are significantly higher than those discharges from facilities with subcategory B and/or D operations because fermentation and chemical synthesis process operations generate substantially greater concentrations of organic material (on average ten times higher untreated BOD₅ concentrations) than extraction or mixing, compounding, and formulating processes.

TSS is the portion of the total solids that can be filtered out of a solution using a 1-micron filter. (Total solids in wastewater is defined as the residue remaining after evaporation at just above the boiling point.) Discharges of TSS for this industry are generally proportional to the amount of BOD₅ discharged and, as a result, A and/or C subcategory facilities discharge significantly more TSS than do B and/or D facilities.

The pollutant parameter, pH, is a measure of the acidity or alkalinity of an aqueous solution. It is defined as the logarithm of the reciprocal of the hydronium-ion concentration of a

solution. A pH of 7.0 indicates neutrality or a balance between free hydronium and free hydroxyl ions. A pH above 7.0 indicates that a solution is alkaline; a pH below 7.0 indicates that a solution is acidic. Untreated wastewaters from the pharmaceutical manufacturing industry range from being highly alkaline (pH 12 or higher) to highly acidic (pH 2 or lower). The pollutant parameter, pH, is currently controlled within the range of 6.0 to 9.0 by promulgated effluent limitations guidelines and standards for all five subcategories of the pharmaceutical manufacturing industry. EPA does not propose to modify the promulgated pH limitations by this rulemaking. Therefore, pH is not included in the following discussion of pollutant parameters.

b. Priority Pollutants. Questionnaire respondents reported discharging 13 different priority pollutants. The annual mass loading of untreated priority pollutants released to the environment from pharmaceutical wastewater (including pollutants emitted to the air from wastewaters) range from 3.6 million pounds per year to 400 pounds per year. The most significant priority pollutants discharged by the industry are methylene chloride, toluene, chloroform, and chloromethane. EPA sampling data at various direct and indirect discharging facilities indicate over 57 different priority pollutants were detected in pharmaceutical wastewaters at various concentrations. Many of the priority pollutants detected during sampling programs were pesticides unrelated to process operations and priority pollutant metals detected at concentrations incapable of being treated by available technologies.

In general, facilities with subcategory A and/or C operations reported discharging a greater variety of priority pollutants and at greater loads than facilities with Subcategory B and/or D operations. The Subcategory B and/or D direct dischargers reported that they did not discharge any priority pollutant load, while the Subcategory B and/or D indirect dischargers reported discharging some priority pollutant load. See Section 9 of the TDD for a presentation of the current priority pollutant discharge loads by subcategory group.

c. Nonconventional Pollutants. Questionnaire respondents reported discharging 105 different nonconventional pollutants, not including COD. The annual mass loadings of nonconventional pollutants released to the environment from pharmaceutical wastewaters (including air emissions from wastewaters) range

from 15.4 million pounds per year to one pound per year. The most significant nonconventional pollutants discharged by the industry are methanol, ethanol, isopropanol, and acetone. EPA sampling data at various direct and indirect discharging facilities indicate over 59 different volatile and semivolatile organic compounds were detected in pharmaceutical wastewaters at various concentrations.

In general, facilities with subcategory A and/or C operations reported discharging a greater variety of nonconventional pollutants and at greater loads than Subcategory B and/or D operations. In addition, the Subcategory B and/or D direct dischargers reported discharging fewer nonconventional pollutants at lower loads than the Subcategory B and/or D indirect dischargers. See Section 9 of the TDD for a presentation of the current nonconventional pollutant discharge loads by subcategory group.

C. Selection of Pollutant Parameters

1. Pollutants Regulated

a. Introduction. This section lists the pollutants covered by today's proposed rule in groups of conventional, priority, and nonconventional pollutants. For this proposed rule, EPA considered each pollutant identified in questionnaire responses and in EPA's sampling programs. In selecting the pollutants for control, EPA took into account their respective discharge loadings, frequency of occurrence, treatability, and environmental significance. In addition, EPA considered whether appropriate analytical methods were available or could be readily developed to detect and quantify the presence of these pollutants in wastewater. Finally, EPA investigated whether bulk parameters (e.g., COD) could be substituted for groups of individual pollutants. EPA concluded preliminarily that no known bulk parameters could be substituted as indicator pollutants for the individual pollutants to be regulated by these proposed effluent limitations and standards. EPA is soliciting comment on this finding. See section XIV of this preamble at solicitation number 37.0. Table IX.C-1 and Table IX.C-2 list the pollutants to be regulated by the various proposed effluent limitations and standards. A complete discussion of the pollutant selection/exclusion process may be found in section 6 of the TDD.

Conventional Pollutants:

BOD₅ and TSS

Priority Pollutants:

Benzene

Chlorobenzene

Chloroform

Chloromethane	Cyclohexane	Isopropyl Acetate*
Cyanide	Diethyl Ether*	Isopropyl Ether*
o-Dichlorobenzene*	Diethylamine*	Methanol*
1,2-Dichloroethane*	N,N-Dimethylacetamide	Methylamine*
Methylene Chloride	Dimethylamine*	Methyl Cellosolve (2-Methoxyethanol)
Phenol	N,N-Dimethylaniline*	Methyl Formate*
Toluene	N,N-Dimethylformamide	Methyl Isobutyl Ketone (MIBK)*
Nonconventional Pollutants:	Dimethyl Sulfoxide	2-Methyl Pyridine*
Acetone*	1,4-Dioxane*	Petroleum Naphtha*
Acetonitrile	Ethanol*	Polyethylene Glycol 600
Ammonia (aqueous)	Ethyl Acetate*	n-Propanol*
n-Amyl Acetate*	Ethylene Glycol	Pyridine*
Amyl Alcohol*	Formaldehyde	Tetrahydrofuran*
Aniline*	Formamide*	Trichlorofluoromethane
2-Butanone (MEK)*	Furfural*	Triethylamine*
n-Butyl Acetate*	n-Heptane	Xylenes
n-Butyl Alcohol*	n-Hexane	
tert-Butyl Alcohol*	Isobutyraldehyde*	
COD (Chemical Oxygen Demand)	Isopropanol*	

*Under co-proposal (2) these pollutants will not be regulated.

TABLE IX.C-1. POLLUTANTS REGULATED IN PROPOSED EFFLUENT LIMITATIONS GUIDELINES AND STANDARDS FOR FACILITIES WITH SUBCATEGORY A AND/OR C OPERATIONS

Pollutants regulated	Effluent regulation					
	BPT	BCT	BAT	NSPS	PSES	PSNS
BOD ₅	X	X		X		
TSS	X	X		X		
COD	X		X	X		
CN	X		X ²	X ²	X ²	X ²
Ammonia			X	X	X	X
Nonconv Vol. Orgs			X	X	X ³	X ³
Pri. Pol. Vol. Orgs			X	X	X	X
Phenol			X	X		
Nonconv. Svol. Orgs ¹			X	X	(4)	(4)

¹ Dimethyl sulfoxide, N,N-dimethyl acetamide, N,N-dimethyl formamide, ethylene glycol and formaldehyde.

² For purposes of proposal, CN limits for BAT, NSPS, PSES, and PSNS are the same as BPT.

³ Does not include two pollutants which do not pass through (acetonitrile and polyethylene glycol 600).

⁴ Limits are not being proposed at this time for these pollutants.

TABLE IX.C-2. POLLUTANTS REGULATED IN PROPOSED EFFLUENT LIMITATIONS GUIDELINES AND STANDARDS FOR FACILITIES WITH SUBCATEGORY B AND D OPERATIONS

Pollutants regulated	Effluent regulation					
	BPT	BCT	BAT	NSPS	PSES	PSNS
BOD ₅	X	X		X		
TSS	X	X		X		
COD	X		X	X		
Nonconv. Vol. Orgs			X	X	X ²	X ²
Pri. Pol. Vol. Orgs			X	X	X	X
Phenol			X	X		
Nonconv. Svol Orgs ¹			X	X	(3)	(3)

¹ Dimethyl sulfoxide, N,N-dimethyl acetamide, N,N-dimethyl formamide, ethylene glycol and formaldehyde.

² Does not include two pollutants which do not pass through (acetonitrile and polyethylene glycol 600).

³ Limits are not being proposed at this time for these pollutants.

b. Conventional pollutants.

Biochemical oxygen demand (BOD₅) and total suspended solids (TSS) are conventional pollutants that have been regulated in this industry by previous BPT and BCT effluent limitations guidelines. These parameters are important because they quantify the biodegradable organic matter and suspended solids generated by all plants in all subcategories of the

pharmaceutical industry. EPA estimates that 3.3 million pounds per year of BOD₅ and 6.4 million pounds per year of TSS are discharged by the 35 facilities EPA has identified as direct dischargers. Most direct discharger plants have some level of secondary biological treatment in-place designed to treat BOD₅ and TSS. EPA is proposing to establish NSPS and to revise the BPT and BCT effluent

limitations for these pollutants in all subcategories. EPA does not propose to set limitations for BOD₅ and TSS applicable to indirect dischargers because EPA has determined that these pollutants can be adequately treated by POTWs. EPA is not proposing to use them as indicators for other pollutants in this industrial category, although this will be given further evaluation.

c. Priority pollutants. The priority pollutants selected for control include cyanide, phenol and various solvents used by the industry. EPA estimates that direct and indirect discharging facilities discharge 0.5 and 1.8 million pounds per year, respectively, of the 10 priority pollutants addressed in this proposal. EPA is proposing to promulgate BPT, BAT, NSPS, PSES, and PSNS for some or all of these pollutants in subcategories A, B, C, and D.

d. Nonconventional pollutants. Nonconventional pollutants include ammonia, COD (Chemical Oxygen Demand), and various volatile and semivolatile organic compounds that are used for the most part as solvents by the industry. EPA estimates that 0.8 and 0.5 million pounds per year of ammonia and 32 and 78 million pounds per year of COD are discharged by direct and indirect discharging facilities, respectively. With respect to COD, EPA is proposing to revise existing BPT limitations and promulgate new BAT limitations and NSPS for subcategories A, B, C, and/or D. With respect to ammonia, EPA is proposing to promulgate BAT, NSPS, PSES, and PSNS for subcategories A and/or C. EPA has determined that ammonia is not a pollutant of concern in wastewaters of facilities with subcategory B and/or D operations and hence does not propose limits for ammonia for those subcategories. See Section 5 of the TDD. See Section XIV, solicitation numbers 20.0 and 23.0. For PSES, EPA is co-proposing a finding of no pass-through for 33 priority and nonconventional pollutants.

2. Pollutants Not Regulated

EPA is not proposing effluent limitations or standards for 85 priority and nonconventional pollutants identified as potentially present in pharmaceutical wastewaters. In Section 6 of the TDD, EPA describes for each pollutant or group of pollutants the reasons each is excluded from this proposal. EPA bases its decision to exclude these pollutants or groups of pollutants on one or more of the following reasons:

(1) The pollutant or group of pollutants is deemed not present in pharmaceutical wastewaters, because it was not detected in the effluent with the use of analytical methods promulgated pursuant to section 304(h) of the Clean Water Act or with other state-of-the-art methods;

(2) The pollutant or group of pollutants is present only in trace amounts and is neither causing nor likely to cause toxic effects in humans or aquatic life;

(3) The pollutant or group of pollutants is detected in the effluent from only one or a small number of sources;

(4) The pollutant or group of pollutants is effectively controlled by the technologies used as a basis for limitations on other pollutants, including those limitations and standards proposed today; or

(5) Insufficient data are available to establish effluent limitations or standards for that pollutant or group of pollutants.

In addition, EPA proposes to control phenol discharged by direct dischargers (through BAT and NSPS) but not by indirect dischargers (through PSES and PSNS) because pass-through has not been demonstrated for phenol. See the discussion on the analysis of pollutant pass-through in Section IX.E.5.a. of this preamble. EPA also is proposing to exclude two nonconventional pollutants from control by PSES and PSNS regulations (acetonitrile and polyethylene glycol 600) because pass-through has not been demonstrated for these pollutants. In addition, as noted in Section C above, EPA is proposing two alternative pass-through for PSES for 33 priority and nonconventional pollutants. Under one of the proposed alternatives, EPA proposes to exclude 33 pollutants because EPA has some doubt as to whether these pollutants pass through. Under the other co-proposal, EPA proposes PSES for those pollutants based on a determination that they do pass through according to the data presently available to EPA.

D. Available Technologies

1. Pollution Prevention Technologies Considered

EPA requested pollution prevention and process information regarding organic solvent use from pharmaceutical manufacturing facilities in its 1990 questionnaire. The responses indicate that while plants can make some process changes that would result in some source reduction, the opportunities to minimize or eliminate solvent use by changes in existing processes are limited, especially for facilities with subcategory A and/or C operations. Fermentation (A) and chemical synthesis (C) processes often involve complicated procedures which utilize solvents according to an exact recipe. In most cases, any change in the specific process or the amount of solvent used may result in a significant reduction in the yield of product obtained. Nonetheless, some Subcategory D (Mixing/Compounding/Formulating) facilities have utilized

aqueous-based solvents instead of organic solvents to coat tablets, thereby eliminating solvent use for that operation. This approach is generally not applicable to all tablet coating operations because most coating materials are not soluble in aqueous solvents.

Pharmaceutical plants sometimes cite an administrative, as well as a technical, impediment to pollution prevention. That is, once a pharmaceutical company gains approval from the Food and Drug Administration (FDA) to manufacture a pharmaceutically active ingredient or drug via a specific procedure, it may not deviate significantly from the approved procedure without additional FDA approval. Thus, if a company wishes to alter significantly an approved manufacturing procedure for any reason, including pollution prevention, it must submit a "supplement" application to FDA, which must be approved before the company can use the altered procedure.

EPA understands that FDA historically needs to take a long period of time to process these requests for approval. However, since the enactment of the "Prescription Drug User Fee Act of 1992," 21 U.S.C. 379 *et seq.*, Pub. L. 102-571, Oct. 29, 1992, the FDA has committed to using the revenues generated under that Act to expedite the prescription drug review and approval process, which include decisions on manufacturing supplements relating to pollution prevention-oriented process changes. EPA understands that the FDA hopes to eliminate its backlog of overdue manufacturing supplements by the end of Fiscal Year 1995 and to achieve, by Fiscal Year 1997, its goal of reviewing and acting upon every complete manufacturing supplement within six months of submission. EPA believes that such expeditious processing of supplements will eliminate impediments that presently discourage pharmaceutical plants from making process changes necessary to achieve source reductions.

In addition to evaluating opportunities for source reduction, EPA also examined potential treatment technologies to determine whether any might promote recovery, recycling, and reuse of chemicals in process wastewater generated by pharmaceutical manufacturing operations, such as solvents. After evaluating the various technologies available to treat solvent-laden wastewaters, EPA concluded that in-plant technologies such as steam stripping and steam stripping with distillation offered the best opportunity for recovery of solvents from wastewater. As discussed in greater

detail in Section IX.E.3 below, steam stripping technology and steam stripping with distillation technology are applied in-plant and minimize the dilution effects of commingling process wastewater streams and the transfer of volatile pollutants to air associated with other technologies. These technologies also allow the pharmaceutical manufacturing operation to recover the stripped solvents from the treatment process in an efficient and cost-effective manner from concentrated streams. These recovered solvents can then be recycled back into the process from which they were removed, reused in other manufacturing operations (e.g., in this industry or in other industries), or reused as "clean fuel" for boilers or other combustion devices. For further discussion of "clean fuels," see section XII.B of this preamble.

2. In-Plant Technologies Considered

EPA considered the following in-plant technologies to control solvent- and cyanide-laden wastewater generated by pharmaceutical manufacturing: (1) Steam stripping; (2) steam stripping with distillation; and (3) cyanide destruction. EPA concludes that steam stripping technology is the best technology available for removing high loadings and high concentrations of volatile organic pollutants from wastewater, and accordingly proposes BAT limitations for facilities with subcategory A and/or C operations on that technology basis. Fourteen plants reported using steam stripping technology and one facility reported using distillation technology for wastewater treatment in 1990. The demonstrated removal efficiencies for both technologies treating streams with high concentrations of highly strippable volatiles are greater than 99 percent. A detailed discussion of steam stripping and steam stripping with distillation (using fractional distillation columns with rectifying sections for difficult to strip volatile organic pollutants) and their use in the pharmaceutical manufacturing industry may be found in Section 7 of the TDD.

3. End-of-Pipe Technologies Considered

The end-of-pipe treatment technologies currently employed by the industry include: preliminary or primary treatment (neutralization, equalization, and primary clarification); biological or equivalent treatment (aerated stabilization basins with and without settling basins, oxidation ponds, and activated sludge systems); and physical/chemical treatment (multimedia filtration and chemically assisted clarification). In addition, EPA

has designated as advanced biological treatment a treatment configuration consisting of primary treatment plus some form of activated sludge treatment, which achieves better than 90 percent BOD₅ and 74 percent COD reduction from raw waste levels. EPA evaluated each of these available technologies in developing the limitations and standards proposed today. In addition to these technologies, the Agency also considered granular activated carbon (GAC) adsorption technology, which is an appropriate and available end-of-pipe treatment technology for pharmaceutical wastewater. All of the various technologies mentioned above are discussed in detail in Section 7 of the TDD.

All 35 direct dischargers responding to EPA's detailed questionnaire reported having some form of primary treatment in place in 1990. Thirty-one facilities reported having some form of biological or secondary treatment in place, either air- or oxygen-activated sludge treatment followed by secondary clarification and, in some cases, multimedia filtration and polishing ponds. One plant reported using GAC technology as end-of-pipe technology, and one plant reported using GAC technology in-plant.

E. Rationale for Selection of Technology Bases for Proposed Regulations

1. BPT

a. Introduction. EPA is today proposing revised BPT effluent limitations guidelines based on the Best Practicable Control Technology Currently Available (BPT) for BOD₅, TSS, and COD for subcategories A, B, C, and D of the pharmaceutical manufacturing industry. EPA is also proposing to revise existing BPT limitations for cyanide for facilities with subcategory A and/or C operations and to repeal the existing BPT cyanide limitations for facilities with B and/or D operations. The Clean Water Act explicitly authorizes EPA to revise all effluent limitations guidelines, including those based on best practicable technology, at least annually if appropriate. See CWA section 304(b). In the 1987 amendments to the Clean Water Act, Congress further required EPA to establish a schedule for the annual review and revision of promulgated effluent guidelines in accordance with section 304(b). See CWA section 304(m). Moreover, as discussed in Section V.A.4, above, EPA entered into a consent decree that requires EPA to propose and promulgate effluent guidelines for the pharmaceutical manufacturing industry,

as appropriate, including those authorized by section 304(b) for existing dischargers. See 304(m) Decree at 4–5. Because BPT guidelines are among those listed in section 304(b), EPA thus is required by the 304(m) Decree to propose and take final action on BPT guidelines for this industry, unless not appropriate.

EPA has determined that revising BPT limitations for the pharmaceutical manufacturing industry is indeed appropriate and important. The existing BPT guidelines for BOD₅, TSS, COD and cyanide for this industry, which were most recently revised in 1983, are based on secondary treatment data collected in the mid-1970s and cyanide destruction technology data collected in the early 1980s. Data from the 1990 detailed questionnaire indicate that there have been significant improvements in secondary treatment and cyanide destruction technologies in the industry since that time. Accordingly, the technology underpinnings of the current BPT limitations no longer reflect the "average of the best" technology currently available. Moreover, substantial environmental benefits would ensue from more stringent BPT limitations. For example, there would be significant reductions in the levels of COD and cyanide in addition to BOD₅ and TSS from current levels if BPT were revised. EPA has determined that revising the BPT limitations to reflect the best practicable control technology currently available is appropriate at this time.

b. Pollutants of concern. EPA is proposing to revise BPT effluent limitations controlling the discharge of BOD₅, TSS, COD, and, for facilities with subcategory A and/or C operations, cyanide (CN). EPA has determined that cyanide is not a pollutant of concern for facilities with subcategory B and/or D operations. Limitations for the pollutant parameter, pH, are not being revised.

c. Determination of technology basis of BPT. To determine the technology basis and performance level that constitutes BPT, EPA developed a database consisting of 1988 and 1989 effluent data supplied in response to the 1990 detailed questionnaire and its pretest form. The Agency determined that more than 29 of 35 direct dischargers and 23 indirect dischargers utilized biological treatment (activated sludge treatment). In addition, 10 direct and indirect discharging plants reported some form of cyanide destruction technology in place. Other technologies utilized include wastewater incineration (12 plants), effluent filtration (6 plants), and polishing ponds (8 plants).

d. Determination of performance level defining BPT. EPA used 1989 and 1990 data supplied in the response to the 1990 detailed questionnaire regarding BOD₅, TSS, and COD effluent and effluent concentrations and loadings in order to calculate long-term average concentrations for BOD₅, TSS, and COD. EPA then used this information to determine the performance level defining proposed BPT for BOD₅, TSS, and COD. EPA has determined that the level of performance necessary for a plant to be considered as a best performer with respect to advanced biological treatment was full compliance with the existing BPT limitations.

In order to develop BPT limitations for BOD₅, TSS, and COD for facilities with subcategory A and/or C and B and/or D operations, EPA first identified those plant datasets that indicated full compliance with the 1983 BPT regulation. BPT in the 1983 regulation was based on activated sludge treatment, which is considered a principal component of advanced biological treatment. Under the intent of the 1983 regulation, facilities with subcategory A and/or C operations must achieve long-term average reductions of 90 and 74 percent in BOD₅ and COD, respectively, and average TSS concentrations equal to 1.7 times their average influent BOD₅ concentrations. As an initial matter, EPA did not consider plants for this rulemaking unless they were consistently achieving such long-term BOD₅ and COD percent reductions and related TSS concentrations.

Having identified the plants that are complying with the 1983 BPT requirements, EPA then undertook to determine which could be considered best performers in the two subcategory groups. To do this, EPA usually develops editing criteria to analyze available performance data. EPA concluded that no such editing criteria were necessary in this case, however, because performance data for the plants employing advanced biological treatment to fully comply with the intent of the 1983 BPT regulation showed that all were achieving similar good performance. Five thus emerged as best performers among facilities with subcategory A and/or C operations; for facilities with subcategory B and/or D operations, EPA identified two as best performers. The Agency then calculated long-term average performance concentrations for BOD₅, TSS, and COD using datasets from the best performing A and C and B and D plants. The limitations derived from these concentrations represent the "average of

the best" performance with respect to advanced biological treatment in the pharmaceutical manufacturing industry.

With respect to the development of the BPT cyanide limitations for facilities with subcategory A and/or C operations, EPA identified ten facilities that used some form of cyanide destruction technology to destroy or oxidize the cyanide in their waste streams. The existing BPT limits for CN were based on alkaline chlorination technology. After evaluating the performance data characteristic of the various cyanide destruction technologies employed, EPA concluded that hydrogen peroxide oxidation appeared to meet the statutory requirements for BPT most effectively. In reaching this decision, EPA used influent and effluent cyanide data from one of these facilities to determine the effectiveness of this form of treatment in reducing cyanide concentrations. This facility achieved substantially more effective treatment than the other two facilities that used the same cyanide destruction technology. As a result, the proposed cyanide limitations for facilities with subcategory A and/or C operations are based on the performance of hydrogen peroxide oxidation technology. EPA is proposing to repeal the current BPT limitations for cyanide for facilities with subcategory B and/or D operations because cyanide is not a pollutant of concern for those operations. See Section 9 of the TDD for discussion of the cyanide content of raw wastewaters generated by facilities with subcategory B and/or D operations.

The development of the variability factors used to determine BPT effluent limitations for BOD₅, TSS, COD, and cyanide from the LTA is discussed in section IX.F below. A detailed explanation of the development of the proposed BPT effluent limitations is found in Section 2.2 of the statistical support document. Additional discussion of the basis for developing treatment effectiveness data for cyanide destruction is presented in Section 8 of the TDD.

2. BCT

a. Methodology for determining revised BCT limits. EPA is today proposing revised BCT effluent limitations guidelines based on the Best Conventional Pollutant Control Technology (BCT) for four subcategories (A, B, C, and D) of the pharmaceutical manufacturing industry. These proposed guidelines, for the conventional pollutants BOD₅ and TSS, are based on the average performance of the best plants in these subcategories that employ advanced biological treatment (the technology basis of the

proposed BPT limitations). In developing and proposing revised BCT limits, EPA considered whether there are technologies that achieve greater removals of conventional pollutants than the proposed BPT, and whether those technologies are cost-reasonable according to the BCT cost test. In the four subcategories for which EPA proposes revised limitations today, EPA identified no technologies that achieve greater removals of conventional pollutants than those associated with the proposed BPT limits that are also cost-reasonable under the BCT cost test, and accordingly proposes BCT limits equal to the proposed BPT limits for those subcategories. The technologies considered for facilities with subcategory A and/or C operations included effluent filtration, polishing ponds, and the combination of effluent filtration and polishing ponds. EPA considered only effluent filtration for facilities with subcategory B and/or D operations.

EPA's analysis had several steps. First, EPA considered how best to define the BPT "baseline" for these purposes. In performing the BCT cost tests, the BPT baseline serves as the starting point against which more stringent technologies are analyzed. EPA considered three possible baselines: (i) the revised BPT limits proposed in today's notice; (ii) the actual long-term average discharge of conventional pollutants from plants in this industry, based on EPA's 1990 survey data; and (iii) a level of control equal to the amount of discharge allowed under existing BPT regulations. Of these, the first is the most stringent and the third is the least stringent level of control. EPA has selected the proposed revised BPT limits because the revised BPT limitations reflect the average performance of the best facilities in the industry as required by the Clean Water Act. Moreover, dischargers would be required to meet these limitations irrespective of the BCT analysis and hence they provide a more realistic starting point against which to analyze potentially more stringent candidate BCT technologies.

As the second step in determining whether to revise BCT limits, EPA identified candidate BCT technologies. Three candidate technologies were identified for facilities with subcategory A and/or C operations. Each incorporates advanced biological treatment plus one of the following: (1) Multimedia filtration; (2) polishing ponds; or (3) polishing ponds followed by multimedia filtration. The only option evaluated for facilities with subcategory B and/or D operations was

multimedia filtration. EPA was able to evaluate these candidate technologies for facilities with subcategory A and/or C operations and for facilities with subcategory B and/or D operations by estimating costs and pollutant removals on a plant-by-plant basis. The design parameters and other engineering assumptions for these cost and pollutant removal estimates applicable to both A and/or C and B and/or D facilities are explained in Section 10 of the TDD. Section 7 of the TDD also discusses EPA's evaluation and selection of the various candidate BCT technologies. The Agency solicits comment on the above described candidate technologies, and other candidate technologies that might be more cost-effective than multimedia filtration, polishing ponds, or the combination thereof. See Section XIV of this preamble, solicitation number 30.0.

EPA found that all candidate technology options failed the BCT cost test in the two subcategory groups (A and C, and B and D). As a result, EPA is today proposing to set BCT equal to proposed BPT in these two subcategory groups. See the Section 14 of the TDD for a complete discussion of the BCT methodology as applied in each of the subcategories.

b. *Alternative methodology for developing BCT limits.* EPA performed an alternative BCT analysis, in addition to the foregoing. This alternative analysis is based on the possibility that, notwithstanding today's proposal, BPT limits for this industry ultimately are not revised. In performing this analysis, EPA considered four candidate technology options for facilities with subcategory A and/or C operations and two candidate technology options for facilities with subcategory B and/or D operations. The technologies identified above plus advanced biological treatment is the first candidate technology option in each case. The analysis also uses, as its baseline, the level of control equal to the discharge allowed under the existing BPT regulations. This baseline was used in the development of the 1986 BCT limitations for the pharmaceutical manufacturing industry. EPA concluded from this alternative analysis that all candidate technology options fail the BCT cost test using the baseline for the 1986 analysis. Section 14 of the TDD provides more discussion of all BCT cost test analyses.

3. BAT

a. *Introduction.* EPA today is proposing both new and revised BAT effluent limitations guidelines based on the Best Available Technology

Economically Achievable (BAT) for four subcategories (A, B, C, and D) of the pharmaceutical manufacturing industry. The BAT effluent limitations proposed today would control certain priority and nonconventional pollutants discharged from plants in these subcategories at an end-of-pipe location. In developing these proposed effluent limitations, EPA identified technologies appropriate for individual priority and nonconventional pollutants.

b. *Establishing BAT limits.* EPA has identified 56 pollutants for possible control by BAT limitations for facilities with subcategory A and/or C operations. The proposed BAT limitations for these subcategories for cyanide and COD are identical to those established under BPT. EPA also is proposing limitations for ammonia for facilities with subcategory A and/or C operations based on incidental removal through steam stripping and advanced biological treatment. Of the remaining 53 priority and nonconventional pollutants for which limitations are being proposed today for facilities with subcategory A and/or C operations, 45 are volatile organic pollutants, which are treatable by steam stripping and steam stripping with distillation technologies. For facilities with subcategory A and/or C operations, EPA is today proposing BAT limitations for those pollutants based on steam stripping technology followed by end-of-pipe advanced biological treatment. The remaining eight pollutants are nonstrippable organic compounds, which are biodegradable. Consequently, EPA is proposing advanced biological treatment as the basis for BAT limitations for these pollutants for facilities with subcategory A and/or C operations.

For facilities with subcategory B and/or D operations, EPA has identified 54 pollutants for control by the proposed BAT limitations based on advanced biological treatment (the technology selected as the basis for the proposed BPT). As discussed under BPT, cyanide is not a pollutant of concern for subcategory B and/or D operations and EPA is proposing to repeal the current BAT limitations for cyanide for facilities with subcategory B and/or D operations. EPA also has determined that ammonia is not a pollutant of concern for these subcategories. EPA is proposing to set BAT limitations for COD for facilities with subcategory B and/or D operations at the levels achieved by compliance with the proposed BPT limitations.

c. *Rationale for BAT limitations by subcategory.* Section V.A.1 summarizes the factors to be considered in establishing the BAT level of control. In general, BAT represents the

performance of the best available technology economically achievable among plants with shared characteristics. Where existing pollution control technologies are uniformly inadequate, BAT may be transferred from a different subcategory or industrial category. BAT limitations may be based upon process changes, as well as upon measures that are not common industry practice.

The Agency is today proposing BAT effluent limitations for facilities with subcategory A, B, C, and D operations. The rationale for the proposed effluent limitations in each subcategory is presented in the following paragraphs.

(1) Fermentation and Chemical Synthesis Subcategories, Subparts A and C

The technology basis for the current BAT limitations is cyanide destruction plus end-of-pipe biological treatment.

In establishing the proposed BAT effluent limitations, EPA considered four regulatory options to reduce the generation of priority and nonconventional pollutants by facilities with subcategory A and/or C operations. These options are as follows:

Option (1)—In-plant cyanide destruction plus advanced biological treatment with nitrification.

This option is identical to the technology selected as the basis for the proposed BPT limitations for facilities with subcategory A and/or C operations, except that provisions for nitrification are added.

Option (2)—In-plant cyanide destruction and steam stripping plus advanced biological treatment.

This option adds in-plant steam stripping to the technology described in option 1 for the purpose of removing strippable volatile organic pollutants prior to dilution from commingled wastestreams and air stripping in treatment basins and impoundments at the end of the pipe. Steam stripping will also remove ammonia, thereby obviating the need to add nitrification to end-of-pipe biological treatment.

Option (3)—In-plant cyanide destruction and steam stripping with distillation plus advanced biological treatment.

This option adds in-plant fractional distillation to the technology described in Option 2 for the fractional purpose of achieving greater removal of difficult to strip volatile organic pollutants (such as methanol) prior to dilution from commingled wastestreams and air stripping in treatment basins and impoundments at the end of the pipe.

Option (4)—In-plant cyanide destruction and steam stripping with

distillation plus advanced biological treatment plus end-of-pipe Granular Activated Carbon (GAC) adsorption technology.

This option adds Granular Activated Carbon adsorption treatment to the technology described in Option 3 for the purpose of achieving additional removal of the pollutant parameter COD beyond that achieved by Option 3.

EPA selected Option 2 as the proposed technology basis for BAT limitations for facilities with subcategory A and/or C operations because EPA believes this option represents the best available technology economically achievable, considering all statutory factors.

The Agency found that the annual incremental increase in electrical power consumption for all facilities to achieve Option 2 was 13,200 MW. This increase is equivalent to an increase of approximately 0.25 percent of the pharmaceutical industry's purchased electrical energy usage in 1990. Using the industry's 1990 purchased electrical energy usage as a baseline, the estimated incremental increases for electrical power consumption for the remaining options were, for Option 3, an increase of 13,800 MW and, for Option 4, an increase of 17,900 MW. With respect to energy needs associated with steam generation for steam stripping and distillation, the Agency found that Option 2 would result in 720,000 MW of incremental energy consumption, or approximately an 8 percent increase above the industry's 1990 total energy consumption. For Option 3, EPA found that 2,220,000 MW of incremental energy consumption, or a 25 percent increase above the industry's 1990 total energy consumption, would be required. EPA did not select Option 3 as proposed BAT because of this large increase in energy consumption required for steam generation. This decision is consistent with the CWA's requirement that EPA take into account energy requirements in selecting BAT. While steam generation under Option 2 requires slightly higher energy consumption than the 1990 baseline, the Agency notes that the potential for solvent recovery and reuse will substantially offset these energy expenditures. See Section XII.B of this preamble for further discussion of "clean fuels." Further discussion of these non-water quality environmental and energy impacts also is presented in Sections 12 and 15 of the TDD.

EPA also is proposing standards to control COD, based upon advanced biological treatment. These proposed BAT limitations are based on the performance of the "best" performers among facilities with subcategory A

and/or C operations. EPA believes that a substantial portion of the raw waste load COD can be removed in plant, prior to advanced biological treatment, by application of steam stripping technology—upon which the proposed BAT limitations for priority pollutants and the other nonconventional pollutants are based. However, EPA lacks sufficient data at this time to quantify the removal of COD achievable through in-plant steam stripping, and in turn the further removal of remaining COD load achievable by advanced biological treatment, and therefore does not propose its subcategory A and/or C BAT limitations for COD based on that combination of technologies. EPA solicits data and comments concerning the establishment of EPA for COD for subcategories A and C based on steam stripping plus advanced biological treatment. See Section XIV, solicitation number 20.

In estimating the energy consumption for steam generation associated with Option 3, EPA assumed, based on available data, that very high volumes of wastewater would need to be stripped and distilled, thus requiring high demands for steam. EPA believes that this assumption is very conservative because the Agency assumed from the 308 questionnaire responses that wastewater streams containing high concentrations of volatile organic pollutants could not be segregated from streams containing minimal or no concentrations of these pollutants. EPA believes that stream segregation is possible. EPA further expects that more recent data will show that the volume of wastewater that would be subject to steam stripping and distillation is substantially lower than the volume assumed in this proposal. Such lower volumes would also invariably result in higher concentrations of the volatile organic pollutants to be stripped. Considerably less steam, and hence considerably less energy, would be necessary to strip (Option 2) or distill (Option 3) such pollutants from low volume, high concentration wastewater. If more recent data fulfills this expectation, the Agency may reconsider Option 3 for A and/or C subcategory facilities. Therefore, EPA invites comments and data regarding the volume of wastewater that may require steam stripping and the pollutant concentrations in those wastestreams. See Section XIV, solicitation numbers 6.0 and 15.6. EPA also solicits comments on the use of distillation technology for the purpose of obtaining additional removal of pollutants such as methanol that are difficult to steam

strip. See Section XIV, solicitation number 15.9.

The Agency considered other non-water quality environmental impacts of the selected option, including the role which this proposal may play in the minimization, recycle, and disposal of characteristic (ignitable) volatile organic wastes. EPA has determined that Options 2 and 3 will generate 52,200 and 61,000 metric tons per year of condensates, respectively (more than Option 1 because of the use of steam stripping and steam stripping with distillation technologies). The condensates may include both halogenated and nonhalogenated solvents. Plants may choose to purify these condensates and then recycle/reuse the purified solvents as raw materials or use the condensate streams as fuel for incinerators either on or off site. If plants choose the latter approach, EPA has determined that adequate commercial incinerator capacity exists. Although EPA believes that most facilities will either recycle or incinerate their steam stripping condensates on-site because, in many cases, adequate recycle or incineration capability exists on-site, the Agency has adopted the conservative approach in its BAT cost estimates by assuming all condensates will be disposed of by off-site incineration. Because Option 3 features distillation in addition to steam stripping and achieves greater organic pollutant removal, resulting in a higher volume of condensates, EPA determined that the estimated costs of off-site incineration of the resulting condensates would be about 10 percent higher for Option 3 than for Option 2. Because the cost differential between Options 2 and 3 represents only a small part of the total costs associated with Option 3, EPA did not regard it as a significant factor. Accordingly, EPA concluded that the generation of condensates as a result of steam stripping and steam stripping with distillation technology does not provide a basis for choosing between technology Options 2 and 3 as the basis for BAT limitations for facilities with subcategory A and/or C operations. A more complete discussion of the Agency's waste minimization and combustion strategy and its relationship to this industry and rulemaking is presented in Section XII.B of this preamble and in Section 7 of the TDD.

The Agency also considered the effect of Options 1, 2, 3, and 4 on the current levels of air emissions from wastewaters at facilities with subcategory A and/or C operations. EPA used the WATER7 computer model employed by the EPA Office of Air and Radiation (OAR) in the

recently promulgated Hazardous Organic NESHAP (HON) for the Synthetic Organic Chemical Manufacturing Industry (SOCMI), in conjunction with Section 308 questionnaire responses, to evaluate the 1990 levels of air emissions from wastewater for this industry. The results of the analyses were used to estimate air emission increases or decreases for the regulatory options. The Agency estimates that Option 1 would result in a minimal increase in air emissions, while Options 2 and 3 would decrease air emissions by 5,300 and 6,350 metric tons per year, respectively. Option 4 would achieve the same air emission reduction as Option 3. In EPA's view, these beneficial non-water quality environmental impacts militate in favor of selecting a technology option employing steam stripping or distillation (i.e., Options 2, 3 or 4).

The Agency did not find that the age of equipment and facilities involved provided any basis for choosing among the options. The Agency also evaluated whether the engineering aspects of the options were compatible with the manufacturing processes employed and potential process changes at facilities with subcategory A and/or C operations. EPA concluded that the engineering aspects of all four options were compatible with current manufacturing processes and possible process changes at these facilities, and the results of this evaluation did not provide a basis for selecting an option.

(2) Biological and Natural Extraction and Mixing/Compounding/Formulating Subcategories, Subparts B and D

EPA considered four regulatory options to reduce the generation of priority and nonconventional pollutants by facilities with subcategory B and/or D operations. In selecting and evaluating these technology options for BAT for these facilities, EPA examined the 1990 questionnaire data supplied by the fourteen facilities with subcategory B and/or D operations only that discharge directly into surface waters. Among other things, EPA undertook to characterize the process wastewater from these facilities in order to identify the best technologies available to treat the pollutants of concern. The data supplied by these facilities indicate that the process wastewater of these direct dischargers is significantly different, in terms of the pollutants present and their concentrations, from the process wastewater of indirect discharging facilities with subcategory B and/or D operations. EPA is unable to account for this marked difference, because the processes employed by the direct and

indirect dischargers with subcategory B and/or D operations seem to be the same, and therefore EPA has some doubts that these data depict the typical wastestreams of direct dischargers with subcategory B and/or D operations. Although EPA proposes BAT limitations for these facilities based on the conclusions it drew from the data, EPA also solicits comment on those conclusions and invites additional data concerning the processes and wastewater characteristics (flow and pollutant concentration) of these facilities. See Section XIV, solicitation number 7.0. Because new data for 1991–1994 may establish greater similarities between the process wastewaters of direct and indirect dischargers with operations than are evident today, EPA is also considering and specifically inviting comment on whether it should promulgate BAT limitations based on the model treatment technology selected by EPA as the basis for its proposed PSES limitations for facilities with subcategory B and/or D operations. See Section IX.E.5 for a discussion of the reasoning underlying that proposal.

In addition, in the event a facility with subcategory B and/or D operations changes its mode of discharge and decides to discharge its wastewater directly to surface waters (rather than through a POTW), EPA is considering establishing BAT limitations for such dischargers that reflect the wastewater characteristics reported by the indirect dischargers with subcategory B and/or D operations. The possibility that an indirect discharger may change its mode of discharge and thus become subject to BAT limitations rather than to PSES further suggests to EPA that it should consider the entire universe of data from facilities with subcategory B and D operations—not just those currently with direct discharges—in setting BAT limits. Therefore, EPA seeks comment on whether it should promulgate BAT limitations for this subcategory based on steam stripping technology, which EPA has determined is appropriate technology for the wastestreams reported by indirect dischargers in this subcategory. See Section XIV, solicitation number 7.0.

The four options considered by EPA are as follows:

Option (1)—Advanced biological treatment.

This option is identical to the proposed technology basis for BPT for facilities with subcategory B and/or D operations.

Option (2)—In-plant steam stripping plus advanced biological treatment.

This option adds in-plant steam stripping to the technology described in

Option 1 for the purpose of removing strippable organic pollutants prior to dilution from commingled wastewater streams and air stripping in treatment basins and impoundments at the end of the pipe.

Option (3)—In-plant steam stripping with distillation plus advanced biological treatment.

This option adds in-plant fractional distillation to the technology described in Option 2 for the fractional purpose of achieving greater removal of difficult to strip volatile organic pollutants (such as methanol) prior to dilution from commingled wastestreams and air stripping in treatment basins and impoundments at the end of the pipe.

Option (4)—Steam stripping with distillation plus advanced biological treatment plus end-of-pipe Granular Activated Carbon (GAC) adsorption technology.

This option adds Granular Activated Carbon adsorption treatment to the technology described in Option 3 for the purpose of achieving additional removal of the pollutant COD beyond that achieved by Option 3.

EPA is proposing Option 1 as the technology basis for BAT limitations for facilities with subcategory B and/or D operations because, on the basis of the data submitted by the direct dischargers in these subcategories, EPA determined that this technology basis is the best available technology economically achievable for these pollutants. However, as discussed above, EPA is seriously considering and specifically invites comment on setting BAT limitations for these plants based on the PSES model technology for facilities with subcategory B and/or D operations. In making the proposed BAT determination, EPA analyzed data for each facility identified through the 1989 Pharmaceutical Screener Questionnaire and the 1990 Detailed Questionnaire as engaging in subcategory B and/or D operations. The results of the screener questionnaire indicate that, nationwide, 14 pharmaceutical manufacturing plants with direct discharges engage only in subcategory B and/or D operations (excluding subcategory E research activities). These 14 facilities reported to EPA in response to the 1990 detailed questionnaire that they discharge BOD₅, TSS, COD, six solvents and no priority pollutants. Of the six solvents, the facilities reported discharging only two in quantities exceeding a combined subcategory total of 1000 lbs/year. EPA's analysis of the questionnaire data indicates that the total nonconventional pollutant loadings discharged, on average, for each facility with subcategory B and/or D operations in

1990 was 1,660 pounds/year. In addition, these 14 facilities reported in their questionnaire responses that they emit from wastewater a total of 170 pounds/year of volatile organic pollutants. Subsequent analysis by EPA using its WATER7 model indicates that these 14 facilities may actually emit closer to 35,000 pounds/year from wastewater. See Section 12 of TDD for discussion of difference between questionnaire results and WATER7 results. By way of comparison, facilities with subcategory A and/or C operations reported in the 1990 questionnaire that they emit from wastewater a total of 3.2 million pounds/year of volatile organic and priority pollutants, and the WATER7 model projected 14 million pounds/year of those pollutants from wastewater.

Based on its evaluation of the data available to it, EPA proposes to base BAT limitations for facilities with subcategory B and/or D operations on advanced biological treatment (PSES Option 1 minus cyanide destruction). In view of the comparatively small quantities of pollutants reported to be discharged and emitted from wastewater from the 14 existing facilities with subcategory B and/or D operations only, EPA has determined that the chosen technology basis for the proposed BAT limit is best suited to the type of wastewater the data describe for direct discharges in these subcategories. Other technology options, which incorporate steam stripping or steam stripping with distillation technologies, are designed to remove large quantities and many varieties of solvents from process wastewater. They are not optimal treatment technologies for the type of wastestreams reported by the 14 direct dischargers in these subcategories, because the 1990 data indicate that these direct dischargers discharge only 6 solvents (in contrast to the 45 solvents reported to be discharged by the facilities with subcategory A and/or C operations), and then in relatively small amounts (an average of 1,660 pounds/year for facilities with subcategory B and/or D operations, compared to an average of 14,600 pounds/year for facilities with subcategory A and/or C operations). Accordingly, based on the data available to EPA for these facilities from the 1990 questionnaire, EPA is not proposing steam stripping or steam stripping with distillation as part of the technology basis for BAT for facilities with subcategory B and/or D operations.

However, in the event that new data for these facilities show that the wastestreams of these facilities actually resemble those of the indirect dischargers in these subcategories, EPA

proposes to base the BAT limitations on steam stripping technology, which EPA has determined is the best available technology for wastestreams of that character. See Section IX.E.5. Accordingly, EPA specifically invites comments on establishing BAT limitations equal to the proposed PSES for those pollutants, including those that EPA has determined pass through as part of co-proposal (1). See Section XIV, solicitation number 7. In addition, if EPA promulgated BAT limitations based on steam stripping or steam stripping with distillation, EPA would include BAT limitations on phenol, acetonitrile and polyethylene glycol 600 (based on advanced biological treatment), which are present in the wastestreams of indirect dischargers but which EPA does not propose to regulate under either PSES co-proposal because EPA has concluded that they do not pass through POTWs.

The Agency has estimated that the facilities with subcategory B and/or D operations would incur total post-tax annualized costs of \$0.71 million in complying with Option 1. The estimated total post-tax annualized costs for complying with other options are \$1.5 million for Option 2, and \$2.9 million for Option 3. The Agency estimated that none of the options would result in any closures or unemployment. These impacts, and the methodology behind them, are explained in greater detail in Section XI.B of this preamble and in the Economic Impact Analysis. Based upon these findings, EPA concluded that all four options are economically achievable. EPA selected Option 1 because it determined that option represented that best available technology from among all the economically achievable options.

In evaluating the non-water quality environmental impacts of the options, specifically electrical power consumption, the Agency found that the annual incremental increase in electrical power consumption for all facilities to achieve Option 1 was 265 megawatts (MW) beyond current usage (the same as for the proposed BPT limits). This is equivalent to an increase of approximately 0.005 percent of the pharmaceutical industry's purchased electrical energy usage in 1990. The incremental increases for electrical power consumption for the remaining options were: for Options 2 and 3, an increase of 182 MW and 364 MW, respectively, for all facilities for which EPA estimated compliance costs; and for Option 4 an increase of 911 MW for all facilities for which EPA estimated compliance costs. Further discussion of these non-water quality environmental

impacts are presented in Section 12 of the Technical Development Document.

The Agency considered other non-water quality environmental impacts of the proposed option, including the role which this proposal may play in the minimization, recycle, and disposal of characteristic (ignitable) volatile organic wastes. EPA has determined that Options 2, 3 and 4 will generate 76 metric tons per year of condensates as a result of the use of steam stripping or steam stripping with distillation technologies at direct discharging plants. Based on the small increase in condensate generation associated with Options 2, 3 and 4 EPA has concluded that the recovery opportunities or incineration issues prompted by condensate generation do not provide a basis for choosing one of the technology options as the basis for proposed BAT limitations for facilities with subcategory B and/or D operations. The Agency also considered the effect of these four options on the current levels of air emissions from wastewater at facilities with subcategory B and/or D operations. To do this, EPA used the WATER7 computer model to evaluate the 1990 levels of air emissions from wastewater for facilities with subcategory B and/or D operations. The results of the analyses were used to estimate air emission increases or decreases for the regulatory options. The Agency estimates that Option 1 would result in a minimal increase in air emissions, while Options 2, 3 and 4 would decrease air emissions by 16 metric tons per year. EPA concluded that the changes from current emission levels are not significant enough to justify selection of Options 2, 3 and 4.

EPA also concluded that the engineering aspects of all four options were compatible with current manufacturing processes employed and potential process changes at facilities with subcategory B and/or D operations and thus did not provide a basis for selecting an option. Similarly, the age of equipment and facilities involved did not provide any basis for selecting among the options.

The selection of Option 1 as BAT for facilities with subcategory B and/or D operations reflects, in large part, EPA's conclusion, based on currently available data, that BPT level biological treatment can degrade the relatively small load of organic pollutants generated by these facilities with a low occurrence of air emissions during advanced biological treatment. The Agency has noted, however, that this industry is dynamic with respect to its production processes. Thus, volatile organic pollutant loading data requested by EPA for 1991-1994

may lead to a different conclusion regarding the need for and feasibility of controlling volatile organic pollutants. See Section XIV, solicitation number 7.

d. Point of regulation. EPA considered three different points of compliance monitoring for facilities with subcategory A and/or C operations in establishing the proposed BAT effluent limitations for control of strippable and nonstrippable organic pollutants, and cyanide and ammonia. These points are located: (1) In-plant prior to dilution by non-process wastewater, commingling with other process wastewater streams not containing the regulated pollutants at treatable levels, and any conveyance, equalization, or other treatment units that are open to the atmosphere; (2) in-plant after commingling with other regulated process wastewater streams but prior to open-air primary treatment; and (3) at the final effluent point or end-of-pipe.

EPA is proposing BAT limitations for 45 volatile and semivolatile pollutants for facilities with subcategory B and/or D operations based on advanced biological treatment at the end of the pipe because currently available data does not support basing such limitations on in-plant steam stripping or steam stripping with distillation technologies. For facilities with subcategory A and/or C operations, EPA is proposing to set BAT limitations based on advanced biological treatment at the end of the pipe for eight semivolatile organic pollutants and COD because these pollutants are not strippable. For these facilities, EPA also proposes to enforce limits on cyanide inside the discharger's facility at in-plant location (1). EPA is proposing BAT limitations for 37 volatile and semivolatile pollutants plus ammonia for facilities with subcategory A and/or C operations based on in-plant steam stripping followed by advanced biological treatment at the end of the pipe.

In the usual case, compliance monitoring for NPDES permits occurs at the end of the pipe. See 40 CFR 122.45(a). However, the NPDES regulations also authorize permitting authorities to impose in-plant monitoring requirements on a case-by-case basis. 40 CFR 122.45(h). Those regulations provides that when permit effluent limitations or standards imposed at the point of discharge are impractical or infeasible, limitations or standards may be imposed on internal wastestreams before mixing with other wastestreams or cooling waters. *Id.* Under that regulation, the permit writer must describe in the fact sheet the exceptional circumstances that make such limits necessary. Section

122.45(h)(2) lists examples of exceptional circumstances that could justify such in-plant monitoring requirements. EPA also proposes to provide in the regulations that the BAT limitations set forth in the tables for subcategories A and C do not apply for any pollutant for which the permit writer finds it necessary to specify in-plant monitoring requirements under 40 CFR 122.44(i) and 122.45(h). EPA proposes that limitations for those pollutants would be established on a best professional judgment basis pursuant to 40 CFR 125.3. Permit writers in such cases should use as guidance the standards proposed as PSES for the particular pollutants as set forth at §§ 439.16(a)(1) and 439.36(a)(1) of the proposed regulation, because the proposed standards for those pollutants reflect in-plant monitoring based or the steam-stripping component of the BAT technology.

In the event that EPA decides to specify an in-plant monitoring location for the 12 highly strippable volatile organic pollutants, EPA would also propose to establish different BAT limitations corresponding to that location. EPA would likely use as a model the proposed pretreatment standards for existing sources in these subcategories for the reasons set forth above.

In developing this proposal, EPA considered establishing in-plant monitoring locations for all 45 volatile organic pollutants for facilities with subcategory A and/or C operations. EPA had several reasons for considering that approach. First, EPA was concerned that limits imposed at the end of the pipe for these pollutants could be impractical or infeasible to enforce. The limitations being proposed for the 45 volatile organic pollutants are based on BAT model technology steam stripping followed by advanced biological treatment. Many of these proposed limitations are only marginally above the levels at which these pollutants can be detected in the wastestreams. Dilution of these regulated wastestreams with other streams not containing the regulated pollutants, followed by incidental air stripping in primary and secondary treatment units, would in most cases cause the pollutants to be present at or below detection by current analytical methods. Thus, EPA was concerned that neither the discharger nor the permitting authority could practicably or feasibly determine, at the end of the pipe, whether the limits in fact were being met. Second, EPA was also concerned that monitoring for some pollutants at the point of discharge would be impractical and infeasible as

measures of the performance of the BAT control technologies, because EPA would have no way of knowing whether reductions in wastewater discharges are being achieved by application of the control technology or by air emissions in wastewater conveyance and treatment facilities. Companies are not required to install EPA's model BAT technology and can choose how they wish to achieve the limitations in these regulations. (EPA uses such information to review existing effluent limitations and to determine, consistent with sections 304(b) and 304(m) of the Clean Water Act, whether revisions are necessary.) Third, in-plant monitoring requirements could promote pollution prevention opportunities for recycle and reuse of volatile organic pollutants, including nonhalogenated volatile organic compounds (e.g., methanol), derived from application of in-plant technologies, like steam stripping. These compounds are considered "clean fuels." See Section XII.B for a discussion of "clean fuels." Reuse of these compounds as fuel could also help reduce a discharger's energy needs, a factor EPA must consider under section 304(b) of the Clean Water Act.

In considering whether to establish in-plant limitations for the 45 volatile organic pollutants, EPA also weighed the likelihood that wastewater pollutants will be transferred to the air in the course of primary or secondary treatment. Based on its analyses using the WATER7 model and questionnaire response data, EPA believes that wastewater from subcategory A and/or C facilities can indeed produce significant air emissions. EPA also believes that the steam stripping component of the proposed BAT technology will significantly reduce the likelihood of these emissions, because it achieves a removal efficiency of 99% for most of these pollutants. EPA further emphasizes that air stripping is not part of the proposed BAT technology.

Although EPA concluded that it has the legal authority to establish in-plant monitoring requirements, EPA has determined as a matter of policy that proposing such requirements today to account for these emissions would be premature because of the impending rulemaking for this industry under the Clean Air Act. As discussed in greater detail in Section X below, EPA expects to propose MACT standards for the pharmaceutical industry on the basis of the same steam stripper design employed in this water rulemaking. EPA also expects in the Clean Air Act rulemaking to regulate all volatile organic hazardous air pollutants (HAPs), including many of the 45 volatile

organic pollutants covered by this proposed rule. The least stringent control option preliminarily identified in Section X would require all wastewater streams with a flow of 100 liters per minute or greater and a 1,000 ppmw or greater volatile organic HAP concentration to be equipped with controls. Thus, the Agency intends that both rules ultimately will be based on the same control technologies for the same high concentration low volume process wastewater streams that contain the pollutants of concern. In short, EPA expects that the non-water quality environmental benefits that could be achieved by establishing in-plant monitoring requirements in this rulemaking will be realized under the statute that provides the most direct and effective means for controlling the air emissions at issue. By coordinating these rulemakings to the extent that external deadlines allow, EPA hopes to address the multi-media issues associated with the manufacture of pharmaceuticals while using, respectively, the statutory tools best suited to the particular media being protected.

EPA specifically solicits comment on all issues pertaining to the establishment of in-plant limitations on a case-by-case basis, including the burden imposed on permit writers, the recommended limitations, and the reasons EPA considered for setting limitations in-plant on a national basis. See Section XIV, solicitation numbers 7.2, 15.1–15.7. EPA also seeks comment on EPA's policy decision to defer at this time to the Clean Air Act rulemaking. See Section XIV, solicitation number 15.8.

4. NSPS

a. Introduction. The Agency today is proposing New Source Performance Standards (NSPS) for facilities with subcategory A, B, C, and D operations in the pharmaceutical manufacturing industry. New plants have the opportunity to incorporate the best available demonstrated technologies, including process changes, in-plant controls, and end-of-pipe treatment technologies. Current regulations establish NSPS for cyanide based on alkaline chlorination for all four manufacturing subcategories. EPA proposes to revise these standards for facilities with subcategory A and/or C operations and to repeal them for facilities with subcategory B and/or D operations.

b. Definitions of new source. EPA's NPDES regulations define the term "new source" at 40 CFR 122.2 and

122.29. Pursuant to those regulations, to be a "new source" a source must:

- (1) be constructed at a site at which no other source is located;
- (2) totally replace the process or production equipment that causes the discharge of pollutants at an existing source; or
- (3) have processes substantially independent of an existing source at the same site, considering the extent of integration with the existing source and the extent to which the new facility is engaged in the same general type of activity as the existing source. 40 CFR 122.29(b).

Any new source subject to part 439 that was a "new source" as defined under 40 CFR 122.29 prior to the date on which the New Source Performance Standards proposed today are promulgated will continue to be subject to the current NSPS regulations for the subpart to which the source is subject until the expiration of the applicable time period specified in 40 CFR 122.29(d)(1). After that time, the source is no longer considered to be a new source and will be required to achieve the BPT, BCT and BAT effluent limitations proposed in this rulemaking applicable to the source for its subcategory. EPA defines new source for the purpose of NSPS in this rulemaking as a source that commences construction after promulgation of the standards being proposed today, rather than after proposal, because, in accordance with the schedule established in the 304(m) Consent Decree, as modified, EPA does not expect to promulgate final standards within 120 days after proposal. See 40 CFR 122.2 (definition of New Source).

c. NSPS options and selection. (1) Fermentation and chemical synthesis subcategory, subparts A and C. EPA today is proposing NSPS for 58 priority, nonconventional, and conventional pollutants for facilities with operations in the fermentation and chemical synthesis (A and C) subcategories. These proposed standards are based on the best available demonstrated control technology, process, operating method, or other alternative. In developing these proposed standards, the Administrator considered factors including the cost of achieving effluent reductions, non-water quality environmental impacts, and energy requirements.

(i) Priority and nonconventional pollutants. EPA today is proposing New Source Performance Standards for 56 priority and nonconventional pollutants for facilities with subcategory A and/or C operations. In so doing, EPA evaluated two technology options described earlier in section IX.E.3.c.1.

The two options are: (1) In-plant cyanide destruction and steam stripping with distillation plus advanced biological treatment; and (2) option 1 plus Granular Activated Carbon adsorption treatment. EPA did not consider a technology option based primarily on steam stripping without distillation because it is not as effective as distillation in removing pollutants such as methanol, that are difficult to strip. EPA is proposing NSPS based on the technology described in Option 1 for subcategories A and C because EPA has determined that it is the best available demonstrated control technology for treating and removing the pollutants of concern for these subcategories. EPA selected a more stringent NSPS technology than its chosen BAT technology because new sources have the opportunity to segregate their process wastewater in such a way as to minimize the amount of wastewater that will require steam stripping with distillation, thereby reducing the adverse energy impacts that prevented EPA from selecting this technology as BAT.

EPA considered the potential cost of the proposed NSPS technology for new plants, as well as the costs associated with Option 2, which EPA did not select. EPA concluded that costs associated with any option would not be so great as to present a barrier to entry, because EPA anticipated no economic impacts for existing source subcategory A and C plants if they were to implement the proposed NSPS technology. The Agency also considered energy requirements and other non-water quality environmental impacts when comparing the GAC technology (Option 2) with Option 1. EPA concluded that there would be only a slight difference in the energy requirements associated with Options 1 and 2. There are no significant differences in the other non-water quality environmental impacts between the two options considered. EPA did not select Option 2 as the proposed basis for NSPS because, as noted above, EPA does not have sufficient data to quantify the amount of COD removed after application of steam stripping with distillation technology and therefore could not determine whether granular activated carbon technology is appropriate to remove remaining COD loads. See Section 16 of the TDD for further discussion of NSPS for all four subcategories.

EPA is proposing standards to control COD based upon advanced biological treatment, which is the BAT technology. These proposed standards are based on the performance of the "best"

performers with subcategory A and/or C operations. EPA believes that a substantial portion of the raw waste load COD can be removed in plant, prior to advanced biological treatment, by application of steam stripping with distillation technology—upon which the proposed NSPS for priority pollutants and the other nonconventional pollutants are based. However, EPA lacks sufficient data at this time to quantify the removal of COD achievable through in-plant steam stripping with distillation, and in turn the further removal of remaining COD load achievable by advanced biological treatment, and therefore is not able to propose subcategory A and/or C NSPS for COD based on that combination of technologies. EPA solicits data and comments concerning the establishment of NSPS for COD for subcategories A and C based on steam stripping with distillation plus advanced biological treatment. See Section XIV, solicitation number 20.

(ii) Conventional pollutants. EPA today is proposing NSPS for BOD₅ and TSS for the fermentation and chemical synthesis subcategories (A and C). As noted above for the proposed revised BPT limitations, EPA is not proposing to change the pH limitations incorporated in the existing NSPS. Based upon data available for this subcategory, the technology basis for these proposed standards—advanced biological treatment—represents the best available demonstrated level of performance (the one best performer) for the control of BOD₅ and TSS in these subcategories.

EPA considered the cost of the proposed technology basis for NSPS for new plants. EPA concluded that such costs are not so great as to present a barrier to entry, as demonstrated by the fact that one currently operating plant is performing at the NSPS level using this technology. The Agency considered energy requirements and other non-water quality environmental impacts and found no basis for any different standards than the proposed NSPS for conventional pollutants.

(2) Biological and Natural Extraction and Mixing/Compounding/Formulating Subcategories, Subparts B and D. EPA today is proposing New Source Performance Standards (NSPS) for 56 priority, nonconventional and conventional pollutants for facilities with Biological and Natural Extraction and Mixing/Compounding/Formulating (B and D) subcategory operations. These proposed standards are based on the best available demonstrated control technology, process, operating method, or other alternative. In developing these proposed standards, the Agency

considered factors including the cost of achieving effluent reductions, non-water quality environmental impacts, and energy requirements.

(i) Priority and Nonconventional Pollutants. EPA today is proposing New Source Performance Standards for 54 priority and nonconventional pollutants for facilities with subcategory B and D operations. In developing NSPS for these subcategories, EPA evaluated two technology options described earlier in Section IX.E.3.c.(2). The two options are: (1) In-plant steam stripping with distillation plus advanced biological treatment; and (2) Option 1 plus Granular Activated Carbon adsorption treatment.

EPA is today proposing Option 1 as the NSPS technology basis for subcategories B and/or D. In making this selection, EPA analyzed all of the questionnaire data supplied by facilities with subcategory B and/or D operations and projected the types and volume of volatile organic pollutants that would be present in treatable levels in process wastewaters from new facilities in these subcategories. Although the 1990 questionnaire data indicated that process wastewater from the 14 direct dischargers contained fewer pollutants in lower concentrations than the process wastewater of indirect dischargers (therefore justifying proposed effluent limitations based on advanced biological treatment alone, not including steam stripping with distillation), EPA has determined that there is no basis to conclude that data would adequately depict the wastewater characteristics of a new direct discharger. Thus, EPA relied instead on the entire universe of facilities with subcategory B and/or D operations, irrespective of their direct or indirect discharger status, on the theory that these facilities are more plentiful and hence statistically more significant. Because EPA has no basis for concluding that the wastewater characteristics are related to the manner of discharge, EPA saw no reason to confine its NSPS analysis to the 14 existing direct dischargers and to ignore the 67 indirect dischargers that reported data. In evaluating all of the data available to it for these subcategories from the 1990 questionnaire, EPA concluded that the vast majority of facilities with subcategory B and/or D operations have process wastewater with a comparatively wide variety of volatile organic pollutants in comparatively high concentrations, as reported by 67 of the 188 existing indirect discharging plants with subcategory B and/or D operations. EPA considers wastestreams of these 67

plants to be more typical of the wastestreams EPA expects to find in new sources in this subcategory. Therefore, EPA concluded that the process wastewater of new facilities with subcategory B and/or D operations was more likely to resemble the more typical subcategory B and/or D wastestreams, not the atypical wastestreams reported by the 14 existing direct dischargers in those subcategories. Based on that conclusion, EPA selected, as the proposed technology basis for NSPS for facilities with subcategory B and/or D operations, in-plant steam stripping with distillation treatment followed by end-of-pipe advanced biological treatment, which EPA has concluded represents the best available demonstrated treatment technology. EPA selected a more stringent NSPS technology than its chosen BAT technology because new sources have the opportunity to segregate their process wastewater in such a way as to minimize the amount of wastewater that will require steam stripping with distillation, thereby reducing the adverse energy impacts that prevented EPA from selecting this technology as BAT. See Section 5 of the TDD for further discussion of process wastewaters that EPA projects would be generated by facilities with subcategory B and D operations.

EPA considered the potential cost of the proposed NSPS technology for new plants. EPA concluded that costs associated with either option would not be so great as to present a barrier to entry. EPA predicted no economic impacts (i.e., closures) for existing source subcategory B and D plants if they were to implement the equivalent technology options considered as possible BAT for those subcategories. The Agency noted, however, that the BAT technology option (based primarily on steam stripping with distillation) was inappropriate treatment for the small reported quantities of volatile organic loadings, because the resulting small pollutant removals did not warrant the additional cost of steam stripping with distillation. See Section IX.E.3.c.(2) above.

The Agency also considered energy requirements and other non-water quality environmental impacts when comparing the GAC technology (Option 2) with Option 1. EPA concluded that there would be only a slight difference in the energy requirements associated with Options 1 and 2. There are no significant differences in the other non-water quality environmental impacts between the two options considered. EPA did not select Option 2 as the proposed basis for NSPS because, as

noted above, EPA does not have sufficient data to quantify the amount of COD removed after application of steam stripping with distillation technology and therefore could not determine whether granular activated carbon technology is appropriate to remove remaining COD loads. See Section 16 of the TDD for further discussion of NSPS for all four subcategories.

For reasons set forth above in the discussion of the proposed NSPS for facilities with subcategory A and/or C operations, EPA is proposing NSPS for the pollutant COD best performing advanced biological treatment. EPA is not proposing NSPS for COD based on in-plant steam stripping with distillation technology because it has not been able to date to quantify the removal of COD achievable through that technology. See Section XIV of this preamble, solicitation number 20.

(ii) Conventional Pollutants. EPA today is proposing NSPS for BOD₅ and TSS for facilities with Biological and Natural Extraction and Mixing/Compounding/Formulating subcategories (B and D). As noted above for the proposed NSPS for facilities with subcategory A and/or C operations, EPA is not proposing to change the pH limitations incorporated in the existing NSPS for facilities with subcategory B and D operations. Based upon data available for this subcategory, the technology basis selected for these proposed standards—advanced biological treatment—represents the most stringent demonstrated level of performance (the one best performer) for the control of BOD₅ and TSS in these subcategories.

EPA considered the cost of the proposed technology basis for the proposed NSPS for new plants. EPA concluded that such costs are not so great as to present a barrier to entry, as demonstrated by the fact that one currently operating plant is performing at the NSPS level using this technology. The Agency considered energy requirements and other non-water quality environmental impacts and found no basis for proposing any different standards than those based on the selected NSPS for conventional pollutants.

d. Point of Regulation. For the reasons set forth in Section IX.E.3.d., above in connection with BAT, EPA is proposing to specify an end-of-pipe monitoring location for its proposed NSPS standards for facilities with A, B, C and/or D operations (excluding cyanide, for which EPA proposes in-plant limitations for facilities with subcategory A and/or C operations). EPA seeks comments on all issues

pertaining to this proposal. See Section XIV, solicitation number 15. EPA also proposes to provide in the regulations that the standards set forth in the NSPS tables for subcategories A, B, C and D do not apply for any pollutant for which the permit writer finds it necessary to specify in-plant monitoring requirements under 40 CFR 122.44(i) and 122.45(h). EPA proposes that NSPS for those pollutants would be established on a best professional judgment basis pursuant to 40 CFR 125.3. Permit writers in such cases should use as guidance the standards proposed as PSNS for the particular pollutants (as set forth at §§ 439.17(a)(1), 439.27(a)(1), 439.37(a)(1) and 439.47(a)(1) of the proposed regulation), because those standards are based on the steam stripping with distillation technology that also represents the NSPS technology. See Section XIV, solicitation number 15.7.

5. PSES

Pretreatment Standards for Existing Sources (PSES) are established to prevent passthrough of pollutants from POTWs to waters of the United States, to prevent pollutants from interfering with the operation of POTWs, and to reduce non-water quality environmental impacts (e.g., concerns for worker safety and health, sludge contamination, and air emissions). CWA Section 307(b). The current PSES is based on cyanide destruction, which does not remove volatile organic pollutants. EPA is proposing to establish PSES for this industry to prevent passthrough from POTWs of the same pollutants proposed to be controlled by BAT for the respective subcategories, except polyethylene glycol 600, acetonitrile, and phenol. Standards for existing indirect discharging plants are based upon the best available technologies economically achievable, which may include process changes, in-plant controls, and end-of-pipe treatment technologies. As discussed in section 5.a below, EPA is also proposing to establish no PSES at this time for 33 volatile organic pollutants because there is some doubt that these pollutants actually pass through.

The Agency today is proposing to establish pretreatment standards for existing sources in the pharmaceutical manufacturing point source category. These standards would apply to plants in the four manufacturing subcategories of the industry. Currently, according to the 1990 detailed survey questionnaire responses, 259 plants report discharging to POTWs, 88 of which conduct predominantly A and C subcategory operations and 171 conduct only B and

D operations. In 1993, EPA solicited comments regarding PSES from nine POTWs that treated significant quantities of pharmaceutical wastewater. EPA received responses from six POTWs, each of which report treating significant amounts of pharmaceutical wastewater discharges. The questionnaires asked the respondents to comment on the need for pretreatment standards for the pharmaceutical manufacturing category and other matters relating to discharges from pharmaceutical plants. The six POTWs that responded to the questionnaire and their locations are: The Onondaga County Department of Drainage and Sanitation, Syracuse, NY; the Greenville Utilities Commission, Greenville, NC; the Bergen County Utilities Authority, Little Ferry, NJ; the North Shore Sanitary District, Gurnee, IL; the Passaic Valley Sewerage Commissioners, Newark, NJ; and the Puerto Rico Aqueduct and Sewerage Authority, Barceloneta, Puerto Rico.

Except as provided in 40 CFR 403.7 and 403.13, any existing indirect discharger subject to subparts A, B, C or D would be required to achieve the proposed PSES for the subcategory to which the facility is subject by a date three years from promulgation of the final rule.

a. Pass-Through Analysis. To determine whether pollutants indirectly discharged by plants in this industry pass through POTWs, EPA reviewed pharmaceutical manufacturing industry treatment performance data, responses to the detailed questionnaire, performance data for POTWs, and technical literature. In today's notice, EPA makes two alternative proposals associated with PSES and its pass-through determinations. Under co-proposal (1), for subcategories A and C, EPA concludes that nine priority and 42 nonconventional organic pollutants plus ammonia pass through POTWs. Therefore, for all but five nonconventional pollutants for which EPA has not selected a treatment basis, EPA proposes to establish categorical pretreatment standards to regulate those pollutants for subcategories A and C. Similarly under that co-proposal, for subcategories B and D, EPA proposes to establish categorical pretreatment standards to regulate the same pollutants (minus ammonia and cyanide, which EPA has determined are not present in the wastewater of facilities in those subcategories). Under co-proposal (2), EPA proposes that 33 volatile pollutants do not pass through and therefore does not propose PSES for those pollutants for any subcategory.

In determining whether to propose pretreatment standards for the four manufacturing subcategories, EPA first identified the pollutants of concern present in the wastewater characteristic of the particular subcategories. EPA determined from the available data that as many as ten priority pollutants and 45 nonconventional pollutants could be present, in varying amounts and frequencies, in the wastestreams of facilities in all four manufacturing subcategories (excluding cyanide and ammonia for subcategories B and D.) In selecting the pollutants for analysis and in performing the pass-through determination, EPA made three threshold decisions in view of the data available to it.

First, with respect to subcategories B and D, EPA used wastestream data pertaining to indirect discharging facilities rather than direct discharging facilities, because, for reasons EPA is unable to explain, the available data indicated that the wastestreams of direct dischargers were significantly different from and hence unrepresentative of the wastestreams for indirect dischargers in those subcategories. Accordingly, EPA concluded that it would be most appropriate to identify the pollutants of concern and ultimately evaluate the need for pretreatment standards based on the wastewater characteristic of the indirect dischargers that would be subject to such standards.

Second, based on that wastestream data, EPA identified cyanide destruction plus steam stripping followed by advanced biological treatment for subcategory A and/or C facilities and advanced biological treatment for subcategory B and/or D facilities as the best available technology economically achievable to remove the pollutants of concern from those wastestreams. EPA then used these technologies in its pass-through analysis as the basis for comparing the removal efficiencies accomplished through secondary treatment by POTWs.

Third, EPA made pass through determinations by pollutant for all four manufacturing subcategories together, because the data from indirect dischargers data available to EPA indicate that steam stripping is applicable to all four subcategory wastestreams at indirect discharging facilities. Based on these decisions, EPA then compared removal efficiencies achievable by well-operated POTWs employing secondary treatment with those achievable by direct dischargers employing the relevant technology for those subcategories. In co-proposal (1), EPA determined for subcategories A and C that 52 pollutants pass through

POTWs and for subcategories B and D that 50 pollutants pass through, based on the information available to it at this time.

For subcategories A and C, EPA also concluded that ammonia passes through because POTWs generally do not have the nitrification capability that comprises part of the technology basis for the proposed BAT limitations for those subcategories. With respect to cyanide for subcategories A and C, EPA found that this pollutant passes through POTWs because the removal of cyanide by BAT-level cyanide destruction units at direct discharging plants with subcategory A and C operations is significantly greater than the documented removals by POTWs with advanced secondary treatment. These findings regarding ammonia and cyanide are not affected by alternative co-proposals (1) and (2).

Based on the pass-through determination in co-proposal (1), EPA proposes to set pretreatment standards for 45 priority and nonconventional organic pollutants for all subcategories in addition to cyanide and ammonia for subcategories A and C. In determining whether these volatile and semi-volatile organic pollutants pass through POTWs, EPA employed its traditional pass through methodology as described above. EPA determined that dischargers in all subcategories could remove up to 99 percent or more of the volatile and semi-volatile organic pollutants from their wastestreams using the BAT technology basis which includes in-plant steam stripping for subcategory A and/or C facilities.

Relying on data reported in the Domestic Sewage Study, EPA then ascertained the removal efficiencies achieved by POTWs for those pollutants using secondary treatment. In evaluating removal efficiencies by POTWs for volatile and semi-volatile pollutants, EPA notes the fact that some of the removal occurring after wastewater leaves a manufacturing facility results from volatilization of these pollutants in the head works and unit operations preceding biological treatment of the POTWs. EPA has consistently refused in these circumstances to regard transfers of pollutants from wastewater to the air as treatment. See, e.g., 59 FR at 50665 (Pesticides guidelines); 58 FR at 36885 (Organic Chemicals, Plastics and Synthetic Fibers guidelines). Therefore, because of this volatilization, the quantity of a particular volatile or semi-volatile pollutant actually available to be removed by the POTW's secondary treatment works was less than the quantity of that pollutant present in the wastestream at the time it entered the

POTW collection system. Thus, the POTW treated—and hence removed—a smaller percentage of the pollutant than it would have achieved through its secondary treatment if volatilization en route had not occurred. For a detailed discussion of volatilization in the context of EPA's pass through determinations for all pollutants in all subcategories, see Section 17 of the TDD.

The pass-through determinations reflected in co-proposal (1) are supported by POTWs that treat wastewater generated by pharmaceutical manufacturing facilities. In a letter sent to EPA dated February 14, 1995, the Association of Metropolitan Sewerage Agencies (AMSA) urged EPA to establish national pretreatment standards for organic pollutants found in pharmaceutical wastewater. A copy of this letter is in the rulemaking docket. AMSA argued that a decision by EPA not to regulate these pollutants at the national level would shift the financial, technical and legal burden of regulation to POTWs, which would need to establish local limits for these pollutants on a plant-by-plant, pollutant-by-pollutant basis. Among other things, AMSA asserted that many of its POTW member organizations lack the on-site technical expertise to develop limits for the wide variety of volatile organic pollutants of potential concern. It further asserted that even where such expertise exists, the costs associated with establishing local limits in the absence of federal standards would be so significant that they would amount to unfunded mandates. AMSA also noted that pretreatment standards established at the national level would facilitate the enforcement of limits to protect against volatility, exfiltration and flammability concerns. AMSA concluded that promulgation of national pretreatment standards such as those contained in co-proposal (1) would be the most environmentally sound, timely, and cost effective method of addressing these pollutants of concern. EPA solicits comment on these arguments in support of co-proposal (1). See Section XIV, solicitation number 24.4.

Under co-proposal (2), EPA is considering a finding of no pass-through for 33 priority and nonconventional pollutants in all four subcategories. EPA is soliciting comments and data with respect to this finding. See Section XIV, solicitation number 24.3. EPA has developed co-proposal (2) because of concerns expressed by industry representatives that EPA's pass-through analysis under co-proposal (1) may not be correct for some of the 33 volatile organic pollutants such as methanol,

ethanol, and acetone. EPA believes that the additional data and comments received concerning the pass-through analysis for these 33 volatile organic pollutants will enable the Agency to make a final pass-through determination for these pollutants. EPA notes that co-proposal (2) does not affect EPA's pass-through findings regarding the 12 highly strippable organic pollutants (and cyanide and ammonia for subcategories A and C) for which EPA proposes to establish PSES independently.

EPA is not proposing pretreatment standards for several pollutants found in subcategory A, B, C and D facility wastestreams for the following reasons. (This part of the proposal is not affected by the issues addressed in co-proposals (1) and (2).) EPA has concluded for all four manufacturing subcategories that phenol does not pass through for the reasons set forth in the **Federal Register** Notices announcing the promulgation of effluent limitation guidelines and standards for the Pesticide Chemicals and Organic Chemicals, Plastics and Synthetic Fibers (OCPSF) industries. See 59 FR 50638, 50664-65 (September 28, 1993); 58 FR 36872, 36885-86 (July 9, 1993). In addition, EPA does not have sufficient data at this time to determine whether *acetonitrile* and *polyethylene glycol 600* pass through POTWs and therefore does not propose pretreatment standards to control them. Similarly, EPA lacks sufficient data to make a pass-through determination for COD generated by facilities with subcategory A and/or C operations, although EPA is concerned that certain refractory organic waste materials measured as COD that are generated by such facilities may pass through POTWs. (EPA has made a preliminary judgment that COD generated by facilities with subcategory B and/or D operations does not pass through POTWs. EPA will review this judgment based on new data as it becomes available.) EPA therefore is soliciting data and comments in order to make a pass-through determination with respect to *acetonitrile*, *polyethylene glycol 600*, and COD. See Section XIV of this preamble, solicitation numbers 26 and 27.3. In addition, as noted above, EPA is not proposing pretreatment standards for five nonconventional organic pollutants (formaldehyde, N,N-dimethyl formamide, N,N dimethyl acetamide, ethylene glycol, and dimethyl sulfoxide) for any subcategory because, although EPA has determined that they pass through based on the BAT-level technology, EPA has concluded that the PSES technology (in-plant steam stripping) is an inappropriate basis for pretreatment

standards because these pollutants are not strippable. Moreover, EPA currently has insufficient data to select a treatment technology that would be an appropriate basis for such standards. EPA is considering package biological treatment of selected wastestreams for this purpose and solicits comments and data on this and other possible technology bases for pretreatment standards. See Section XIV, solicitation numbers 27.1 and 27.2. EPA also solicits comment and data regarding other pollutants that may pass through or interfere with POTWs, e.g., sulfates and sulfides. See Section XIV, solicitation number 28.

b. Options Considered. EPA considered four technology options for PSES under two different regulatory co-proposal scenarios for facilities with subcategory A, B, C, and D operations. Under co-proposal (1), EPA would propose PSES for 12 highly strippable organic pollutants (plus cyanide at an in-plant location (1) for subcategory A and/or C facilities) and 33 less strippable pollutants (plus ammonia for subcategory A and/or facilities) at the point of discharge to the POTW sewer. In-plant location (1) is described in IX.E.3.d, above. Under co-proposal (2), EPA would propose PSES only for the 12 highly strippable organic pollutants, plus cyanide at an in-plant location (1) and ammonia at the point of discharge to the POTW sewer for subcategory A and/or C facilities. As discussed in subsection a, above, EPA would not propose any pretreatment standards for the 33 less strippable organic pollutants under co-proposal (2) because of issues raised concerning EPA's pass-through analysis for those pollutants.

Under co-proposals (1) and (2), EPA considered basing PSES on the following four technology options for facilities with subcategory A and/or C operations for those pollutants found to pass through:

Option (1) In-plant steam stripping plus in-plant cyanide destruction.

Standards based on this option would control up to eight priority and 38 nonconventional volatile organic pollutants plus cyanide (depending on the pass-through co-proposal considered). Twelve pollutants plus cyanide would be controlled at the in-plant location (1) and 34 pollutants (including ammonia) at the point of discharge to the POTW sewer.

Option (2) In-plant steam stripping/distillation plus in-plant cyanide destruction.

Standards based on this option would control up to eight priority and 38 nonconventional volatile organic pollutants plus cyanide (depending on

the pass-through co-proposal considered). Distillation affords significantly greater removal of volatile organic pollutants that are difficult to strip, such as methanol. Under this option, 22 volatile organic pollutants plus cyanide would be controlled at the in plant location (1) and 24 pollutants (including ammonia) would be controlled at the point of discharge to the POTW sewer.

Option (3) In-plant steam stripping/distillation plus in-plant cyanide destruction plus advanced biological treatment. The addition of advanced biological treatment would achieve additional volatiles removal beyond that achieved by the technology described in Option 2 as well as significant reductions in discharge levels of COD. Advanced biological treatment would also reduce discharge levels of nonstrippable organic pollutants that are biodegradable.

Option (4) In-plant steam stripping/distillation plus in-plant cyanide destruction plus advanced biological treatment plus granular activated carbon (GAC) treatment. The addition of granular activated carbon treatment to the technology described in Option 3 would further reduce COD discharge levels.

EPA considered the same four technology options for PSES for facilities with subcategory B and/or D operations, excluding in-plant cyanide destruction (cyanide and ammonia are not regulated pollutants at subcategory B and/or D facilities). EPA has selected Option 1 for PSES under both co-proposals for indirect discharging facilities with subcategory A and/or C operations. The Agency has evaluated the costs of this option based on co-proposal (1) and found that there would be no closures among affected facilities (for which costs were estimated by EPA) as a result of these costs. Therefore EPA determined the costs of Option 1 to be economically achievable based on co-proposal (1). EPA also found the other options to be economically achievable. EPA selected Option 1 because it determined that this option represents the best available technology among all economically achievable options, insofar as it achieves pollutant reductions necessary to prevent pass-through of volatile organic pollutants, allows for recovery and recycling of volatile organic pollutants, and reduces non-water quality environmental impacts caused by air emissions of pollutants from wastewater. See Section XII.B of this preamble for a discussion of the Administrator's waste minimization and combustion strategy. Although Options 2, 3, and 4 would

achieve essentially the same decrease in the emission of wastewater pollutants to the air as Option 1, the increase in energy use requirements associated with Options 2, 3, and 4 would be equivalent to an increase of 31 percent above the 1990 pharmaceutical industry energy use. For this reason, EPA selected Option 1 over Options 2, 3, and 4.

EPA did not select Options 3 or 4 because EPA has not determined whether refractory organic materials measured as COD that are generated by facilities with subcategory A and/or C operations pass through POTWs and therefore is not proposing standards based on potentially unnecessary technology. Moreover, as noted above in EPA's discussion of the proposed BAT limitations for these subcategories, even assuming COD does pass through, EPA lacks data to estimate the COD reductions achievable by steam stripping and thus cannot compare COD reductions achievable by Options 2, 3, and 4.

EPA has also selected Option 1 as the proposed technology basis for PSES (minus cyanide destruction) for facilities with subcategory B and/or D operations. Under co-proposal (1), EPA would propose PSES for 12 highly strippable organic pollutants at in-plant location (1) and 33 less strippable pollutants at the point of discharge to the POTW sewer. In-plant location (1) is described in IX.E.3.d., above. Under co-proposal (2), EPA would propose PSES only for the 12 highly strippable organic pollutants at in-plant location (1).

In selecting steam stripping (PSES Option 1 minus cyanide destruction) as the technology basis for the proposed PSES for facilities with B and/or D subcategory operations, EPA relied upon the 1990 questionnaire data supplied by 188 facilities with subcategory B and/or D operations that send their wastewater to POTWs for treatment. For reasons that EPA is not able to explain, these data show that the wastestreams characteristic of indirect dischargers with subcategory B and/or D operations are significantly different (for regulatory purposes) than the wastestreams of direct dischargers with subcategory B and/or D operations. See Section IX.E.3.c(2) for discussion of basis for proposed BAT limitations for facilities with subcategory B and D operations. In view of this reported difference, EPA has based today's proposed pretreatment standards on a different technology—steam stripping—than the BAT limitations proposed for the direct dischargers in this subcategory, which are based on advanced biological treatment.

The data supplied by the 188 indirect facilities in this subcategory show that these facilities discharge BOD₅, TSS, COD, 18 nonconventional pollutants and four priority pollutants. See Section 9 of the TDD. EPA's analysis of the questionnaire data indicates that the total nonconventional and priority pollutant loadings discharged, on average, for each indirect discharger with subcategory B and D operations in 1990 was 14,600 pounds/year (in contrast to the average of 1,660 pounds/year reported by the 14 direct dischargers in these subcategories). The 188 facilities also reported in their questionnaire responses that they emit from wastewater a total of 1.5 million pounds/year of volatile organic pollutants (in contrast to the emissions totaling 170 pounds/year reported by the direct dischargers). Subsequent analysis by EPA using its WATER7 model indicates that these indirect dischargers may actually emit closer to 3.3 million pounds/year from wastewater (in contrast to the emissions totaling 35,000 pounds/year for the direct dischargers). See Section 12 of TDD for discussion of difference between questionnaire results and WATER7 model results. Based on its evaluation of the data available to it, EPA proposes to base pretreatment standards for facilities with subcategory B and D operations on in-plant steam stripping (Option 1). This technology is designed to remove large quantities and many varieties of solvents from process wastewater. According to the data supplied by the 188 indirect dischargers with subcategory B and D operations, EPA has concluded that the wastewater characteristic of these facilities—with its comparatively high volume and concentration of solvents—is well-suited to this form of treatment. Accordingly, EPA has determined for the reasons set forth above in connection with establishing BAT limitations for facilities with A and C subcategory operations, see Section IX.E.3.c(1) above, that in-plant steam stripping is the most appropriate technology basis for pretreatment standards for facilities with subcategory B and/or D operations. Even though EPA's 1990 data indicates that subcategory B and/or D facilities discharge only 22 priority and nonconventional pollutants, EPA is proposing to establish pretreatment standards for 45 priority and nonconventional pollutants because all 45 pollutants potentially can be discharged to POTWs. (EPA is soliciting comment on mechanisms by which dischargers that do not use or generate

pollutants for which standards are proposed can be exempted from monitoring for those pollutants. See Section XIV, solicitation number 38.) In addition, EPA found that none of the 67 facilities (of the 188 indirect dischargers with subcategory B and D operations) that would incur costs as a result of the proposed PSES limitations would close as a result of this option. Therefore EPA determined that the costs of the pollutant reduction achieved by this option were economically achievable.

In considering the various technology options available as possible bases for the proposed pretreatment standards for these subcategories, EPA rejected advanced biological treatment as a viable technology option and therefore did not consider it. Because indirect discharging facilities with subcategory B and/or D operations generate levels of BOD₅, TSS and COD comparable to levels found in ordinary domestic sewage, EPA concluded that biological treatment afforded by POTWs is adequate for these levels of pollutants. Accordingly, EPA has determined that BOD₅, TSS and, preliminarily, COD from facilities with subcategory B and/or D operations do not pass through. Thus, advanced biological treatment at these facilities prior to POTW treatment would be duplicative.

The Agency considered age, size, processes, other engineering factors, and non-water quality environmental impacts in developing the proposed PSES for all four subcategories. The Agency did not identify any basis for establishing different pretreatment standards based on age, size, processes, or other engineering factors. EPA has concluded that the technology upon which EPA proposes to base PSES for facilities with subcategory B and/or D operations would significantly decrease air emissions and would be consistent with the Administrator's waste minimization and combustion strategy. See Section XII.B of this preamble for a discussion of this strategy. EPA did not choose Option 2 because, although this option would result in approximately the same decrease in air emissions as Option 1, it would result in a significant increase in total energy use over that required under Option 1. (See section 16 of the TDD and the BAT discussion above.)

c. Point of Regulation. EPA is proposing to specify an in-plant compliance monitoring location for each of the 12 highly strippable volatile organic pollutants for which EPA is proposing PSES. (This is not affected by the co-proposals addressing the 33 less strippable pollutants.) This location is described as in-plant location (1) in

section E.3.d., above. For facilities with subcategory A and/or C operations, EPA also proposes to require in-plant monitoring for cyanide based upon cyanide destruction technology.

EPA acknowledges that it reached a different conclusion regarding the point of regulation for direct dischargers with subcategory A and/or C operations. As discussed in section E.3.d., above, EPA is proposing to specify end-of-pipe monitoring requirements for the 12 highly strippable volatile organic pollutants in deference to the forthcoming Clean Air Act rule for this industry, which will control air emissions of these pollutants. EPA also noted in that section, however, that the permit writer has the authority under the NPDES permit regulations to establish limits in-plant on a case-by-case basis when it would be impractical or infeasible to monitor for the pollutants at the end of the pipe because of dilution or other considerations. Indeed, EPA observed that the BAT limitations being proposed for the 12 highly strippable volatile organic pollutants in subcategories A and C are at levels that are only marginally above the analytical minimum levels established for these pollutants and expressed its concern that dilution or air stripping might make detection of the pollutants infeasible at the end of the pipe. Nevertheless, EPA concluded that this concern could be addressed for direct dischargers on a case-by-case basis by the permit writer and therefore proposed that establishing in-plant compliance requirements on a national level was not essential.

EPA is proposing to reach a different conclusion for indirect dischargers. Like the proposed BAT limitations, the proposed pretreatment standards for existing dischargers are only marginally above the minimum levels established for these pollutants. Similarly, EPA is concerned that dilution with process and non-process wastewater might cause the pollutants to be undetectable by current analytical methods. Under EPA regulations, however, indirect dischargers are prohibited from substituting dilution for treatment, except where dilution is expressly authorized by an applicable pretreatment standard. See 40 CFR 403.6(d). This prohibition theoretically could be enforced by POTWs through the establishment of local limitations at in-plant locations on a pollutant-by-pollutant, case-by-case basis in the same way that a permit writer could do so for direct dischargers. By establishing in-plant monitoring requirements, the POTW, like the permit writer, would be able to determine whether compliance

is being achieved by dilution or by treatment. The difference, however, is this pollutant-by-pollutant, case-by-case solution to the detection and dilution problems may impose a financial and technical burden on POTWs. There are six times as many indirect dischargers as direct dischargers, and unlike state and EPA permit writers, POTWs commonly lack the on-site technical expertise to establish and justify in-plant monitoring requirements on a case-by-case basis. Even when such expertise exists, EPA is concerned that the accompanying burden and expense would be significant. Therefore, EPA is proposing to establish in-plant points of regulation on a nationwide level.

EPA is proposing pretreatment standards in large measure because of the concern registered by some POTWs that discharges containing substantial concentrations of these volatile organic pollutants may interfere with the operation of the sewerage system and the health and safety of employees of the POTW system. EPA solicits comment and supporting data regarding whether this objective may be satisfied by assuring that discharges to the POTW sewer are near or at the level of detection. See Section XIV, solicitation number 24.0. In addition, as discussed in Section X, EPA is developing a separate rulemaking under the requirements of Section 112 of the Clean Air Act to address the air emissions from pharmaceutical plants, including the emissions of these 12 highly strippable volatile organic pollutants. EPA's air rulemaking may complement this proposal so that standards set at the point of discharge to the POTW sewer may satisfy EPA's objectives in this rulemaking. EPA expects to propose these air emission standards next year. As a result, EPA is also considering whether to establish limits for the 12 highly strippable volatile organic pollutants at the point of discharge to the POTW sewer. See Section XIV, solicitation number 24.5.

6. PSNS

Section 307(c) of the Act requires EPA to promulgate pretreatment standards for new sources (PSNS) at the same time it promulgates new source performance standards (NSPS). New indirect discharging plants, like new direct discharging plants, have the opportunity to incorporate the best available demonstrated technologies, including process changes, in-plant controls, and end-of-pipe treatment technologies.

Any new source subject to part 439 that was a "new source" as defined under 40 CFR 122.29 prior to the date on which the pretreatment standards for

new sources proposed today are promulgated will continue to be subject to the current PSNS regulations for the subpart to which the source is subject until the expiration of the applicable time period specified in 40 CFR 122.29(d)(1). After that time, the source is no longer considered to be a new source and will be required to achieve the PSES standards proposed in this rulemaking applicable to the source for its subcategory. EPA defines new source for the purpose of PSNS in this rulemaking as a source that commences construction after promulgation of the standards being proposed today, rather than after proposal, because, in accordance with the schedule established in the 304(m) Consent Decree, as modified, EPA does not expect to promulgate final standards within 120 days after proposal. See 40 CFR 122.2 (definition of New Source).

EPA considered three technology options for PSNS under two different regulatory co-proposal scenarios for facilities with subcategory A and/or C operations. Under co-proposal (1), EPA would propose PSNS for 12 highly strippable organic pollutants plus cyanide at an in-plant location (1) and 33 less strippable pollutants plus ammonia at the point of discharge to the POTW sewer. Under co-proposal (2), EPA would propose PSNS only for the 12 highly strippable organic pollutants, plus cyanide at in-plant location (1) and for ammonia at the end-of-pipe (3).

Under co-proposals (1) and (2), EPA considered the following three technology options for facilities with subcategory A and/or C operations for those pollutants found to pass through:

Option (1): In-plant steam stripping with distillation plus in-plant cyanide destruction.

Option (2): In-plant steam stripping with distillation plus in-plant cyanide destruction plus advanced biological treatment.

Option (3): In-plant steam stripping with distillation plus in-plant cyanide destruction plus advanced biological treatment plus granular activated carbon (GAC) treatment.

Under co-proposals (1) and (2), EPA considered the following two technology options for facilities with subcategory B and/or D operations for those pollutants found to pass through:

Option (1): In-plant steam stripping with distillation.

Option (2): In-plant steam stripping with distillation plus granular activated carbon (GAC) treatment.

EPA selected a more stringent PSNS technology than its chosen PSES technology because new sources have the opportunity to segregate their

process wastewater in such a way as to minimize the amount of wastewater that will require steam stripping with distillation, thereby reducing the adverse energy impacts that prevented EPA from selecting this technology as PSES.

EPA is proposing to set pretreatment standards for new sources based on PSNS Option 1 (steam stripping with distillation plus cyanide destruction) for priority and nonconventional pollutant for indirect discharging facilities with subcategory A and/or C operations. Similarly, EPA is proposing to set pretreatment standards for new sources based on PSNS Option 1 (steam stripping with distillation) for facilities with subcategory B and/or D operations.

EPA considered the cost of the proposed PSNS technologies for new plants. EPA has concluded that such costs are not so great as to present a barrier to entry, as demonstrated by the fact that currently operating plants are using these technologies. The Agency also considered energy requirements and other non-water quality environmental impacts when comparing the three PSNS technology options for facilities with subcategory A and/or C operations and the two PSNS technology options for facilities with subcategory B and/or D operations. EPA concluded that there would be only a slight difference in the energy requirements associated with Options 1, 2, and 3 for subcategory A and/or C facilities and with Options 1 and 2 for subcategory B and/or D facilities. There are no significant differences in the other non-water quality environmental impacts between the options considered.

7. BMP

EPA is not proposing any Best Management Practices (BMPs) today for the Pharmaceutical Manufacturing Category. However, EPA is soliciting comment on whether BMPs are applicable to the pharmaceutical manufacturing industry and, if so, what they should include. See Section XIV, solicitation number 31.0. See also the TDD at Appendix B for specific BMPs that EPA is considering adopting.

F. Determination of Long-Term Averages, Variability Factors, and Limitations

A detailed description of the statistical methodology used for the calculation of limitations is described in the Statistical Support Document. A summary of the methodology follows.

Limitations were based on actual concentrations of constituents measured in wastewaters treated by BAT

treatment systems when such data were available. Limitations were transferred based on engineering analysis when actual monitoring data were unavailable. For steam stripping and distillation technology, engineering analysis involved grouping constituents on the basis of their Henry's Law Constant. For biological treatment, the engineering analysis involved grouping constituents on the basis of their chemical structure and published data on relative biodegradability.

The calculation of the BAT daily limitations for constituents other than cyanide was performed by the following steps. The arithmetic long-term mean concentration was calculated for each facility dataset representing BAT treatment technology, and the median of the means was determined. A modified delta-lognormal distribution, the distribution model used by EPA in the Organic Chemicals, Plastics and Synthetic Fibers (OCPSF) and Pesticides Manufacturing rulemakings, was fit to daily concentration data from each facility dataset that had enough detected concentration values for parameter estimation. Variability factors were then computed for each of these datasets, and the average variability factor was determined. Finally, the daily maximum limitation was calculated by multiplying the median long-term mean by the average variability factor. The monthly average maximum limitation was calculated similarly except that the variability factor corresponding to the 95th percentile of the distribution of monthly averages was used instead of the 99th percentile of daily concentration measurements. The monthly average maximum limitation calculation assumes four measurements per month, or one per week.

The modified delta-lognormal distribution models the data as a mixture of non-detects and measured values. This distribution was selected because the data for most constituents consisted of a mixture of measured values and non-detects. The modified delta-lognormal distribution assumes that all non-detects have a value equal to the detection limit and the detected values follow a lognormal distribution.

A beta distribution rather than a delta-lognormal was used to model cyanide data. The BAT treatment for cyanide requires the reprocessing of wastewater if effluent cyanide concentrations exceed 1 ppm. Therefore, the cyanide data from a properly operated treatment system should range between 0 and 1 ppm. Such data are appropriately modelled by the beta distribution. The parameters of the beta distribution were estimated from the cyanide dataset by

the method of moments. Parameter estimates were then substituted in the beta distribution from which the daily limitation (99th percentile) was calculated. The monthly average cyanide (based on 4 daily measurements) limitation was estimated in a similar fashion.

The calculation of the proposed BPT limitations was based on measured concentrations of BOD₅, COD, and TSS measured in wastewaters treated by BPT systems. A 1-day and 30-day limitation was determined for each BPT facility dataset from a modified delta-lognormal distribution that was fit to the data. These limitations were then averaged across the datasets to determine the overall 1-day and 30-day maximum limitations. An intermediate step involved adjusting the modeled variability to account for day-to-day correlation in concentrations of BOD₅, COD, and TSS. The adjustment was based on a lag-1 autocorrelation time series model estimated from adjacent day observations, the same approach adopted in the OCPSF rulemaking. For datasets having an insufficient number of adjacent day observations to estimate an autocorrelation an average value was assumed.

G. Costs

The Agency estimated the cost for the pharmaceutical manufacturing industry to achieve each of the effluent limitations and standards proposed today. These estimated costs are summarized in this section and discussed in more detail in section 10 of the Technical Development Document. All cost estimates are expressed in 1990 dollars (the year for which EPA received questionnaire responses and data submissions). The cost components reported in this section are engineering estimates of the capital cost of purchasing and installing equipment and the annual operating and maintenance costs associated with that equipment. The total annualized cost, which is used to estimate economic impacts, better describes the actual compliance cost that a company will incur because it allows for interest, depreciation, and taxes. A summary of the economic impact analysis for the proposed regulation is contained in Section XI.B of today's notice. See also the Economic Impact Analysis.

1. BPT

The Agency used a plant-specific engineering cost assessment to estimate the costs of achieving the proposed BPT limitations. If a plant's reported 1990 discharges of BOD₅, TSS, COD and, in the case of facilities with subcategory A

and/or C operations, cyanide were less than the long-term average loads achievable by the technology basis for today's proposed BPT limitations, the plant was estimated to have no compliance costs. If the resulting pollutant loads exceeded the proposed BPT long-term average loads, EPA estimated costs for treatment system upgrades and, in the case of cyanide, in-plant hydrogen peroxide oxidation technology. Based on this analysis, EPA concluded that 20 pharmaceutical manufacturing facilities would incur costs to comply with the proposed BPT limitations. EPA estimated the total capital expenditures for complying with the proposed BPT limitations to be \$15.3 million and the annual operating and maintenance (O&M) costs to be \$7.5 million. The estimated cost for implementing the proposed BPT limitations is summarized for the A and C and B and D subcategories below in Table IX.G.1.

2. BAT

EPA estimated the costs to comply with today's proposed BAT limitations

on priority and nonconventional pollutants on plant-by-plant and pollutant-by-pollutant basis. If the loading data provided by the facility in its Section 308 questionnaire response indicated that its discharge was above the proposed limitation target load for a given pollutant, EPA developed cost estimates for the control technology EPA believes is appropriate for that pollutant (e.g., steam stripping for all strippable pollutants).

For direct dischargers with subcategory A and C operations, BAT costs include, where necessary, the costs for in-plant steam stripping followed by end-of-pipe advanced biological treatment upgrades to comply with the proposed limitations for priority and nonconventional pollutants. The operation and maintenance costs include monitoring of strippable pollutants in-plant and nonstrippable biodegradable pollutants at the end-of-pipe.

For direct dischargers with subcategory B and D operations, BAT costs include the costs for end-of-pipe advanced biological treatment upgrades.

The upgrades are designed around treating conventional pollutants to specific targets, equivalent to BPT long-term mean performance. In a few cases, additional compliance costs were estimated for direct discharging facilities with subcategory B and D operations that already achieve these conventional pollutant upgrade targets, but require more closely controlled treatment system operation to comply with the priority and nonconventional pollutant BAT limitations.

The BAT operation and maintenance costs for subcategories B and D include monitoring for priority and nonconventional pollutants at the end-of-pipe. EPA estimated the total capital expenditures for complying with the proposed BAT limitations to be \$57.0 million, and the annual operating and maintenance (O&M) costs to be \$36.8 million. These costs are not incremental and include the advanced biological treatment upgrades also presented under BPT. See Table IX.G.2-1 for a breakdown of the costs by subcategory.

TABLE IX.G.1.—COST OF IMPLEMENTING PROPOSED BPT REGULATIONS

[In millions of 1990 dollars]

Subcategory	No. of plants	Capital costs	Annual O&M costs
Fermentation (A) and Chemical Synthesis (C)	15	14.7	7.0
Biological and Natural Extraction (B) and Mixing/Compounding/Formulating (D)	5	0.6	0.5

TABLE IX.G.2.—COST OF IMPLEMENTING PROPOSED BAT REGULATIONS

[In millions of 1990 dollars]

Subcategory	No. of plants	Capital costs	Annual O&M costs
Fermentation (A) and Chemical Synthesis (C)	23	56.4	35.7
Biological and Natural Extraction (B) and Mixing/Compounding/Formulating (D)	13	0.64	1.1

3. PSES

EPA developed PSES costs for compliance with the proposed pretreatment standards for strippable priority and nonconventional pollutants in the same manner that it developed BAT compliance costs for these pollutants. In developing these costs, EPA based the number of pollutants

proposed to be regulated under PSES on the pass-through findings of PSES co-proposal (1), which include the 33 less strippable volatile organic pollutants. EPA did not include cost estimates for nonstrippable nonconventional pollutants in the PSES costs because EPA is requesting comment on its technology basis for controlling the

discharge of these pollutants. See Section XIV, solicitation numbers 27.1 and 27.2. The estimated total capital expenditure for complying with the proposed PSES limitations are \$91.8 million and the annual operating and maintenance (O & M) costs are \$54.1 million. See table IX.G.3 for a breakdown of the costs by subcategory.

TABLE IX.G.3.—COST OF IMPLEMENTING PROPOSED PSES REGULATIONS

[In millions of 1990 dollars]

Subcategory	No. of plants	Capital costs	Annual O&M costs
Fermentation (A) and Chemical Synthesis (C)	71	70.8	46.4
Biological and Natural Extraction (B) and Mixing/Compounding/Formulating (D)	75	21.0	7.7

H. Pollutant Reductions

The Agency estimated the reduction in the mass of pollutants that would be discharged from pharmaceutical manufacturing plants after the implementation of the regulations being proposed today. The reduction in pollutant mass is attributable both to in-plant treatment technologies and improved end-of-pipe treatment. In-plant technologies such as steam stripping achieve pollutant load reductions by physical removal or extraction of volatile organic pollutants. Other technologies such as end-of-pipe biological treatment and in-plant

cyanide destruction achieve pollutant reduction by chemically or biochemically altering the nature of the pollutants (e.g., by converting them to different substances like carbon dioxide and water). Additional information on the methodology used to estimate the pollutant reductions resulting from the implementation of the proposed effluent limitations and standards is included in Section 9 of the Technical Development Document.

1. Conventional Pollutants

For each subcategory, the Agency developed an estimate of the annual

average mass loadings of BOD₅ and TSS that would be discharged after the implementation of the proposed BPT limitations. Since EPA proposes to set BCT limitations for conventional pollutants equal to the proposed BPT limitations for all subcategories, there would be no further reduction in BOD₅ and TSS achieved through BCT. Then EPA subtracted these loadings from the discharge loadings reported in the Section 308 questionnaire responses for 1990. The resultant pollutant reductions for BOD₅ and TSS are summarized in Table IX.H.1.

TABLE IX.H.1.—BPT, BOD₅ AND TSS REDUCTIONS

Subcategories	BOD ₅ reduction (lbs. per yr.)	TSS reduction (lbs. per yr.)
A and C	931,000	2,150,000
B and D	10,000	4,820

2. Priority Pollutants

For the ten priority pollutants EPA proposes to regulate, EPA estimated the removals achieved by the various BPT, BAT, and PSES technologies based on

raw waste load data provided by plants in their Section 308 questionnaire responses. In estimating these pollutant reductions, EPA did not include pollutant reductions being achieved by

existing technology, including advanced biological treatment, already in place. The resultant priority pollutant reductions are summarized in Table IX.H.2.

TABLE IX.H.2.—BPT, BAT AND PSES PRIORITY POLLUTANT REDUCTIONS

Subcategories	BPT reduction (cyanide) (lbs. per yr.)	BAT reduction (lbs. per yr.)	PSES reduction (lbs. per yr.)
A and C	38	2,650,000	7,140,000
B and D	¹ N/A	0	694,000

¹ Cyanide is not a pollutant of concern for facilities with subcategory B and D operations.

3. Nonconventional Pollutants

For the 45 nonconventional pollutants (excluding COD) for which limitations and standards are being proposed, EPA estimated the removals achieved by the

various proposed BPT, BAT, and PSES technology bases, using raw waste load data provided by plants in their Section 308 questionnaire responses. In estimating these pollutant reductions, EPA did not include pollutant

reductions being achieved by technology already in place, including in many cases advanced biological treatment. The resultant priority pollutant reductions are summarized in Table IX.H.3.

TABLE IX.H.3.—BPT, BAT AND PSES NONCONVENTIONAL POLLUTANT REDUCTIONS

Subcategories	BPT reduction (lbs. per yr.) COD only	BAT reduction (lbs. per yr.)	PSES reduction (lbs. per yr.)
A and C	9,840,000	16,800,000	30,900,000
B and D	59,600	22,600	3,440,000

I. Regulatory Implementation

1. Applicability

The regulation proposed today is just that—a proposed regulation. As such, although it represents EPA's best judgment at this time, it is not intended to be relied upon by permit writers in establishing effluent limitations. Indeed,

because EPA solicits comment and data (see specific solicitation numbers 1.2 and 1.3) regarding the proposed effluent limitations and standards specified in today's notice as well as on the technologies upon which they are based, the proposed limitations and standards and any conclusions set forth in this notice are subject to change.

2. Upset and Bypass Provisions

A "bypass" is an intentional diversion of waste streams 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 are set forth at 40 CFR 122.41(m) and (n).

3. Variances and Modifications

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 toxic, conventional and nonconventional pollutants.

a. Fundamentally Different Factors Variances. EPA will develop effluent limitations or standards different from the otherwise applicable requirements if an individual discharging facility is fundamentally different with respect to factors considered in establishing the limitation 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 toxic and non-conventional pollutants and BCT limitation for conventional pollutants for direct dischargers. For indirect dischargers, EPA provided for FDF modifications from pretreatment standards. FDF variances for toxic 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 categorical 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 standard. No FDF variance is available for new sources subject to NSPS or PSNS. Section 301(n) also defined the conditions under which EPA may establish alternative requirements. Under section 301(n), an application for approval of an 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 Part 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 direct dischargers. Thus, 40 CFR 125.31(d) identifies six factors (e.g., 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 (e.g., 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 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).

b. Economic Variances. Section 301(c) of the CWA authorizes a variance from

the otherwise applicable BAT effluent guidelines for nonconventional pollutants due to economic factors. The request for a variance from effluent limitations developed from BAT guidelines must normally be filed by the discharger during the public notice period for the draft permit. Other filing time periods may apply, as specified in 40 CFR 122.21(l)(2). Specific guidance for this type of variance is available from EPA's Office of Wastewater Management.

c. Water Quality Variances. Section 301(g) of the CWA authorizes a variance from BAT effluent guidelines for certain nonconventional pollutants due to localized environmental factors. These pollutants include ammonia, chlorine, color, iron, and total phenols.

d. 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 modification of a permit modification be made. 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.

e. Removal credits. As described previously, many industrial facilities discharge large quantities of pollutants to POTWs where their wastewaters mix with wastewater from other sources, domestic sewage from private residences and run-off from various sources prior to treatment and discharge by the POTW. Industrial discharges frequently contain pollutants that are generally not removed as effectively by treatment at the POTWs as by the industries themselves.

The introduction of pollutants to a POTW from industrial discharges may pose several problems. These include

potential interference with the POTW's operation or pass-through of pollutants if inadequately treated. As discussed, Congress, in section 307(b) of the Act, directed EPA to establish pretreatment standards to prevent these potential problems. Congress also recognized that, in certain instances, POTWs could provide some or all of the treatment of an industrial user's wastewater that would be required pursuant to the pretreatment standard. Consequently, Congress established a discretionary program for POTWs to grant "removal credits" to their indirect dischargers. The credit, in the form of a less stringent pretreatment standard, allows an increased concentration of a pollutant in the flow from the indirect discharger's facility to the POTW.

Section 307(b) of the CWA establishes a three-part test for obtaining removal credit authority for a given pollutant. Removal credits may be authorized only if (1) The POTW "removes all or any part of such toxic pollutant," (2) the POTW's ultimate discharge would "not violate that effluent limitation, or standard which would be applicable to that toxic pollutant if it were discharged" directly rather than through a POTW and (3) the POTW's discharge would "not prevent sludge use and disposal by such [POTW] in accordance with section [405] * * *." Section 307(b).

EPA has promulgated removal credit regulations in 40 CFR Part 403.7. The United States Court of Appeals for the Third Circuit has interpreted the statute to require EPA to promulgate comprehensive sewage sludge regulations before any removal credits could be authorized. *NRDC v. EPA*, 790 F.2d 289, 292 (3d Cir. 1986), *cert. denied*, 479 U.S. 1084 (1987). Congress made this explicit in the Water Quality Act of 1987 which provided that EPA could not authorize any removal credits until it issued the sewage sludge use and disposal regulations required by section 405(d)(2)(a)(ii).

Section 405 of the CWA requires EPA to promulgate regulations that establish standards for sewage sludge when used or disposed for various purposes. These standards must include sewage sludge management standards as well as numerical limits for pollutants that may be present in sewage sludge in concentrations which may adversely affect public health and the environment. Section 405 requires EPA to develop these standards in two phases. On November 25, 1992, EPA promulgated the Round One sewage sludge regulations establishing standards, including numerical pollutant limits, for the use or disposal

of sewage sludge. 58 FR 9248¹. EPA established pollutant limits for ten metals when sewage sludge is applied to land, for three metals when it is disposed of on a surface disposal site and for seven metals and a total hydrocarbon operational standard, a surrogate for organic pollutant emissions, when sewage sludge is incinerated. These requirements are codified at 40 CFR Part 503.

The Phase One regulations partially fulfilled the Agency's commitment under the terms of a consent decree that settled a citizens suit to compel issuance of the sludge regulations. *Gearhart, et al. v. Reilly*, Civil No. 89-6266-JO (D.Ore). Under the terms of that decree, EPA must propose and take final action on the Round Two sewage sludge regulations by December 15, 2001.

At the same time EPA promulgated the Round One regulations, EPA also amended its pretreatment regulations to provide that removal credits would be available for certain pollutants regulated in the sewage sludge regulations. See 58 FR 9386. The amendments to Part 403 provide that removal credits may be made potentially available for the following pollutants:

(1) If a POTW applies its sewage sludge to the land for beneficial uses, disposes of it on surface disposal sites or incinerates it, removal credits may be available, depending on which use or disposal method is selected (so long as the POTW complies with the requirements in Part 503). When sewage sludge is applied to land, removal credits may be available for ten metals. When sewage sludge is disposed of on a surface disposal site, removal credits may be available for three metals. When the sewage sludge is incinerated, removal credits may be available for seven metals and for 57 organic pollutants. See 40 CFR 403.7(a)(3)(iv)(A).

(2) In addition, when sewage sludge is used on land or disposed of on a surface disposal site or incinerated, removal credits may also be available for additional pollutants so long as the concentration of the pollutant in sludge does not exceed a concentration level established in Part 403. When sewage sludge is applied to land, removal credits may be available for two additional metals and 14 organic pollutants. When the sewage sludge is disposed of on a surface disposal site, removal credits may be available for

seven additional metals and 13 organic pollutants. When the sewage sludge is incinerated, removal credits may be available for three other metals. See 40 CFR 403.7(a)(3)(iv)(B).

(3) When a POTW disposes of its sewage sludge in a municipal solid waste landfill that meets the criteria of 40 CFR Part 258 (MSWLF), removal credits may be available for any pollutant in the POTW's sewage sludge. See 40 CFR 403.7(a)(3)(iv)(C). Thus, given compliance with the requirements of EPA's removal credit regulations,² following promulgation of the pretreatment standards being proposed here, removal credits may be authorized for any pollutant subject to pretreatment standards if the applying POTW disposes of its sewage sludge in a MSWLF that meets the requirements of 40 CFR Part 258. If the POTW uses or disposes of its sewage sludge by land application, surface disposal or incineration, removal credits may be available for the following metal pollutants (depending on the method of use or disposal): arsenic, cadmium, chromium, copper, iron, lead, mercury, molybdenum, nickel, selenium and zinc. Given compliance with section 403.7, removal credits may be available for the following organic pollutants (depending on the method of use or disposal) if the POTW uses or disposes of its sewage sludge: benzene, 1,1-dichloroethane, 1,2-dibromoethane, ethylbenzene, methylene chloride, toluene, tetrachloroethene, 1,1,1-trichloroethane, 1,1,2-trichloroethane and trans-1,2-dichloroethene.

Some facilities may be interested in obtaining removal credit authorization for other pollutants being considered for regulation in this rulemaking for which removal credit authorization would not otherwise be available under Part 403. Under sections 307(b) and 405 of the CWA, EPA may authorize removal credits only when EPA determines that, if removal credits are authorized, that the increased discharges of a pollutant to POTWs resulting from removal credits will not affect POTW sewage sludge use or disposal adversely. As discussed in the preamble to amendment to the Part 403 regulations (58 FR 9382-83), EPA has interpreted these sections to authorize removal credits for a pollutant only in one of two circumstances. Removal credits may be

² Under Section 403.7, a POTW is authorized to give removal credits only under certain conditions. These include applying for, and obtaining, approval from the Regional Administrator (or Director of a State NPDES program with an approved pretreatment program), a showing of consistent pollutant removal and an approved pretreatment program. See 40 CFR § 403.7(a)(3)(i), (ii), and (iii).

¹ The U.S. Court of Appeals for the District of Columbia Circuit has remanded portions of these regulations not pertinent here for modification or additional justification. *Leather Industries of America, Inc. v. EPA*, 40 F.3d 392 (D.C. Cir. 1994).

authorized for any categorical pollutant (1) for which EPA have established a numerical pollutant limit in Part 503; or (2) which EPA has determined will not threaten human health and the environment when used or disposed of in sewage sludge. The pollutants described in paragraphs (1)–(3) above include all those pollutants that EPA either specifically regulated in Part 503 or evaluated for regulation and determined would not adversely affect sludge use and disposal.

Consequently, in the case of a pollutant for which EPA did not perform a risk assessment in developing the Phase One sewage sludge regulations, removal credit for pollutants will only be available when the Agency determines either a safe level for the pollutant in sewage sludge or that regulation of the pollutant is unnecessary to protect public health and the environment from the reasonably anticipated adverse effects of such a pollutant.³ Therefore, any person seeking to add additional categorical pollutants to the list for which removal credits are now available would need to submit information to the Agency to support such a determination. The basis for such a determination may include information showing the absence of risks for the pollutant (generally established through an environmental pathway risk assessment such as EPA used for Phase One) or data establishing the pollutant's presence in sewage sludge at low levels relative to risk levels or both. Parties, however, may submit whatever information they conclude is sufficient to establish either the absence of any potential for harm from the presence of the pollutant in sewage sludge or data demonstrating a "safe" level for the pollutant in sludge. Following submission of such a demonstration, EPA will review the data and determine whether or not it should propose to amend the list of pollutants for which removal credits would be available.

EPA has already begun the process of evaluating a number of pollutants for adverse potential to human health and the environment when present in sewage sludge. In May, 1993, pursuant to the terms of the consent decree in the *Gearhart* case, the Agency notified the United States District Court for the

District of Oregon that, based on the information then available at that time, it intended to propose 31 pollutants for regulation in the Round Two sewage sludge regulations. These are acetic acid (2,4-dichlorophenoxy), aluminum, antimony, asbestos, barium, beryllium, boron, butanone (2-), carbon disulfide, cresol (p-), cyanides (soluble salts and complexes), dioxins/dibenzofurans (all monochloro to octochloro congeners), endsulfan-II, fluoride, manganese, methylene chloride, nitrate, nitrite, pentachloronitrobenzene, phenol, phthalate (bis-2-ethylhexyl), polychlorinated biphenyls (co-planar), propanone (2-), silver, thallium, tin, titanium, toluene, trichlorophenoxyacetic acid (2, 4,5-), trichlorophenoxypropionic acid ([2-(2,4,5-)], and vanadium.

The Round Two regulations are not scheduled for proposal until December, 1999 and promulgation in December 2001. However, given the necessary factual showing, as detailed above, EPA could conclude before the contemplated proposal and promulgation dates that regulation of some of these pollutants is not necessary. In those circumstances, EPA could propose that removal credits should be authorized for such pollutants before promulgation of the Round Two sewage sludge regulations. However, given the Agency's commitment to promulgation of effluent limitations and guidelines under court-supervised deadlines, it may not be possible to complete review of removal credit authorization requests by the time EPA must promulgate these guidelines and standards.

4. Relationship of Effluent Limitations to NPDES Permits and Monitoring Requirements

Effluent limitations act as a primary mechanism to control the discharges of pollutants to waters of the United States. These limitations are applied to individual facilities through NPDES permits issued by the EPA or authorized States under section 402 of the Clean Water Act.

The Agency has developed the limitations and standards for this proposed rule to cover the discharge of pollutants for this industrial category. In specific cases, the NPDES permitting authority may elect to establish technology-based permit limits for pollutants not covered by this proposed regulation, on a case-by-case basis using best professional judgment. See section 402(a)(1)(B) of the Clean Water Act; 40 CFR 125.3. 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 on covered pollutants), the permitting authority must apply those limitations. See, e.g., section 301(b)(1)(C) of the Clean Water Act.

For determination of effluent limits where there are multiple products or multiple categories and subcategories, the effluent guidelines would be applied using a flow-weighted combination of the appropriate guideline for each category or subcategory. Where a facility has added a new production facility in conjunction with an existing production facility, the effluent guidelines would also be applied by using a flow-weighted combination of the NSPS limit for the new line and the BAT and BCT standards to the existing lines to derive the limitations. However, as stated above, 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 on covered pollutants), the permitting authority must apply those limitations regardless of the limitation derived using the production-weighted combinations.

The Agency does not consider certain wastewaters or materials to be process wastewaters; therefore, these proposed effluent limitations guidelines and standards would not apply to the discharge of such wastewaters. Such materials include, for example, any active anti-microbial materials, wastewater from imperfect fermentation batches, or process area spills. Any pharmaceutical manufacturing facility wishing NPDES authorization to discharge any materials and/or non-process wastestream(s) must specifically disclose this in its permit application. If the permitting authority wishes to authorize this discharge, the permit must specifically authorize the discharge of the specified materials and/or non-process wastestream(s). The effluent limitations in the permit must also reflect a separate analysis, done by the permitting authority on a best professional judgment basis, of the levels of pollutants in such materials and/or non-process wastestream(s) that are commensurate with the application of BPT, BCT, BAT, and PSES. Caution should be exercised in permitting such discharges. Treatment systems may not be designed to accommodate these types of materials and their discharge could adversely affect the treatment systems and receiving waters.

Working in conjunction with the effluent limitations are the monitoring conditions set out in an NPDES permit. An integral part of the monitoring conditions are the monitoring points. The point at which a sample is collected

³In the Round One sewage sludge regulation, EPA concluded, on the basis of risk assessments, that certain pollutants (see Appendix G to Part 403) did not pose an unreasonable risk to human health and the environment and did not require the establishment of sewage sludge pollutant limits. As discussed above, so long as the concentration of these pollutant in sewage sludge are lower than a prescribed level, removal credits are authorized for such pollutants.

can have a dramatic effect on the monitoring results for that facility. Therefore, it may be necessary to require internal monitoring points in order to assure compliance. Authority to address internal waste streams is provided in 40 CFR 122.44(i)(1)(iii) and 122.45(h). In some instances, today's proposed rule establishes internal monitoring points to ensure compliance with the effluent limitations guidelines and standards. Permit writers may establish additional internal monitoring points to the extent consistent with EPA's regulations.

5. Best Management Practices

EPA is not proposing in today's notice best management practices (BMPs) pursuant to Section 304(e) of the Clean Water Act. BMPs established under Section 304(e) may be different from effluent limitations guidelines and standards principally because BMPs are specific requirements for conduct, not performance standards. When EPA sets technology-based effluent limits, those limits may be achieved by any technology a discharger chooses. However, when EPA establishes BMPs under Section 304(e) of the CWA, and those BMPs are incorporated into a dischargers permit, the discharger must perform those specific BMPs. The fact that a discharger had met all its technology-based effluent limits would not be a defense, if the discharger were charged with a permit violation for failing to perform its BMPs.

BMPs for the pharmaceutical manufacturing industry, which might include spill prevention, control provisions, and other aspects to prevent the release of raw materials, solvents, and process chemicals to wastewaters, would control the release of constituents listed in sections 307(a) and 311(e) of the CWA, such as methylene chloride, toluene, chloroform, and chloromethane (methyl chloride).

The EPA believes these BMPs are important because: discharges of raw materials, process chemicals and other materials are not recognized process wastewaters and contribute to significant portions of untreated wastewater loadings and to final effluent discharge loadings of oxygen demanding substances and priority and nonconventional pollutants. Prevention and control of discharges of materials used in pharmaceutical manufacturing processes will result in less demand for make-up chemicals; energy efficiency through recovery of process materials; more effective and less costly wastewater treatment system operations; reduced formation of wastewater treatment sludges; and reduced

atmospheric emissions of hazardous air pollutants (HAPs) and other volatile organic pollutants.

EPA is soliciting comment on whether BMPs are applicable to pharmaceutical manufacturing facilities in any or all subcategories for which effluent limitations guidelines and standards are being proposed. The principal focus of the BMPs are prevention and control of losses of raw materials, process chemicals and other process materials from spills and equipment leaks. More information related to the BMPs is outlined in Section XIV regarding solicitation of comments and data (see specific solicitation number 31.0). Appendix B of the Technical Development Document presents details on the specifics of BMPs that may be appropriate.

6. Analytical Methods

Section 304(h) of the Clean Water Act (CWA) directs the EPA to promulgate guidelines establishing test procedures (methods) for the analysis of pollutants. These methods are used to determine the presence and concentration of pollutants in wastewater, and for compliance monitoring. Dischargers seeking NPDES permits must supply information on the characteristics of their effluent, analyzed in accordance with approved test procedures, as part of their permit applications. 40 CFR 122.21(g)(7). Similarly, holders of NPDES permits are required to conduct monitoring in accordance with such test procedures. 40 CFR 122.41(j)(4). Information and analysis performed in accordance with these methods are also required under the pretreatment program, 40 CFR 403.12(d)(5)(vi), and as a condition for receiving a conditional removal credit under 40 CFR 403.7(d).

EPA has promulgated analytical methods for monitoring discharges to surface water at 40 CFR part 136, and has promulgated methods for parameters specific to a given industrial category and for other purposes at parts 400–480 of the CFR. In today's notice, EPA also proposes to establish appropriate analytical methods at 40 CFR part 439 to support regulation of discharges in the pharmaceutical manufacturing industrial point source category. Those methods are presented in "Analytical Methods for the Determination of Pollutants in Pharmaceutical Industry Wastewater," a compendium of analytical methods and are incorporated herein by reference. See Section XIV, solicitation number 33.

Methods 1624 and 1625 are two of the previously promulgated methods applicable to the determination of volatile and semivolatile organic

pollutants in water and wastewater for the proposed effluent guidelines. They employ gas chromatography coupled to a mass spectrometer (GC/MS) to separate and quantify volatile and semivolatile organic pollutants. Detected pollutants are quantified by isotope dilution. For volatile organic pollutants, samples of water or solids suspended in water are purged by a stream of inert gas into the gaseous phase where they are concentrated into a trap. Subsequent heating of the trap introduces the concentrated volatile organics into a GC/MS for separation and quantification. The sensitivity of these methods are sufficient to detect and quantify volatile and semivolatile organics at parts per billion (ppb) levels in environmental samples. EPA also solicits comment on whether it may be appropriate to allow facilities to use analytical methods for organic pollutants other than those used to generate data upon which this proposal is based. See Section XIV, solicitation number 38.3.

Many of the non-conventional pollutants that may be released from the pharmaceutical manufacturing industry are not included in methods previously promulgated for monitoring effluents from other industries. For this reason it has been necessary to develop methods for these pollutants. Some are amenable to extraction from aqueous solution and can be analyzed by GC/MS after extraction and concentration. Method 1665 has been developed for these analytes. Others may be concentrated by purging from aqueous solution and trapping in a column containing sorbent material. For these substances, purge-and-trap followed by GC/MS analysis as described in Method 1666 was developed. Some highly water soluble analytes, however, could not be extracted from aqueous solution and could not be efficiently purged from water. For this reason, it was necessary to develop a direct aqueous injection technique for GC/MS analysis by Method 1666. A subset of these highly water soluble substances, all containing nitrogen, were found not to chromatograph well on the column used. For this reason, a third technique, Method 1668, was developed using a different GC column and detection by electrolytic conductivity. Formaldehyde is not extractable from water and can not be readily analyzed by either purge-and-trap GC/MS or direct aqueous injection. For this reason a fourth approach, Method 1667, was developed for formaldehyde and the other aldehydes included in the analyte list. A complete description of these

methods can be found in the Methods Compendium mentioned previously.

Methods 410.1 and 410.2 are two of several methods allowed for determination of chemical oxygen demand (COD) in water and wastewater. Other methods allowed for the determination of COD in this industry are those in 40 CFR part 136 that use analytical technologies equivalent to the technologies used in EPA methods 410.1 and 410.2, specifically oxidation by potassium dichromate and titration with ferrous ammonium sulfate, as described below. Method 410.2 is specific for levels of COD less than 50 mg/L, and Method 410.1 for levels greater than 50 mg/L. Other methods for COD that are intended for brines (e.g., EPA method 410.3) and that are interfered with by color (e.g., EPA method 410.4) and the methods in 40 CFR part 136 equivalent to these methods are allowed for monitoring pharmaceutical manufacturing wastewaters.

X. Regulation of the Pharmaceutical Manufacturing Industry Under the Clean Air Act Amendments of 1990

Section 112 of the Clean Air Act Amendments of 1990 (CAAA) requires EPA to develop National Emission Standards for Hazardous Air Pollutants (NESHAP) based on maximum achievable control technology (MACT) for sources that emit 10 or more tons per year of a single hazardous air pollutant (HAP) or 25 or more tons per year of a mixture of HAP. The CAAA contain a list of 189 pollutants identified as HAPs. It also establishes a schedule for issuing these standards over a ten-year period. Pharmaceutical plants are among the source categories for which MACT standards must be promulgated by November 15, 1997.

EPA's Office of Water, which is developing the effluent limitations and standards being proposed today, has been working closely with EPA's Office of Air and Radiation since the beginning of this effluent guidelines effort in order to ensure that the present rulemaking is consistent, within the constraints of the governing statutes, with the air emissions standards EPA will be promulgating for the pharmaceutical manufacturing industry. As noted in Section V.A above, EPA's promulgation of this effluent guideline—including the date of this proposal—is subject to a court-ordered schedule, which at this time requires EPA to issue this regulation in final form by August 1996. Meanwhile, EPA has established November 15, 1997, as the date by which it will promulgate air emissions standards for this industry. See Section

V.B above. In determining priorities for promulgating standards for this and other industries, EPA was required by section 112(e) of the Clean Air Act to consider several factors, including anticipated adverse effects on public health and the environment. Thus, the promulgation date for the pharmaceutical industry NESHAP reflects EPA's consideration of these statutory criteria, as well as resource limitations that reinforced the Agency's need to rank its rulemakings in priority order. Despite the different schedules and resource constraints necessitating separate rulemakings under the Clean Water Act and Clean Air Act for the pharmaceutical manufacturing industry, EPA is making every effort to reconcile these activities.

Consistent with this intent, EPA is providing the following information to put the affected public on notice that EPA is developing regulations and guidance to reduce air emissions from wastewater operations at pharmaceutical manufacturing facilities under the Clean Air Act. Section X of this notice also sketches in preliminary form the approach EPA is considering to regulate such air emissions and provides preliminary cost and emission reduction information associated with that approach. By this notice, EPA solicits comment on the possible combined effect of the proposed Clean Water Act regulation and the tentative Clean Air Act approach for the pharmaceutical manufacturing industry. See Section XIV, solicitation number 32. This notice is also intended to provide the industry with an opportunity to plan for integrated least-cost multimedia compliance.

A. Preliminary Development of Air Emissions Standards

EPA is in the early stages of developing the MACT standard for pharmaceutical plants; the standards will require the control of several different emission points, including organic air emissions from wastewater operations. EPA recently promulgated a similar MACT standard for organic HAP emissions from the Synthetic Organic Chemical Manufacturing Industry (SOCMI). This rule, often referred to as the Hazardous Organic NESHAP or HON, was published on April 22, 1994 (59 FR 19402). On January 7, 1993, EPA published amendments to the Benzene Waste Operations NESHAP, which controls benzene emissions from wastewater operations based upon Clean Air Act authority predating the 1990 amendments (40 CFR part 61 subpart FF).

The control approach that EPA is considering for the pharmaceutical manufacturing industry is similar to the approach EPA used in the SOCMI HON and the Benzene Waste Operations NESHAP to control organic air emissions from wastewater collection and treatment operations. That approach consists first of identifying a subset of wastewater streams that require control through a combination of wastewater flowrate and concentration action levels, and second, the control requirements for these affected streams. The flowrate and concentration of each wastewater stream would be determined to reflect the characteristics at the point of generation of the wastewater stream.

The point of generation is defined to be where each individual wastewater stream exits production process equipment prior to any form of wastewater treatment. The characteristics of a wastewater stream at the point of generation are used to determine which streams to control because this is where the organic concentration is the highest and the flow is the lowest. The use of the point of generation characteristics in this way results in the identification of the most cost effective streams for control. If the characteristics of the streams were determined at some point downstream of the point of generation, there would be losses of organics due to air emissions and an increase in the wastewater flowrate due to mixing with other wastewater streams, both of which would result in the subsequent control of the stream being less cost effective. In addition, if wastewater treatment were allowed before the point of generation, the treatment unit, such as an air stripper, would not be required to have air emission control.

The flowrate action level is generally expressed as the liters per minute of wastewater flow. Values of flowrate used in previous regulatory analyses range from 0.02 to 10 liters per minute.

The concentration action level is based on the "volatile organic" concentration of the wastewater stream rather than the total concentration. EPA has developed a test method, Method 305 in Appendix A of 40 CFR part 63, to determine the volatile organic HAP concentration for use with wastewater MACT standards. The purpose of this test method is to determine a relative measure of the emission potential of a typically controlled wastewater stream by measuring essentially all of an organic HAP compound that is likely to be emitted in significant quantities while measuring essentially none of an organic HAP compound that is unlikely

to be emitted. Previous regulatory analyses have used an action level of 10,000 ppmw at any flowrate and coupled with a range of action levels from 10 to 1,000 ppmw tied to a flowrate cutoff as described above.

Examples of the use of these action levels in recent rules include the Benzene Waste Operations NESHA, which has action levels of 0.02 liters per minute and 10 ppmw benzene, and the HON, which has a 10,000 ppmw volatile organic HAP concentration action level at any flow rate coupled with an action level pair of 10 liters per minute and 1,000 ppmw volatile organic HAP concentration.

The control requirements for affected wastewater streams include managing the identified wastewater streams in controlled units during collection and treatment to remove or destroy the organics. This control approach includes: (1) Suppression or control of air emissions from the point of wastewater generation to the treatment device by installing controls on the sewer system, tanks, and containers used to transport the wastewater; (2) treatment of the wastewater to remove or destroy the organics; (3) control of air emissions from the treatment device (e.g., the non-condensable air emissions from the stripper condenser); and (4) control or recycling of the organics removed by the treatment device (e.g., the condensed residuals collected by the stripper condenser). See also Section XII.B of this preamble for discussion of the Administrator's strategy for waste minimization and combustion (incineration) of ignitable organic wastes.

The treatment device used as the basis for the HON is a steam stripper, the same device proposed as the primary technology basis for today's proposed limits and standards. The HON requirements are performance standards, so that any device that achieves the desired performance can be used. In addition, the HON allows several compliance alternatives including the use of open biological treatment units to treat the wastewater if a controlled collection and treatment system is used up to the unit and the unit can be demonstrated to achieve the required level of biological degradation. The HON requires the use of the procedures outlined in Appendix C of 40 CFR part 63 to demonstrate that the organics are being degraded by the biological treatment unit and not emitted to the air.

The CAAA also requires EPA to establish Control Techniques Guideline (CTG) documents for the States to use to develop VOC emissions control plans

for ozone nonattainment areas.

Industrial wastewater, which includes the pharmaceutical manufacturing industry, is one of the source categories for which EPA is developing a CTG document (see the draft document entitled "Control of Volatile Organic Compound Emissions from Industrial Wastewater," EPA-453/D-92-056, September 1992; available in the public docket for this Clean Water Act rulemaking). Based on this guidance, certain States will write rules for VOC emissions from wastewater operations at pharmaceutical plants located in ozone nonattainment areas. These rules are expected to be similar to the MACT standards, except they would control additional wastewater streams based on their potential for VOC emissions rather than HAP emissions. The concentration action level used in the draft CTG is based on the volatile organic concentration, which is determined by Method 25D in Appendix A of 40 CFR part 60.

The volatile organic HAP and flowrate action levels for the MACT standard for pharmaceutical plants have not yet been determined. For this notice, EPA has conducted a preliminary analysis of the impacts of a set of control options (action levels) for direct and indirect dischargers of A and C, and B and D effluent guideline subcategory production process wastewaters based on the approaches used in the HON. EPA emphasizes that this analysis is still preliminary. Wastewater data from the recent Section 308 pharmaceutical industry questionnaire responses were used in the analysis; however, a number of assumptions were made. See the draft document entitled "Control of Volatile Organic Compound Emissions from Industrial Wastewater, EPA-453/D-92-056, September 1992, for presentation of the assumptions and methodology used for this preliminary analysis. During the development of the MACT standard, this analysis will be refined based on new information and comments from the public.

Tables X.A.1 and X.A.2 summarize the results of this preliminary analysis. Two sets of preliminary results are presented based on two ways to evaluate the existing data for effluent guideline subcategory A, B, C, and D plants. The actual results of a rule based on any of the control options could be very different than these preliminary impacts. Table X.A.1 presents results based on applying the controls described above to wastewater streams that are equal to or greater than the identified action levels as the streams were reported in the Section 308 questionnaire responses. This database

reflects the characteristics of combined process area wastewater streams, not the point of generation of the wastewater. Table X.A.2 presents results based on the same criteria, but the Section 308 questionnaire wastewater data have been disaggregated in an attempt to simulate the characteristics at the point of generation. This disaggregation was performed in the manner described in Appendix B of the draft CTG document.

The control options (action levels), which encompass different combinations of volatile organic HAP (VOHAP) and wastewater stream flowrates, identified in both tables are ones that were considered in the development of the HON. All of the control options would require control of any wastewater stream that has 10,000 ppmw or greater volatile organic HAP concentration. The least stringent control option identified would require all wastewater streams with a flow of 10 liters per minute or greater and a 1,000 ppmw or greater volatile organic HAP concentration be equipped with controls. Wastewater streams below these criteria would not require control. Other more stringent control options would have lower action levels and require more wastewater streams to be controlled. The most stringent control option shown would require all streams with a flow of 1.0 liters per minute or greater and a 100 ppmw or greater volatile organic HAP concentration be controlled.

The analysis will be refined, and these results, along with other statutory criteria in the Clean Air Act, will be considered before a MACT standard for the pharmaceutical manufacturing industry is proposed. Information on the controls that may be required for wastewater streams exceeding the action levels, however, is provided in today's notice to allow pharmaceutical manufacturing facility owners and operators to consider these additional controls in their planning and to allow the public to comment on the combined effect of the MACT standard and today's proposed effluent limitations guidelines.

It is the Agency's intent for both the effluent guidelines being proposed today and the MACT standards to be proposed at a later date that upon promulgation the in-plant technology basis of both rules will be applicable to essentially the same high concentration low volume process wastewater streams in which the bulk of the volatile organic pollutants are contained, as represented preliminarily by Tables X.A.1 and X.A.2. The practical effect of this approach will be that only a relatively small portion (i.e., substantially less

than half) of all process wastewaters will require control by a treatment device (e.g., steam stripping) to achieve both rules. EPA has been informed by the industry that additional data will be submitted (some data have been submitted) in order to characterize, in greater detail than available in

responses to the Section 308 questionnaire, the individual process wastewater streams at the point of generation. This additional data and any other information available to EPA will be considered prior to promulgation in identifying the small portion of process wastewater streams that would require

control of volatile organic pollutants under both the effluent guideline and the MACT standard for this industry. The methodology to be used in analyzing these data will likely be the same as presented above and the preliminary results of which are presented in the following tables.

TABLE X.A.1.—PRELIMINARY IMPACTS OF CONTROL OPTIONS FOR A, B, C, AND D SUBCATEGORY PHARMACEUTICAL PLANTS BASED ON PROCESS AREA STREAMS

Control Option	VOHAP conc. ¹ cutoff (PPMW)	Flow cutoff (LPM)	Total flow controlled by option (percent)	HAP emissions (MG/yr)	HAP emission reduction (percent)	Total annual cost (\$M/yr)	HAP cost effectiveness (\$/MG HAP ER ²)
Baseline				12,500			
1	1,000	10	46	1,650	87	19.0	1,750
2	800	5	47	1,640	87	19.8	1,830
3	500	1	72	1,520	88	26.1	2,380
4	200	1	75	1,510	88	27.6	2,520
5	100	1	80	1,500	88	29.5	2,680

Notes:

¹"VOHAP CONC. CUTOFF" means the volatile organic HAP concentration determined by Method 305 in 40 CFR Part 63, Appendix A.

²"\$/MG HAP ER" means the dollars per megagram of HAP emission reduction by the given control option, which is determined by dividing the annual cost of the option by the annual emission reduction.

- All options include an action level of 10,000 ppmw volatile organic HAP concentration at any flowrate.
- Total industry wastewater flow equals 75,300 liters per minute.

TABLE X.A.2.—PRELIMINARY IMPACTS OF CONTROL OPTIONS FOR A, B, C, AND D SUBCATEGORY PHARMACEUTICAL PLANTS BASED ON DISAGGREGATED STREAMS

Control Option	VOHAP conc. ¹ cutoff (PPMW)	Flow cutoff (LPM)	Total flow controlled by option (percent)	HAP emissions (MG/yr)	HAP emission reduction (percent)	Total annual cost (\$M/yr)	HAP cost effectiveness (R/MG HAP ER ²)
Baseline				12,500			
1	1,000	10	7	2,790	78	6.6	680
2	800	5	10	2,440	80	8.0	800
3	500	1	16	2,120	83	10.6	1,020
4	200	1	25	1,680	87	13.7	1,270
5	100	1	29	1,630	87	15.9	1,460

Notes:

¹"VOHAP CONC." means the volatile organic HAP concentration determined by Method 305 in 40 CFR Part 63 Appendix A.

²"\$/MG HAP ER" means the dollars per megagram of HAP emission reduction by the given control option, which is determined by dividing the annual cost of the option by the annual emission reduction.

- All options include an action level of 10,000 ppmw volatile organic HAP concentration at any flowrate.
- Total industry wastewater flow equals 75,300 liters per minute.

B. Potential Interaction of Proposed Effluent Limitations Guidelines and Future Air Emission Standards

Because both the effluent limitations guidelines and standards being proposed today and the future MACT standards for this industry are likely to regulate similar pollutants and to reflect similar technology bases, EPA acknowledges that there is considerable interest in the industry concerning the potential interaction of these rulemakings. In this section, EPA addresses various issues that thus far have come to EPA's attention.

The effluent limitations guidelines and standards proposed today for nonconventional and priority pollutants are based on actual performance data obtained for specific pollutants over a

range of influent concentrations. The future MACT standards for HAPs emissions from pharmaceutical wastewater, like the HON, probably will employ data on Volatile Organic HAP concentration and flow rate of the wastewater stream to determine applicability of its standards to covered sources. Like the HON, the pharmaceuticals NESHAP will probably authorize percent reduction standards, effluent concentration limitations and mass removal requirements as options for measuring compliance.

EPA considered proposing percent reduction limitations and standards in this water rulemaking, but for the following reasons has determined that such limitations and standards would not adequately control the discharge of

wastewater pollutants of concern, particularly volatile pollutants. First, in EPA's view, effluent limitations guidelines and standards based on percent reduction do not reflect the performance of the best available technology in removing wastewater pollutants for the pharmaceutical manufacturing industry. EPA's analysis of actual performance data shows that the proposed concentration-based effluent limitations and standards can be met, regardless of variations in the influent concentrations of the target volatile compounds, using well-designed and well-operated technology. Second, percent reduction effluent limitations, as previously promulgated under the Clean Water Act for this industry, may discourage source

reduction programs (programs whose goal is to reduce raw waste loadings of volatiles) because plants with high raw waste loadings of volatiles can more easily comply with percent reduction regulations than plants with moderate or low volatile loadings. Finally, the percent reduction approach for effluent limitations guidelines and standards imposes special burdens on permit writers and facilities. The percent reduction approach would require the gathering and evaluation of long-term raw waste data from each facility in order to develop plant-specific limitations on individual pollutants, and to demonstrate continuing compliance with the limitations.

The Agency solicits comments and data on potential alternative formats for effluent limitations guidelines and standards, such as percent removal limitations and standards and minimum treatment threshold concentrations for individual wastewater streams. See Section XIV of this preamble, solicitation number 32.4.

Another issue arises in connection with the design of the steam stripper being proposed as a technology basis for various limitations and standards in today's rule. Today's notice proposes performance standards, based on a specific steam stripper design, that correspond to the wastestreams being treated. EPA also expects that the MACT standards for this industry also will be a performance standard based on a specific steam stripper design. However, the control approach contained in the air rule will include four components: (1) Suppression or control of air emissions from the point of generation to the treatment device by installing controls on the sewer system, tanks, and containers used to transport the wastewater; (2) a treatment device (such as a steam stripper); (3) control of air emissions from the treatment device itself (e.g., the non-condensable air emissions from the steam stripper condensor); and (4) control or recycling of the organics removed by the treatment device (e.g., the condensed residuals collected by the steam stripper condensor). The treatment device itself is a major component of the air emissions control approach for wastewater. It is the Agency's intent that a facility that installs steam stripping for the purpose of complying with this proposed rule also will achieve the requirements of the MACT standards to be developed for this industry. By the time public comments on the effluent guideline are being considered, EPA will have a better understanding of the stripper design that will serve as the basis for the MACT standards to be

proposed for this industry. This understanding, as well as the public comments on the water rule, will be considered in formulating the final effluent guideline as it pertains to stripper design. The Agency's intent is that the same stripper design will be able to achieve the requirements of both final rules, and will be applicable both to direct dischargers (BAT) and indirect dischargers (PSES). It is possible, however, that the stripper design upon which today's proposed water rule is based could change before promulgation based upon additional data and any comments received. Any information or comment on this subject is welcomed. See Section XIV, solicitation number 32.3. EPA also will develop air emission standards for other emission points (e.g., process vents, process area fugitive emissions, etc.).

A third issue relates to the possibility that the future MACT standard for the pharmaceutical manufacturing industry will allow plants to use an enclosed collection system to suppress emissions while transporting the wastewaters containing volatile pollutants to a central treatment unit, which in turn can be controlled for air emissions. In today's notice, EPA has selected in-plant steam stripping for controlling volatile organic pollutants. Under this proposal, plants would be required to treat all wastewater streams that contain regulated volatile organic pollutants at concentrations greater than the long-term average concentrations established for these regulated pollutants. However, a plant could choose to meet the proposed effluent limitations guidelines and standards by combining all such streams and treating the combined wastestreams at a central treatment unit prior to their dilution by wastestreams that do not contain volatile organic pollutants. This approach to the treatment of wastestreams containing volatile organic pollutants not only would satisfy the proposed regulations, but also appears to be more efficient than treating individual wastestreams at the wastewater generation source. However, in certain cases individual plants may find that streams containing recoverable quantities of individual volatile organic pollutants (e.g., methanol) may be more cost-effectively managed as segregated binary streams (i.e., water and one solvent), rather than mixing them with streams containing all other volatile organic pollutants generated at the facility, prior to either steam stripping or steam stripping/distillation. EPA solicits data and comment on this option. See Section

XIV of this preamble, solicitation number 32.5.

A fourth issue concerns the possibility that the future MACT standards will allow the use of open biological treatment units to treat organic compounds with limited volatility (e.g., methanol) from enclosed primary treatment systems, provided that a facility-specific emission limit or a 95 percent destruction of the organic HAP by biodegradation is achieved. In demonstrating the destruction, losses due to air emissions and effluent discharge would not be considered destruction. EPA did not select this technology as BAT for subcategories A and C because all known A and C direct discharger plants have open biological treatment systems and no air emissions data were available from plants with biological treatment systems that demonstrate 95 percent biodegradation of volatiles. In addition, the use of biodegradation for volatiles treatment eliminates the potential for their recovery and reuse. Nevertheless, EPA solicits comment on whether it is appropriate and feasible, considering recycle opportunities and control of air emissions, to develop a separate subcategory for the effluent limitations guidelines and standards with alternate limits that would allow for end-of-pipe biological treatment in place of or in combination with in-plant steam stripping for volatile organic pollutants. See Section XIV of this preamble, solicitation number 32.6.

XI. Impacts of Regulatory Options Considered in this Rulemaking

The purpose of this section is to analyze the projected economic impacts and non-water quality environmental impacts associated with the various technology options considered as possible bases for the limitations and standards proposed in today's notice.

A. Regulatory Options

In developing the proposed effluent limitations and standards set forth in today's notice, EPA developed technology options based upon a variety of different technologies and combinations of technologies. EPA developed technology options for direct dischargers and indirect dischargers, and for different industry subcategory groupings, i.e., facilities with subcategory A and C operations and facilities with subcategory B and D operations. For direct dischargers, EPA proposes limitations and standards based on options for Best Practicable Control Technology Currently Available (BPT), Best Conventional Pollutant Control Technology (BCT), Best

Available Technology Economically Achievable (BAT), and New Source Performance Standards (NSPS) options. For indirect dischargers, EPA proposed

Pretreatment Standards for Existing Sources (PSES) and Pretreatment Standards for New Sources (PSNS), based on a variety of technology options

considered. Table XI.A-1 presents the technology options considered in this rulemaking. The economic impact analysis discussed below reflects each of these options.

TABLE XI.A-1.—TECHNOLOGY OPTIONS CONSIDERED IN THE ECONOMIC IMPACT ANALYSIS

Type of option	Name	Description
Direct Dischargers		
Best Practicable Technology (BPT).	BPT-A/C#1	Current biological treatment
	BPT-A/C#2	Cyanide destruction + advanced biological treatment.
	BPT-A/C#3	Cyanide destruction + advanced biological treatment + effluent filtration.
	BPT-A/C#4	Cyanide destruction + advanced biological treatment + polishing pond.
	BPT-A/C#5	Cyanide destruction + advanced biological treatment + effluent filtration + polishing pond.
	BPT-B/D#1	Current biological treatment.
Best Conventional Technology (BCT)*.	BPT-B/D#2	Advanced biological treatment.
	BPT-B/D#3	Advanced biological treatment + effluent filtration.
	BCT-A/C#1	Advanced biological treatment + effluent filtration.
	BCT-A/C#2	Advanced biological treatment + polishing pond.
	BCT-A/C#3	Advanced biological treatment + effluent filtration + polishing pond.
	BCT-B/D#1	Advanced biological treatment.
Best Available Technology (BAT)	BCT-B/D#2	Advanced biological treatment + effluent filtration.
	BAT-A/C#1	Cyanide destruction + advanced biological treatment with nitrification, where necessary.
	BAT-A/C#2	Cyanide destruction + in-plant steam stripping + advanced biological treatment.
	BAT-A/C#3	In-plant cyanide destruction + in-plant steam stripping/distillation + advanced biological treatment.
	BAT-A/C#4	In-plant cyanide destruction + in-plant steam stripping/distillation + advanced biological treatment + granular activated carbon.
	BAT-B/D#1	Advanced biological treatment.
	BAT-B/D#2	In-plant steam stripping + advanced biological treatment.
	BAT-B/D#3	In-plant steam stripping/distillation + advanced biological treatment.
New Source Performance Standard (NSPS).	BAT-B/D#4	In-plant steam stripping/distillation + advanced biological treatment + granular activated carbon.
	NSPS-A/C#1	In-plant cyanide destruction + in-plant steam stripping/distillation + advanced biological treatment.
	NSPS-A/C#2	In-plant cyanide destruction + in-plant steam stripping/distillation + advanced biological treatment + granular activated carbon.
	NSPS-B/D#1	Advanced biological treatment + in-plant steam stripping/distillation.
	NSPS-B/D#2	In-plant steam stripping/distillation + advanced biological treatment + granular activated carbon.
Indirect Dischargers		
Pretreatment Standards for Existing Sources (PSES).	PSNS-A/C#1	In-plant steam stripping + cyanide destruction.
	PSNS-A/C#2	In-plant steam stripping/distillation + in-plant cyanide destruction.
	PSNS-A/C#3	In-plant steam stripping/distillation + in-plant cyanide destruction + end-of-pipe advanced biological treatment.
	PSNS-A/C#4	In-plant steam stripping/distillation + in-plant cyanide destruction + advanced biological treatment + granular activated carbon.
	PSNS-B/D#1	In-plant steam stripping.
	PSNS-B/D#2	In-plant steam stripping/distillation.
Pretreatment Standard for New Sources (PSNS).	PSNS-B/D#3	In-plant steam stripping/distillation + granular activated carbon.
	PSNS-A/C#1	In-plant steam stripping/distillation + in-plant cyanide destruction.
	PSNS-A/C#2	In-plant steam stripping/distillation + in-plant cyanide destruction + end-of-pipe advanced biological treatment.
	PSNS-A/C#3	In-plant steam stripping/distillation + in-plant cyanide destruction + end-of-pipe advanced biological treatment + granular activated carbon.
	PSNS-B/D#1	In-plant steam stripping/distillation.
	PSNS-B/D#2	In-plant steam stripping/distillation + granular activated carbon.

* In the Development Document, BCT-A/C#1, #2, and #3 in this table actually correspond to Options 3, 4, and 5, and BCT-B/D#1 and #2 in this table actually correspond to Options 2 and 3. The options not listed in this table were never considered in the EIA because they are equal to or less stringent than the requirements of the selected BPT options, and thus no incremental costs are incurred.

EPA has selected the following technology options as bases for the effluent limitations and standards proposed in today's notice:

- For direct discharging A/C facilities, BPT-A/C#2 is the technology

basis for conventional pollutants and BAT-A/C#2 is the technology basis for priority and nonconventional pollutants.

- For direct discharging B/D facilities, BPT-B/D#2 is the technology basis for

conventional pollutants and BAT-B/D#1 is the technology basis for nonconventional pollutants.

- NSPS-A/C#1 is the technology basis for new A/C facilities that are direct dischargers.

• NSPS-B/D#1 is the technology basis for new B/D facilities that are direct dischargers (this option is identical to BAT-B/D#3).

• PSES-A/C#1 is the technology basis for A/C facilities that are indirect dischargers.

• PSES-B/D#1 is the technology basis for B/D facilities that are indirect dischargers.

• PSNS-A/C#1 is the technology basis for new A/C facilities that are indirect dischargers (this option is identical to PSES-A/C#2).

• PSNS-B/D#1 is the technology basis for new B/D facilities that are indirect dischargers (this option is identical to PSES-B/D#2).

B. Economic Impact Considerations

1. Introduction

EPA's economic impact assessment is documented in the report titled "Economic Impact Analysis of Proposed Effluent Limitations Guidelines and Standards for the Pharmaceutical Manufacturing Industry" (hereinafter

EIA). This report estimates the economic effect of compliance with the proposed regulation in terms of annualized costs, facility closures, changes in rate of return on assets and the interest coverage ratio at the company level, and profit losses at the company level. In addition, impacts on affected communities, foreign trade, specific demographic groups, and new sources also are considered. Finally, a Regulatory Flexibility Analysis detailing the impacts on small businesses within the pharmaceutical industry is included in the EIA. The methodologies for these analyses are detailed in the EIA. The major source of information for this EIA is the 1990 Detailed Questionnaire, which was conducted under the authority of Section 308 of the Clean Water Act.

2. Projected Facility Economic Impacts

The annual costs of regulatory compliance may have a negative effect on facility earnings. Facility closures are identified when the salvage value (i.e., liquidation value) of the facility exceeds

the present value of its future earnings. A post-compliance facility closure analysis was performed for all technology options.

a. Annual Costs. The aggregate post-tax annualized costs for all the regulatory options are given in Tables XI.B.2-1 through XI.B.2-3. The annualized costs for the selected options for this proposed rulemaking are shown in Table XI.B.2-4. The aggregate post-tax annualized costs were estimated at \$30.6 million (1994 \$) for facilities with subcategory A and C operations to implement BAT Option 2 (BAT-A/C#2), \$0.8 million (1994 \$) for facilities with subcategory B and D operations to implement BAT Option 1 (BAT-B/D#1), \$39.5 million (1994 \$) for facilities with subcategory A and C operations to implement PSES Option 1 (PSES-A/C#1), and \$9.1 million (1994 \$) for facilities with subcategory B and D operations to implement PSES Option 1 (PSES-B/D#1), for a total of \$80.0 million (1994 \$) for the selected options.⁴

TABLE XI.B.2-1.—ESTIMATED COMPLIANCE COSTS FOR A/C DIRECT DISCHARGERS
(Millions of 1994 dollars)

Option No.	Total capital costs	Total O&M costs	Total post-tax annualized costs	Average annual cost per facility ¹
BPT Option Costs				
BPT-A/C#1	0	0	0	0
BPT-A/C#2	16.9	8.1	6.5	0.3
BPT-A/C#3	25.0	8.6	7.7	0.3
BPT-A/C#4	42.8	24.9	19.0	0.8
BPT-A/C#5	50.5	26.8	21.0	0.9
BCT Option Costs				
BCT-A/C#1	19.3	3.4	4.1	0.17
BCT-A/C#2	37.1	18.9	15.0	0.62
BCT-A/C#3	44.8	21.8	17.5	0.73
BAT Option Costs				
BAT-A/C#1	17.2	9.8	7.5	0.3
BAT-A/C#2	64.5	40.8	30.6	1.3
BAT-A/C#3	77.8	66.3	46.8	1.9
BAT-A/C#4	106.1	130.6	87.0	3.6

Footnotes:

¹ Total Post-Tax Annualized Costs divided by the total number of A/C direct discharge facilities.

b. Post-compliance Facility Closures. The selected options result in no closures of any facilities. When the most stringent options are considered, one

direct discharging facility with subcategory A and C operations is predicted to close under BAT-A/C#4, and one indirect discharging facility

with subcategory B and D operations is predicted to close under PSES-B/D#3. No other options were determined to result in any other facility closures.

⁴ The Development Document presents costs in 1990 dollars. These costs are inflated to 1994 dollars in this preamble using a factor of 1.143 derived from *Engineering News Record* "Construction Cost Index."

TABLE XI.B.2-2.—ESTIMATED COMPLIANCE COSTS FOR B/D DIRECT DISCHARGERS
[Millions of 1994 dollars]

Option No.	Total capital costs	Total O&M costs	Total post-tax annualized costs	Average annual cost per facility ¹
BPT Option Costs				
BPT-B/D#1	0	0	0	0
BPT-B/D#2	0.69	0.59	0.42	0.030
BPT-B/D#3	3.4	0.86	0.87	0.062
BCT Option Costs				
BCT-B/D#1	0.64	0.51	0.37	0.026
BCT-B/D#2	3.3	0.78	0.82	0.058
BAT Option Costs				
BAT-B/D#1	0.74	1.3	0.81	0.058
BAT-B/D#2	2.0	1.1	0.84	0.060
BAT-B/D#3	3.4	2.2	1.7	0.12
BAT-B/D#4	11.8	3.5	3.3	0.24

Footnotes:

¹ Total Post-Tax Annualized Costs divided by the total number of B/D direct discharge facilities.TABLE XI.B.2-3.—ESTIMATED COMPLIANCE COSTS FOR INDIRECT DISCHARGERS (PSES)
[Millions of 1994 dollars]

Option No.	Total capital costs	Total O&M costs	Total post-tax annualized costs	Average annual cost per facility ¹
A/C Facilities				
PSES-A/C#1	80.9	53.1	39.5	0.4
PSES-A/C#2	103.0	93.6	65.3	0.7
PSES-A/C#3	164.6	120.9	87.8	1.0
PSES-A/C#4	213.7	203.0	140.6	1.6
B/D Facilities				
PSES-B/D#1	28.8	10.2	9.1	0.06
PSES-B/D#2	34.8	19.4	15.0	0.10
PSES-B/D#3	70.8	112.2	72.5	0.5

Footnotes:

¹ Total Post-Tax Annualized Costs divided by the total number of indirect discharge facilities.TABLE XI.B.2-4.—ESTIMATED COMPLIANCE COSTS FOR SELECTED REGULATORY OPTIONS
[Millions of 1994 dollars]

Option No.	Total capital costs	Total O&M costs	Total post-tax annualized costs	Average annual cost per facility ¹
BAT-A/C#2	64.5	40.8	30.6	1.3
BAT-B/D#1	0.7	1.3	0.8	0.06
PSES-A/C#1	80.9	53.1	39.5	0.4
PSES-B/D#1	28.8	10.2	9.1	0.06
Total ²	174.9	105.4	80.0	0.29

Footnotes:

¹ Total Post-Tax Annualized Costs divided by the total number of facilities for each subcategory.² Total number of facilities includes seven non-discharging facilities.

3. Projected Owner Company-Level Economic Impacts

Firm failures are identified when the return on assets and the interest

coverage ratio, common financial indicators, fall below benchmarks for the industry.

Table XI.B.3.b2-1 presents the results of the postcompliance analysis under

the selected regulatory options. This analysis determined that none of the firms owning direct discharging facilities with subcategory A and C or B and D operations are expected to

experience significant impacts (i.e., firm failure) as a result of implementing the selected regulatory options. In addition, only two firms with indirect discharging facilities with subcategory A and C operations and one firm owning an indirect discharging facility with subcategory B and D operations would be expected to experience significant impacts as a result of compliance costs. Thus, a total of three firms are projected

to fail under the conservative assumption of no costs being passed through to consumers. Overall, these firms represent 3.8 percent of all firms with indirect discharging facilities with subcategory A and C operations, 1.4 percent of firms with subcategory B and D operations, and 2.3 percent of all regulated firms. As indicated by the Profitability Analysis, 15 firms (11 percent of firms in the postcompliance

analysis) are anticipated to have major impacts short of firm failure (i.e., will experience a change in ROA of greater than 5 percent). Impacts are most likely overstated, however, because this analysis assumes that firms cannot pass any increased costs through to consumers. If half the costs can be passed through to consumers there would be no firm failures.

TABLE XI.B.3.b2-1.—PROJECTED FIRM FAILURE: ¹ POST COMPLIANCE ANALYSIS ²

	Total No. of firms	Regulatory impact on firms			
		No significant impact		Significant impact	
		No.	Percent	No.	Percent
Firms with A/C Direct Facilities	15	15	100.0	0	0.0
Firms with B/D Direct Facilities	7	7	100.0	0	0.0
Firms with A/C Indirect Facilities	53	51	96.2	2	3.8
Firms with B/D Indirect Facilities	72	71	98.6	1	1.4
All Firms ³	133	130	97.7	3	2.3

Note: Analysis excludes three firms because of lack of financial data.

¹ Firm failure is defined when a firm's return on assets or interest coverage ratio falls below industry benchmarks. This analysis assumes no costs can be passed through to consumers.

² This scenario analyzes impacts from regulating A/C Direct Facilities under options BAT-A/C#2 and BPT-A/C#2, B/D Direct Facilities under options BAT-B/D#1 and BPT-B/D#2, A/C Indirect Facilities under option PSES-A/C#1, and B/D Indirect Facilities under option PSES-B/D#1.

³ Number of firms for All Firms may be less than the total firms by subcategory because some firms have more than one type of facility. Total number of All Firms includes firms that have nondischarging facilities.

4. Projected Employment Losses and Gains and Community-Level Economic Impacts

Based on facility closures and firm failures, the employment losses analysis sums the number of jobs lost in the postcompliance scenario and compares these losses to community employment measures. Job gains are calculated based on the cost of manufacturing, installing, and operating compliance equipment.

No employment losses were projected to occur as a result of regulatory options for direct dischargers. For indirect dischargers, however, total projected primary employment losses resulting from the selected regulatory options were 78 full time equivalent (FTE) positions among indirect discharging facilities with subcategory A and C operations and 13 FTEs among indirect discharging facilities with subcategory B and D operations, for a total of 91 FTEs or 0.07 percent of total employment for the affected portion of the industry. Secondary employment losses were predicted to be 541 FTEs.

None of these losses is expected to result in a change of employment rates of more than 1 percent in the affected communities.

Employment losses are offset to some extent by the need to hire workers to manufacture, install, and maintain the pollution control equipment. Primary employment gains are expected to total 68 annual FTEs for manufacturing

equipment, 10 annual FTEs for installing equipment, and 0 to 889 annual FTEs for operating and maintaining equipment for a total of 78 to 967 annual FTE gains. The sum of primary and secondary gains is calculated to range from 218 FTEs to 2,890 FTEs. Net gains and losses thus range from a loss of 323 FTEs to a gain of 2,349 FTEs.

5. Projected Foreign Trade Impacts

The impact of effluent guidelines on pharmaceutical exports and the U.S. balance of trade was found to be negligible. The one firm/facility predicted to close as a result of the effluent guidelines had pharmaceutical exports totaling \$0.09 million (1994 \$). The loss of these exports would have virtually no effect on U.S. pharmaceutical exports, which, according to the U.S. Department of Commerce, totalled \$5.7 billion in 1991.

6. Regulatory Flexibility Analysis

a. Purpose of the Regulatory Flexibility Analysis. The Regulatory Flexibility Act requires the federal government to consider the impacts on small entities as part of rulemaking procedures. The goal of the analysis is to ensure that small entities potentially affected by a new regulation will not be disproportionately burdened. Small entities have limited resources, and it is the responsibility of the regulating

federal agency to avoid, if possible, disproportionately or unnecessarily burdening such entities.

b. Projected Impacts on Small Businesses. (i) Size Distribution. Small firms make up 76 percent of the 190 firms in the survey universe. The largest percentage of firms are in the 100 to 499 employees size group (37 percent of all firms in the survey universe).

(ii) Recordkeeping and Reporting Requirements. The proposed effluent guidelines for the pharmaceutical industry are revisions to existing effluent guidelines and, accordingly, most of the recordkeeping and reporting requirements to which the industry would be subject are not new requirements. There are some new monitoring requirements. The new monitoring costs total \$10.3 million (1994 \$) annually, and are 15 percent of the total annual compliance cost for the selected options. Large firms incur the largest proportion of the new monitoring costs (61 percent of total monitoring costs).

(iii) Other Federal Requirements. EPA is aware of no federal rules that duplicate, overlap, or conflict with the proposed effluent guidelines for the pharmaceutical industry.

(iv) Significant Alternatives to the Proposed Rule. No significant alternatives to the proposed rule will substantially reduce impacts on small entities, thus the Agency believes the

stated objectives of the Clean Water Act are met with this proposed rule and the impacts to small firms have been considered, where possible.

(v) **Projected Impacts on Small Firms.**

Projected Impacts on small firms measured as firm failure are as follows. Two of the three firms that were projected to fail in the firm-level analysis under the selected regulatory options have fewer than 750 employees, although only 2 percent of small firms in the postcompliance analysis are affected in this manner. In addition, 14 of 15 firms found to experience a significant decline in ROA (over 5 percent) have fewer than 750 employees. These firms represent about 14 percent of all small firms in the post-compliance analysis.

When cash flow is analyzed, however, impacts seem less disproportionate. Except in the 19 to 99 employees group, the total present value of compliance costs as a percentage of the present value of net income is smaller among small firms than among large firms. Over all small firms (or all large firms), the present value of compliance costs is less than 1 percent of the present value of net income.

The above analyses indicate that although small firms do bear a large portion of the impacts such as firm failures, these impacts are felt by a very small percentage of all small firms. Additionally, the percentages of the present value of compliance costs to the present value of net income are expected to be smaller, on average, among small firms than among large firms; thus, impacts to small firms are not expected to be disproportionate to those for large firms.

7. Projected Distributional Impacts

a. Impacts on Drug Prices. Assuming that all costs are passed on to consumers and that price increases will reflect 100 percent of the cost increases to manufacturers, the following observations can be made. For all the selected regulatory options, the ratio of compliance costs to total pharmaceutical costs was 1.6 percent. Most facilities would incur compliance costs less than 1 percent of total pharmaceutical costs. Only three facilities (1 percent of all facilities) would incur compliance costs greater than 10 percent of total pharmaceutical costs.

b. Impacts on Specific Demographic Groups. When possible uses for products produced by a sampling of highly affected facilities (those where compliance costs exceed 10 percent of total pharmaceutical costs) were investigated, it appeared that children,

women, and the elderly were likely to be the major consumers of many of these products. It was further determined that individuals who lack any health insurance, those who are covered by government insurance, and those who are covered by nonwork-related medical insurance might be least likely to have drug coverage. These groups include Hispanics, young adults, African Americans, young children, and the elderly. Thus, young adult women, children, and the elderly are likely to be the most heavily affected by potential cost increases, if such increases can be passed through to consumers.

Because on average any potential price increases are likely to be very low (1.6 percent), impacts on mass consumers of drugs such as HMOs, governments, and, indirectly, third-party insurers should be minimal.

8. Projected Impacts on New Sources

The projected selected options for new sources are NSPS-A/C#1, NSPS-B/D#1, PSNS-A/C#1, and PSNS-B/D#1. In all cases, the requirements for new sources are more stringent than those for existing sources. However, the difference in cost between new source requirements and existing source requirements for typical facilities are relatively small when compared to the average facility costs of production. In most cases, existing facilities would be required to retrofit in-plant steam stripping systems, whereas new sources would have to install in-plant steam stripping/distillation systems. Because designing in pollution control equipment in a new source is typically less expensive than retrofitting the same equipment in an existing source, the cost differential between the selected requirements for existing sources and those higher existing source options that are technically equivalent to new source requirements should be an upper limit on the differential annual cost faced by new sources. Where this differential is not substantial relative to the typical costs of doing business in this industry, no significant barrier to entry is likely to exist.

The average per-facility compliance costs were investigated to determine what the cost differentials would be between proposed new source and existing source requirements. The average per-facility cost differentials ranged from about a \$39,000 to a \$674,000 difference (1994 \$) (for A/C direct dischargers), depending on the type of facility. The maximum \$674,000 difference generates the highest percentage of compliance cost differential to pharmaceuticals manufacturing cost—about 1.4 percent

of total manufacturing costs and about 3.0 percent of pharmaceutical manufacturing costs. Since this cost differential is likely to be less than that assumed here, this small premium estimated to be paid by new sources is not likely to have much impact on the decision to enter the market. Furthermore, these same options, when applied to existing sources, were found to have nearly identical impacts on existing sources as the selected options for existing sources. Thus no significant barriers to entry are estimated to result from the proposed new source requirements.

9. Regulatory Impact Assessment

The Agency has prepared a regulatory impact assessment (RIA) for the proposed regulatory alternative. The RIA responds to the requirements in Executive Order 12866 to assess both the costs and benefits to society of significant regulatory actions. Significant regulatory actions are those that impose an annual cost to the economy of \$100 million or more, or have certain other regulatory, policy or economic impacts. The RIA is detailed in "Regulatory Impact Assessment of the Proposed Effluent Guidelines for the Pharmaceutical Manufacturing Industry" (see Section II for availability of this and other supporting documents). This RIA was submitted to OMB for review as required by Executive Order 12866.

The RIA analyzes the effects of current air and water emissions and assesses the benefits of reductions in these emissions resulting from the proposed regulation. EPA expects a variety of human health, environmental, and economic benefits to result from these reductions in effluent loadings and air emissions. In particular, the benefits assessment addresses the following benefit categories: human health and agricultural benefits due to reductions in emissions of ozone precursors (i.e., reductions in VOC emissions); human health benefits due to reductions in excess cancer risk; human health benefits due to reductions in non-carcinogenic risk; ecological and recreational benefits due to improved water quality; and benefits to publicly owned treatment works (POTWs) from reductions in interference, pass through, and sludge contamination problems and improvements in worker health and safety. EPA monetizes the estimated benefits for reductions in air emissions of ozone precursors and cancer risk reductions, but is unable to quantify the dollar magnitude of benefits from the other benefit categories. Air benefits are estimated separately for Section 308

survey air emissions data and for air emissions estimated by the WATER7 model which estimates the maximum emissions.

a. Human Health/Agricultural Benefits from Reductions in Emissions of Ozone Precursors. The proposed effluent guidelines are expected to result in reductions in ambient ozone concentrations due to reductions in VOC emissions. Controlling VOC emissions is beneficial because VOCs are precursors to ozone, which negatively affects human health and the environment.

(1) Human Health Benefits.

The RIA estimates that the annual human health benefits resulting from reductions in VOC emissions due to the proposed rule range from \$31,000 to \$1.9 million (1994 \$). EPA monetizes these benefits using a benefits-transfer-based approach. Specifically, the estimated reductions in VOC emissions in nonattainment areas (1,396 Mg) are multiplied by an existing estimate of the range of the value of a unit reduction in VOC emissions (\$22/Mg to \$1,382/Mg, 1994 \$). This range is taken from an existing study that evaluated the human health benefits of ozone reductions in nonattainment areas.

(2) Welfare Benefits from Increased Agricultural Crop Yields.

Studies of the relationship between ambient ozone concentrations and greenhouse-controlled ozone concentrations and agricultural crop yields demonstrate that ozone negatively affects crop yields. Reductions in crop yields in turn affects agricultural production, crop prices, and incomes of agricultural producers, and thus affects social welfare. Thus, reductions in ozone concentrations that lead to improved crop yields will generate welfare benefits.

The RIA estimates that the annual agricultural-related economic welfare benefits from reductions in VOC emissions range from \$186,000 to \$315,000 (1994 \$). To generate these welfare benefit estimates, EPA applies an existing estimate of the benefits per unit reduction in VOC emissions (\$134/Mg to \$226/Mg, 1994 \$) to the total expected reduction in VOC emissions in nonattainment areas. The existing value estimates were developed using economic models that estimate the net change in social welfare resulting from higher crop yields as a result of lower ambient ozone levels in rural areas.

b. Human Health Benefits Due To Cancer Risk Reduction. The benefits from the proposed rule include human health benefits from reductions in excess cancer risk. EPA expects the proposed rule to reduce loadings of

toxic substances that otherwise would volatilize and pose a cancer risk to humans, resulting in reductions in excess cancer risk in exposed populations from inhalation of VOCs. In addition, EPA expects that reduced loadings to surface waters will improve water quality and thus reduce cancer risk to the exposed populations from consumption of contaminated drinking water and fish tissue.

Based on the cancer risk assessment conducted for the RIA, EPA estimates that the proposed guidelines will result in 0.02 to 0.35 excess cancer cases avoided per year nationwide. The estimated value of the human health benefits from these cancer risk reductions ranges from \$14,000 to \$5.4 million (1994 \$) annually. 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 \$0.7 million to \$15.4 million (1994 \$). This estimated range is based on a review of literature pertaining to the value of life.

c. Human Health Benefits from Reductions in Noncarcinogenic Risk.

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. The proposed rule might generate human health benefits by reducing exposure to these substances, thus reducing the risks of these associated effects.

As in the case of the cancer risk assessment, systemic risks from exposure to air emissions and consumption of contaminated fish tissue and drinking water are evaluated. Modeled pollutant concentration levels are compared to human health criteria or estimated toxic effect levels. Based on this analysis, reductions in air emissions might result in reduced systemic risk, with benefits ranging from reduced risk to zero individuals (since estimated baseline risks are low) to reduced risk to 126,000 individuals due to reduced exposure to two toxic pollutants. No systemic risk reductions are expected to result from reduced exposure to contaminated fish tissue or drinking water. Sufficient data to quantify these benefits further are not available.

d. Ecological and Recreational Benefits Due to Improved Water Quality. EPA expects the proposed effluent guidelines 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., provision 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 of recreational experiences of users, such as anglers fishing in the affected streams. In the RIA, EPA considers the value of the recreational benefits resulting from the proposed rule, but does not evaluate the other types of ecological and environmental benefits due to data limitations.

To estimate the benefits from the improvements in water quality expected to result from this rule, instream concentration estimates are modeled and then compared to EPA's freshwater acute and chronic aquatic life criteria to evaluate whether these discharges pose risk to aquatic organisms. The projected reductions in toxic loadings to surface waters are significant. Pollutant loadings are estimated to decline by 57 percent, from 39.9 million pounds per year under current conditions to 17.1 million pounds per year under the proposed rule. The analysis comparing instream concentration levels to aquatic life water quality criteria estimates that current discharge loadings result in excursions of aquatic water quality criteria at two locations. The analysis also indicates that no excursions are expected to occur at these two sites under the proposed rule.

EPA estimates that the annual recreational benefits associated with the expected changes in water quality are on the order of thousands of dollars. EPA evaluates these recreational benefits, applying a simple model that considers the change in consumer welfare likely to result from improved catch rates by recreational anglers at these two sites. EPA assumes that catch rates improve due to larger fish populations that are assumed to result from improved water quality.

e. Benefits from Reductions in Loadings Discharged to POTWs. The RIA considers three potential sources of benefits to POTWs from the proposed regulation: Reductions in the likelihood of interference, pass through, and sewage sludge contamination problems, reductions in health and safety risks to POTW workers, and 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, the RIA does not quantify these benefits due to data limitations.

First, regarding potential interference, pass through and sewage sludge contamination problems, the proposed rule is expected to help reduce these problems by reducing toxic loadings in the industry's effluent and reducing shock releases. Anecdotal evidence from POTW responses to an EPA survey and analytic results indicate that such effects can occur. In addition, based on an analysis comparing POTW influent levels to available data on inhibition levels, inhibition problems are projected to occur at six POTWs for seven pollutants under current conditions. Inhibition problems are projected to occur at five POTWs for three pollutants after the proposed rule. Sufficient data are not available to further quantify this benefit category.

Furthermore, toxic substances in effluent discharges to POTWs pose health risks to POTW workers. The proposed rule is expected to reduce these risks, thus generating human health benefits. Based on the assessment of the risk posed to POTW workers from

exposure to toxic pollutants, the proposed rule is estimated to reduce occupational risk at six POTWs. Data are not available to monetize this benefit category.

Finally, in implementing local programs to control pollutants discharged to their systems, authorized POTWs often must set numerical limits on toxic loadings in discharges to the POTW, based on national categorical pretreatment standards or local limits determined by the POTW. In setting these local limits, POTWs sometimes need to undertake analyses to determine which pollutants warrant local limits and at what numerical level. Conducting these analyses is expensive, costing on the order of hundreds of thousands of dollars. Several POTWs contacted as part of EPA's survey of POTWs indicated that they will benefit from the establishment of national pretreatment standards by avoiding these analytical costs. In addition, they indicated that the pretreatment standards will bolster the legal authority of the limits they set. EPA solicits comments on this issue. See Section XIV, solicitation number 24.4.

f. Summary of Benefits. EPA estimates that the annual benefits resulting from the proposed rule will range from \$231,000 to \$7.6 million (1994 \$). Table XI.B.9.f summarizes these benefits by category. The range reflects the uncertainty in evaluating the effects of the proposed rule and in placing a dollar value on these effects. As indicated in the table, these benefit ranges do not reflect many of the benefit categories expected to result under the proposed rule, including human health benefits associated with potential reductions in chronic effects from ozone exposure, human health benefits associated with reductions in acute effects in attainment areas, agriculture-related benefits from reductions in emissions of ozone precursors in attainment areas, ecological and recreational benefits from improvements in water quality, benefits from avoided interference and pass through problems and improved worker health and safety at POTWs, and human health benefits from potential reductions in systemic risk. Therefore the reported benefit estimate understates the total benefits of the proposed rule.

TABLE XI.B.9.f.—POTENTIAL ECONOMIC BENEFITS FROM THE PROPOSED EFFLUENT GUIDELINES FOR THE PHARMACEUTICAL INDUSTRY

Benefit category	Thousands of 1994 dollars per year
Reductions in Emissions of Ozone Precursors: ¹	
Human Health	31–1,929.
Agricultural	186–315.
Cancer Risk Reductions	14–5,401.
Non-carcinogenic Risk Reductions	Unquantified.
Ecological and Recreational Benefits	Unquantified.
POTW Reductions in Interference and Sludge Inhibition	Unquantified.
Total quantifiable benefits	231–7,646.

¹ The estimates presented only include benefits associated with reductions in acute health effects and improvements in agricultural yields in nonattainment areas. Potential welfare benefits associated with forest yield, materials damage, and visibility are not addressed in this analysis.

g. Costs to Society. A major component of social cost (beyond the cost to industry of compliance) is the cost to government of providing the tax deductions on pollution control costs to industry. In addition, there are other monetary and nonmonetary outlays made by government. Government administrative costs and costs of reallocating displaced workers are two

additional monetary costs. Nonmonetary costs include losses in consumers' or producers' surpluses in product markets, discomfort or inconvenience, loss of time, and slowing the rate of innovation. The social costs estimated here, which include compliance costs to industry and the costs of government tax subsidies, therefore, are a very large

portion of, but not the true total social cost of the proposed regulation. The costs reported here are thus only a close estimate of this true cost.

The estimate of total annual social costs for all selected options is shown in Table XI.B.9.g. Total social costs resulting from the proposed effluent guideline are estimated to be \$123.9 million (1994 \$).

TABLE XI.B.9.g.—SOCIAL COSTS FOR SELECTED REGULATORY OPTIONS
[Millions of 1994 dollars]

Option No.	Total capital costs	Total O&M costs	Total annualized costs ¹
BAT-A/C#2	64.5	40.8	47.6
BAT-B/D#1	0.7	1.3	1.3

TABLE XI.B.9.g.—SOCIAL COSTS FOR SELECTED REGULATORY OPTIONS—Continued
[Millions of 1994 dollars]

Option No.	Total capital costs	Total O&M costs	Total annualized costs ¹
PSES—A/C#1	80.9	53.1	61.6
PSES—B/D#1	28.8	10.2	13.3
Total ²	174.9	105.4	123.9

Footnotes:

¹ The total annualized costs of compliance are calculated prior to accounting for the tax deductibility of the pollution control costs.

² Total number of facilities includes seven non-discharging facilities.

Note: These numbers are for all facilities and do not reflect closures predicted by the analyses in this report.

h. Benefit-Cost Comparison. Because not all of the benefits resulting from the regulatory alternative can be valued in terms of dollars, a complete cost-benefit

comparison cannot be performed. The social cost of the alternatives considered in the proposed rule, discussed in the preceding section is estimated to be

\$123.9 million (1994 \$). The sum of total benefits that can be valued in dollar terms ranges from \$0.2 to \$7.6 million per year (1994 \$) (see Table XI.B.9.h).

TABLE XI.B.9.h.—COMPARISON OF ANNUAL BENEFITS AND COSTS FOR THE PHARMACEUTICAL RULEMAKING
[Thousands of 1994 dollars]

Benefits	
Cancer risk reductions	14–5,401
Reductions in emissions of ozone precursors	31–1,929
Human health	186–315
Agricultural benefits	
Total quantifiable benefits	231–7,646
Costs	
Total Annual Costs to Industry	80,000
Total Annual Social Costs	123,900

XII. Relationship of Proposed Effluent Guidelines to EPA's Hazardous Waste Initiatives

A. Relationship to Rulemaking Activities Under RCRA

1. Introduction and Overview of Land Ban Regulations

EPA's Office of Solid Waste Phase 3 proposed land disposal restriction regulations under the Resource Conservation and Recovery Act (RCRA) for certain hazardous wastes streams common to the pharmaceutical manufacturing industry on February 16, 1995. These regulations will be codified at 40 CFR Part 268 after they are finalized (scheduled for January 1996).

The proposed RCRA regulations signed on February 16, 1995 cover decharacterized ignitable (I), corrosive (C), reactive (R) and toxic (TC) wastes (i.e., wastes that initially exhibit a characteristic but, as a result of dilution, no longer do so when they are land disposed) that are managed in surface impoundments whose ultimate discharge is regulated under the Clean Water Act. These regulations also potentially apply to decharacterized wastes disposed in Class I

nonhazardous deep injection wells regulated under the Safe Drinking Water Act's Underground Injection Control program. The definitions of these waste streams are listed in Table XII.A. The September 1992 Third decision in *Chemical Waste Management v. EPA*, 976 F.2d 2 (D.C. Cir. 1992) requires EPA to assure that decharacterized wastes disposed in surface impoundments are treated to the same extent they would be if disposed in surface disposal units. However, the opinion specifically allows this showing of equivalent treatment to be measured at the eventual discharge point, so that treatment occurring in the wastewater treatment system (including the surface impoundment) can be taken into account.

2. The Land Disposal Restrictions Program

a. Introduction to RCRA Land Disposal Restrictions. The Hazardous and Solid Waste Amendments (HSWA) to 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).

The treatment standards may be expressed as either constituent concentration levels or as specific methods of treatment. These standards 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. Discharge of wastewater streams containing hazardous wastes to surface impoundments is considered temporary land disposal. RCRA section 3004(k).

EPA has implemented these requirements by requiring treatment standards for hazardous wastes to be based on performance of Best Demonstrated Available Technology (BDAT).

b. Regulation of Characteristic Wastes. On May 8, 1990, EPA promulgated land disposal prohibitions and treatment standards for hazardous wastes that exhibited one or more of the following characteristics: ignitability, corrosivity, reactivity, or EP toxicity (40 CFR 261.21–261.24). These regulations established treatment standards for the characteristic wastes in one of four forms: (1) A concentration level equal to, or greater than, the characteristic level; (2) a concentration level less than the characteristic level; (3) a specified treatment technology (e.g., for ignitable wastes containing high levels of total organic carbon); and (4) a treatment standard of “deactivation” which allowed the use of any technology, including dilution, to remove the characteristic.

Such treatment frequently occurs in centralized wastewater management systems subject to regulation under the Clean Water Act or Safe Drinking Water Act. Furthermore, the deactivation can occur as a result of mixing wastewaters together (for example, to equalize wastewater flow into a centralized wastewater management unit). This mixing, however, is a type of dilution, and dilution is normally an impermissible means of achieving a land disposal regulation (LDR) treatment standard. EPA addressed at length the question of whether dilution incidental to such centralized wastewater management should be allowed. See generally 55 FR 22653–59 (June 1, 1990). The Agency found, generally, that mixing waste streams to eliminate certain characteristics was appropriate and permissible for corrosive wastewaters and, in some cases, reactive or ignitable wastewaters. Furthermore, EPA stated that the dilution prohibition did not normally apply to characteristic wastewaters that are managed in treatment trains, including surface impoundments, whose ultimate discharge is regulated

under the pretreatment and NPDES programs under sections 307(b) and 402 of the CWA, or in Class I underground injection well systems regulated under the Safe Drinking Water Act (SDWA). The Agency stated that the treatment requirements and associated dilution rules under the CWA are generally consistent with the dilution rules under RCRA, and that the Agency should rely on the existing CWA provisions. The Agency also singled out certain particularly toxic wastewaters to which the dilution prohibition still applies notwithstanding management in CWA systems. 40 CFR 268.3(b). Similarly, EPA stated that a regulatory program had been established under the SDWA to prevent underground injection that endangers drinking water sources.

c. The Third Third Court Decision.

On September 25, 1992, the United States Court of Appeals for the District of Columbia Circuit ruled on the various petitions for review filed against the 1990 land disposal rule, also known as the Third Third rule. See *Chemical Waste Management v. EPA*, 976 F.2d 2, cert. denied, 113 S.Ct. 1961 (1993). The court issued three principal holdings of the case with respect to characteristic wastes. First, EPA may require treatment under RCRA section 3004(m) to more stringent levels than those at which wastes are identified as hazardous, *Id.* at 12–14. Second, section 3004(m) requires that treatment standards address both short-term and long-term potential harms posed by hazardous wastes, and consequently must result in destruction and removal of hazardous constituents as well as removal of the characteristic property, *Id.* at 16, 17, 23. As a consequence, dilution without destruction or removal of hazardous constituents is permissible as an exclusive method of treatment only for those characteristic wastes that do not contain hazardous constituents “in sufficient concentrations to pose a threat to human health or the environment” (*i.e.*, the minimize threat level in section 3004(m)). *Id.* at 16. Third, situations where characteristic hazardous wastes are diluted, lose their characteristic(s) and are then managed in centralized wastewater management

land disposal units (*i.e.*, subtitle D surface impoundments or Class I nonhazardous injection wells) are legal only if it can be demonstrated that hazardous constituents are removed or destroyed to the same extent they would be pursuant to otherwise-applicable RCRA treatment standards. *Id.* at 7.

As a consequence of these holdings, the court held that the deactivation standard for ignitable and corrosive wastes did not fully comply with RCRA section 3004(m). This was because that standard could be achieved by dilution, and dilution fails to destroy or remove the underlying hazardous constituents that can be present in the wastes. *Id.*

3. Phase 3 and the Pharmaceutical Effluent Guidelines

The RCRA regulations EPA proposed on February 16, 1995 are known as the Phase 3 rule. In response to the D.C. Circuit court decision requiring treatment beyond decharacterization or dilution for ignitable, corrosive, reactive and characteristically toxic wastes, the proposed rule addresses underlying hazardous constituents of these wastes.

EPA believes that the practices of disposal of spent solvents used extensively in pharmaceutical processes for cleaning out batch units result in the discharge of significant amounts of characteristically ignitable (D001) hazardous waste. Many of these streams are disposed in surface impoundments and will be covered by the Phase 3 proposal.

The Phase 3 rule sets out EPA’s general approach to have the RCRA standards be the same as BAT under the CWA. This is because the BAT standards reflect an industry-specific evaluation of best treatment for that industry’s wastewater. Thus, the RCRA technology-based standards will typically match those of the Clean Water Act. This approach works well for the pharmaceutical manufacturing industry because the Clean Water Act rule effluent limitations guidelines and standards are being revised contemporaneously with the Phase 3 LDR rules, and thus reflect current BAT.

TABLE XII.A.—IGNITABLE/CORROSIVE/REACTIVE/TOXICITY CHARACTERISTIC WASTES D001, D002, D003 AND D004–32

D001	IGNITABLE.
D001	Liquid—flash point<60 C—High TOC—261.21(a)(1).
D001	Liquid—flash point<60 C—Low TOC—261.21(a)(1).
D001	Nonliquid—burns vigorously/persistently—261.21(a)(2).
D001	Ignitable compressed gas—49 CFR 173.300—261.21(a)(3).
D001	Oxidizer—49 CFR 173.151—261.21(a)(4).
D002	CORROSIVE.
D002	pH<2—261.22(a)(1).
D002	pH>10—261.22(a)(1).

TABLE XII.A.—IGNITABLE/CORROSIVE/REACTIVE/TOXICITY CHARACTERISTIC WASTES D001, D002, D003 AND D004–32—Continued

D002	Corrodes steel—261.22(a)(2).
D003	REACTIVE.
D003	Violent change without detonating—261.23(a)(1).
D003	Violent reaction with water—261.23(a)(2).
D003	Generates toxic gases—261.23(a)(3).
D003	Contains CN or S—261.23(a)(4).
D003	Capable of detonating under stress—261.23(a)(5).
D003	Capable of detonating spontaneously—261.23(a)(6).
D003	Forbidden, Class A or Class B explosive—261.23(a)(7).
D004–D043	TOXICITY CHARACTERISTIC (TC) WASTES.
D004	Arsenic.
D005	Barium.
D006	Cadmium.
D007	Chromium.
D008	Lead.
D009	Mercury.
D010	Selenium.
D011	Silver.
D012	Endrin.
D013	Lindane.
D014	Methoxychlor.
D015	Toxaphene.
D016	2,4-D.
D017	Silvex.
D018	Benzene.
D019	Carbon tetrachloride.
D020	Chlordane.
D021	Chlorobenzene.
D022	Chloroform.
D023	o-Cresol.
D024	m-Cresol.
D025	p-Cresol.
D026	Cresol.
D027	1,4-Dichlorobenzene.
D028	1,2-Dichloroethylene.
D029	1,1-Dichloroethylene.
D030	2,4-Dinitrotoluene.
D031	Heptachlor and epoxide.
D032	Hexachlorobenzene.
D033	Hexachlorobutadiene.
D034	Hexachloroethane.
D035	Methyl ethyl ketone.
D036	Nitrobenzene.
D037	Pentachlorophenol.
D038	Pyridine.
D039	Tetrachloroethylene.
D040	Trichloroethylene.
D041	2,4,5-Trichlorophenol.
D042	2,4,6-Trichlorophenol.
D043	Vinyl chloride.

B. Coordination With Waste Minimization and Combustion Strategy

In May 1994, the Administrator announced a Draft Hazardous Waste Minimization and Combustion Strategy that is pertinent to this rulemaking for the pharmaceutical manufacturing industry. The Draft Strategy provides the central framework for EPA's federal effort to maximize the source reduction and recycling of hazardous wastes under RCRA. The Draft Strategy focuses on a number of specific goals, including reducing the amount and toxicity of hazardous waste that is generated, particularly when such reductions would benefit more than one

environmental medium. The Draft Strategy also encompasses a number of other features, including public outreach, public involvement and environmental justice, permitting, enforcement, risk assessments, and good science.

1. Waste Minimization

The Draft Strategy has both short-term and a longer-term phases. In the short-term, EPA will address the source reduction and environmentally sound recycling of halogenated (and metal-bearing) combustible wastes. The longer-term effort will encompass all RCRA hazardous wastes, taking a more

comprehensive approach to how wastes are generated and managed, and the role waste minimization can play as a preferred "mode of management" over other forms of waste management (e.g., treatment, storage, and disposal). This source reduction (waste minimization) strategy should reduce the long-term demand for combustion and other waste management facilities. Section VI of this preamble presents EPA's efforts toward increasing opportunities for source reduction (e.g., process changes) in the pharmaceutical manufacturing industry.

The Agency also has released a draft report by the EPA Office of Solid Waste's Definition of Solid Waste Task

Force. This report, *Reengineering RCRA for Recycling*, presents recommendations of the Task Force to improve the regulation of hazardous waste recycling under RCRA. One of the recommendations of the Task Force was that provision should be made to exempt "clean" waste-derived fuels from the regulatory requirements of RCRA for hazardous wastes. "Clean fuels" are fuels with "*de minimis*" levels of halogens (primarily chlorine in this case) or toxic metals, especially fuels that are characteristically hazardous only because of ignitability. EPA has initiated a rulemaking effort to address the recommendations of the Task Force, including the recommendation on "clean fuels."

In the case of the pharmaceutical manufacturing industry, the volatile organic pollutants that are generated in the largest quantities are non-halogenated volatile organic pollutants, including methanol, ethanol, isopropanol, and acetone.

Implementation of in-plant steam stripping or steam stripping with distillation technology affords the opportunity to recover these potentially "clean fuels" for recycle in industrial boilers, such as those on-site at pharmaceutical manufacturing facilities.

Implementation of in-plant steam stripping or steam stripping with distillation technology also affords the opportunity to recover halogenated volatile organic pollutants (e.g., methylene chloride) for recycle in the pharmaceutical manufacturing process. Recovered chlorinated solvents that are not of sufficient quality for reuse in pharmaceutical manufacturing processes may be sold for reuse in other industries.

2. Combustion

The Draft Strategy also addresses rigorous controls on hazardous waste combustion facilities using best available technologies to ensure that these facilities do not impose unacceptable risk to human health and the environment. EPA's regulatory activities are scheduled to be directed toward upgrading technical standards for residual wastes and emissions from hazardous waste combustion facilities, including incinerators, cement kilns, light-weight aggregate kilns, and smelter furnaces, as well as boilers and industrial furnaces.

EPA estimates that approximately 115,000 metric tons per year of solvents (halogenated and nonhalogenated) would be recovered from in-plant steam stripping technology at pharmaceutical manufacturing facilities. There is currently adequate capacity at

commercial incinerators to combust the entire mass of solvents (in excess of 1 million metric tons per year) if none was recovered and recycled. However, it is the Agency's policy, as stated in the Draft Waste Minimization and Combustion Strategy, that the most appropriate mode of management for solvents removed from pharmaceutical manufacturing wastewaters by steam stripping is recycle of "clean fuels" in boilers, recycle in the process, or recycle at other facilities.

XIII. Administrative Requirements

A. Changes In Format and Name

EPA is not proposing any changes in format to part 439 of the Code of Federal Regulations.

B. Docket and Public Record

The Record for this rulemaking is available for public review at EPA Headquarters, 401 M Street SW, Washington, DC 20460. The Record supporting the effluent limitations guidelines in part 439 is located in the Office of Water Docket, Room L102 (in the basement of Waterside Mall). The Docket is staffed by an EPA contractor, Labat-Anderson, Inc., and interested parties are encouraged to call for an appointment. The telephone number for the Water Docket is (202) 260-3027.

EPA notes that many documents in the record supporting these proposed rules have been claimed as confidential business information and, therefore, are not included in the record that is available to the public in the Water Docket. To support the rulemaking, EPA is presenting certain information in aggregated form or is masking plant identities to preserve confidentiality claims. Further, the Agency has withheld from disclosure some data not claimed as confidential business information because release of this information could indirectly reveal information claimed to be confidential.

C. Clean Water Act Procedural Requirements

As required by the Clean Water Act, EPA will conduct a public hearing on the pretreatment standards portion of the proposed rule. The location and time of this public hearing will be announced in a future notice.

D. Executive Order 12866

Under Executive Order 12866, (58 FR 51735 (October 4, 1993)) requires EPA and other agencies to assess the potential costs and benefits of all significant regulatory actions, and submit these actions to the Office of Management and Budget (OMB). Significant regulatory actions are those

that impose a cost on the economy of \$100 million or more annually or have certain other regulatory, policy, or economic impacts. Today's rule meets the criteria of a significant regulatory action as set forth in section 3(f) of the Executive Order. The regulatory analysis for this proposed rule is presented in "Regulatory Impact Assessment of Proposed Effluent Guidelines for the Pharmaceutical Industry." This analysis (referred to as the RIA) is summarized in section XI.B. Today's proposed rule and the RIA were submitted to the OMB for review.

E. Regulatory Flexibility Act

The Regulatory Flexibility Act, 5 U.S.C. 601 *et. seq.*, requires EPA and other agencies to prepare an initial regulatory flexibility analysis for regulations that have a significant impact on a substantial number of small entities. EPA projects that today's proposed rule, if promulgated, could affect small businesses. The initial regulatory flexibility analysis for these proposed rules is incorporated into the economic impact analysis and is discussed in section XI.B. Reporting and other compliance requirements are summarized in sections IX.I and detailed in the TDD. While the Agency has not identified any duplicative, overlapping, or conflicting Federal rules, a discussion of other related rulemakings is presented in sections V.B, V.C, V.D, X.A, X.B, XII.A, and XII.B.

F. Reduction of Unfunded Mandates and Consultation with State, Local, and Tribal Governments

Executive Order No. 12875 supplements Executive Order No. 12866 [Sec. 1(b)(9)], and is intended "to reduce the imposition of unfunded mandates upon State, local, and tribal governments." Facilities in the pharmaceutical manufacturing industry are not associated with tribal governments, and the burden to states and local authorities is expected to be minimal, if not decreased, by the implementation of this rule.

These proposed requirements, when promulgated, will be implemented via the existing regulatory structure and no additional burden is expected beyond that previously estimated by EPA for the NPDES and general pretreatment programs. In the absence of effluent limitations guidelines and pretreatment standards, establishing BAT, BCT, NSPS, PSES, and PSNS permit limitations are to be developed on a case-by-case "Best Professional Judgment" (BPJ) basis. In addition, NPDES permits for all direct dischargers

and POTWs must incorporate state water quality standards where necessary. Once these revised pharmaceutical effluent guidelines and standards are in place, regulatory burdens on the states and local POTWs in developing pollutant control requirements that heretofore have not been addressed for this industry, particularly for volatile organic pollutants and other wastewater discharge characteristics, will be reduced. For example, the Agency is aware that certain POTWs have expended considerable resources for outside contractors (e.g., engineering consultants) to secure technical support in developing the basis for local limits or other special requirements, for POTW maintenance and equipment replacement, and for special treatment systems. These requirements were needed to prevent pollutant pass through, interference, or sludge contamination attributable to pharmaceutical facility discharges.

In compliance with E.O. 12875, EPA has involved state and local governments in the process of developing this rule. Since the inception of the project in 1986, there have been periodic meetings with the industry and its trade association, the Pharmaceutical Research and Manufacturers of America (PhRMA), to discuss progress on the rulemaking. The Agency also has met with the Natural Resources Defense Council (NRDC) to discuss progress on this rulemaking. Because most of the facilities affected by this proposal are indirect dischargers, the Agency conducted an outreach survey to a limited number of POTWs substantially affected by one or more pharmaceutical manufacturing facilities to solicit their input on the need for this proposed rule and pertinent technical issues. The Agency has worked with the Food and Drug Administration (FDA) to explore pollution prevention opportunities to the maximum extent feasible. As described previously in this preamble, EPA shared with FDA information and data gathered from the industry in responses to EPA's detailed Section 308 questionnaire. This was done to assist FDA in evaluating the environmental impacts of revised drug manufacturing processes (as described in "supplement" applications) and of new drug manufacturing processes. These reviews will ensure that opportunities for solvent use minimization/elimination and water-based manufacturing processes (e.g., water-based tablet coating) are considered and adopted within the constraints of maintaining the efficacy

of both existing and new pharmaceutical products.

The Agency also held a public meeting on May 23, 1994. EPA representatives of the Office of Water and the Office of Air and Radiation outlined the underlying technical basis and options being considered for this proposal, the efforts to coordinate the future air rule and this proposed water rule, and took comments and questions from the audience. The Agency also consulted with representatives of selected POTWs regarding underlying technical aspects of this proposal.

The Agency will continue this process of consulting with state, local, and other affected parties after proposal in order to further minimize the potential for unfunded mandates that may result from this rule.

G. Paperwork Reduction Act

The proposed effluent guidelines and standards for the pharmaceutical manufacturing industry contain no information collection activities beyond those required for the NPDES permit program and the general pretreatment program. Therefore, an information collection request (ICR) has not been submitted to the Office of Management and Budget (OMB) for review and approval under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*

OMB has approved the existing information collection requirements associated with NPDES discharge permit applications and the general pretreatment program under the provisions of the Paperwork Reduction Act.

The collection of information required for NPDES discharge permit applications has an estimated reporting burden averaging 12 hours per response and an estimated annual recordkeeping burden averaging two hours per respondent. These estimates include time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

XIV. Solicitation of Data and Comments

A. Introduction and General Solicitation

EPA invites and encourages public participation in this rulemaking. The Agency asks that comments address any perceived deficiencies in the record of this proposal and that suggested revisions or corrections be supported by data.

The Agency invites all parties to coordinate their data collection activities with EPA to facilitate

mutually beneficial and cost-effective data submissions. EPA is interested in participating in study plans, data collection and documentation. Please refer to the "For Further Information" section at the beginning of this preamble for technical contacts at EPA.

When responding to these comment solicitations, please identify for each comment or data submission the comment solicitation number or numbers that the comment or data submission addresses. Commenters should also submit an electronic version on diskette if possible.

B. Specific Data and Comment Solicitations

EPA has solicited comments and data on many individual topics throughout this preamble. The Agency incorporates each of these solicitations here, and reiterates its interest in receiving data and comments on the issues addressed by those solicitations. EPA particularly requests comments and data on the following issues:

1.0 General

1.1 Comments on Options and Technologies Evaluated

The Agency solicits comments on all of the technologies and technology options identified in today's proposal.

1.2 Comments on Options/Technologies Selected for Proposal

The Agency solicits comments on the options and technologies and compliance monitoring points selected for proposal today, and the technical, policy, and legal bases expressed by EPA in support of such selections.

1.3 Comments on Proposed Effluent Limitations and Standards

The Agency solicits comments on the effluent limitations and standards proposed today.

1.4 Comments on the Methodology Used to Develop Steam Stripper- and Steam Stripper With Distillation-Based Limitations and Standards

The Agency solicits comment regarding its methodology for developing the proposed limitations and standards based on available steam stripper and steam stripper/distillation performance data.

2.0 Adequacy of the 308 Questionnaire Database

The Agency has collected a significant amount of technical and economic data from pharmaceutical manufacturing facilities. Nonetheless, the Agency is open to suggestions regarding any additional data collections that may be

required. The Agency also solicits information, comments, and data on the following technical areas:

a. Data characterizing in-facility process wastewater streams bearing pollutants proposed to be regulated, including ammonia concentration in the wastewater stream, stream pH, stream TDS and TSS, and information on the ionic species in the stream.

b. Information on new steam strippers installed since 1990 for the treatment of pharmaceutical process wastewater.

c. Information on the storage capacity used by facilities prior to steam stripping.

d. Information on steam generation and cost, including how much steam is generated on-site and at what cost, how much steam is purchased from off-site sources and at what cost, steam condition, and steam pressure used by the facility.

e. Information on scaling in steam strippers including information concerning the issues, problems, and solutions to scaling.

f. Information on the operation and maintenance costs for running steam strippers at pharmaceutical manufacturing facilities.

3.0 Basis for Pollutant Loading Estimates

EPA requests information from plants that completed Table 3-2 of the "1990 Pharmaceutical Manufacturing Survey" but did not indicate a technical basis for their loadings estimates (i.e., air emissions from wastewater, discharges to surface waters/sewers etc.). The Agency requests that facilities specify the method and underlying assumptions used in making air emission and water discharge estimates for individual pollutants, the loading estimate values either estimated or measured, and the uncertainty associated with the method used to estimate these quantities.

4.0 Subcategorization

EPA is proposing to maintain the existing subcategorization scheme. The rationale for maintaining this scheme is discussed in Section IX.A.3 of this preamble.

4.1 Comments on Maintaining the Existing Subcategorization Scheme

EPA solicits comments regarding the decision to maintain the existing scheme.

4.2 Alternative Regulatory Schemes

The Agency also solicits suggestions for alternative regulatory schemes.

5.0 Definition of Research Operations

5.1 Definition

Research operations are defined and discussed in section IX.A.4 of this preamble. EPA solicits comments regarding the definition of research operations for the pharmaceutical manufacturing category.

5.2 Research Operation Wastewater in Combination With Other Subcategory Wastewater

EPA solicits comment on whether wastewaters generated from bench-scale pharmaceutical research operations at facilities with other pharmaceutical subcategory wastewaters (A, B, C, D) should be subject to the proposed subcategory A, B, C, and/or D standards and limitations rather than the existing BPT limitations for subcategory E.

6.0 Characterization of Individual Process Wastewater Streams

The Agency anticipates that at most facilities, a greater mass of volatile organic pollutants will be concentrated in specific wastewater streams rather than being evenly distributed in all wastewater streams. Nonetheless, EPA has assumed for purposes of this proposal that wastewater streams with volatile organic pollutants at concentrations above the distillation treatability target concentrations would require steam stripping. Because of a lack of detailed and consistent flow and pollutant characterization data in the plant responses to the section 308 questionnaire, EPA assumed, when estimating costs associated with the steam stripping and steam stripping with distillation options, that facilities would be treating all or most of the process wastewater generated by their individual plants. EPA believes that this is not a realistic assumption and that the costs developed for in-plant steam stripping and steam stripping with distillation are substantially overstated. As a practical matter, EPA anticipates that plants will attempt to segregate and treat the most concentrated volatile pollutant-bearing wastewater streams from those not requiring treatment, thus reducing the amount of wastewater that will be treated. Since amount of flow entering a steam stripper or steam stripper with distillation unit is a significant cost component in the design of these units (i.e., the greater the flow the greater the cost), reductions in input flows should result in significant cost reductions.

6.1 Data on Flow and Organic Pollutant Distribution

In order to obtain better estimates of the volume and pollutant characterization of wastewaters requiring treatment, EPA solicits data from plants in the industry on the distribution of volatile organic pollutants in process wastewater streams. These data should specify: (1) The number and measured or estimated volume of individual process wastewater streams; (2) the types of organics in these waste streams and the ranges of organic pollutant concentrations either measured or estimated in these streams (e.g., <1 mg/l, 1-10 mg/l, 10-100 mg/l, 100-1,000 mg/l, >1,000 mg/l); and (3) the ten organic pollutants found or expected to be found in these streams in the highest concentrations. In any cases where these data are estimates, the underlying assumptions for these estimates will need to be specified. In cases where plants undertake to generate data from process wastewater flow measurements and pollutant analyses, the measurement and analytical methods used to generate these data also will need to be specified. The Agency strongly suggests that any such plants which choose to generate these data should contact EPA staff (please refer to the **FOR FURTHER INFORMATION** section of this preamble) for guidance on details of the scope and methods of data collection and supporting documentation.

6.2 Wastewater Stream Segregation

EPA anticipates that plants would segregate volatile bearing wastewater from non-volatile bearing wastewater. EPA solicits comments supported by data concerning whether stream segregation of volatile bearing streams from non-volatile bearing streams is feasible and/or practical.

7.0 BAT Limitations for Direct Discharging Facilities With Subcategory B and D Operations Based on Steam Stripping or Steam Stripping With Distillation

In section IX.E.3.c(2) of this preamble, EPA speculated that pollutant loading data from years other than 1990 may indicate that in-plant steam stripping technology or in-plant steam stripping with distillation technology is an appropriate basis for BAT regulations for facilities with subcategory B and/or D operations. Accordingly, EPA solicits volatile pollutant loading data from direct discharging facilities with subcategory B and D operations for

years other than 1990 (i.e., 1991–1994, or any later period if available).

7.1 Feasibility and Appropriateness of Such Limits

EPA also solicits comment concerning the feasibility and appropriateness of setting BAT limitations on volatile organic pollutants for facilities with subcategory B and/or D operations based on steam stripping or steam stripping with distillation.

7.2 Point of Regulation for BAT Limitations and NSPS Standards Based on In-Plant Technologies

EPA also solicits comment on the point of regulation for any BAT limitations and NSPS standards based on in-plant technologies.

7.3 Limitations if Facilities Change Their Mode of Discharge

EPA also solicits comment on the issue of whether it should promulgate separate BAT limitations, based on in-plant technologies, for facilities with subcategory B and/or D operations that change their mode of discharge from indirect to direct (in view of EPA's proposal today to base PSES on steam stripping for these subcategories).

8.0 Definition of Process Wastewater

The Agency is proposing a definition of process wastewater for the effluent limitations guidelines regulation set out at 40 CFR section 122.2. The definition specifically includes any water which, during manufacturing or processing, comes into direct contact with or results from the production or use of any raw material, intermediate product, finished product, by-product, or waste product. The types of wastewaters considered to be process wastewater are set out in the proposed regulation at § 439.01(m), and discussed in detail in section 5 of the TDD. EPA solicits comment on the wastewaters being defined as process wastewater.

9.0 Prohibited Discharges

The Agency is proposing to prohibit the discharge of certain materials to POTWs or waters of the United States without an NPDES permit or individual control mechanism authorizing such discharge. See proposed regulation at §§ 439.10, 439.20, 439.30 and 439.40. A list of these materials is set forth at § 439.01(m)(1) of the proposed regulation. The Agency believes that discharge and loss of these materials is inappropriate from the standpoint of productivity loss, pollution prevention, adverse impacts on wastewater treatment (i.e., in POTWs) and worker safety and health.

9.1 List of Prohibited Materials

EPA solicits comment on the specific proposed list of materials prohibited for discharge. EPA is separately soliciting comment on whether BMPs are appropriate for application to control the discharge of these materials through leaks, spills, and intentional diversions (see solicitation number 31 in this section of the preamble).

9.2 Non-Process Wastewaters

EPA solicits comment on the following waters and wastewaters proposed to be excluded from the definition of process wastewater: noncontact cooling water, utility wastewaters, general site surface runoff, groundwater (e.g., contaminated groundwaters from on-site or off-site groundwater remediation projects), and other nonprocess water generated on site. EPA also solicits comment on the proposal that the discharge of such waters and wastewaters be regulated separately.

9.3 Costs of Complying With the Prohibitions

EPA solicits comment on the potential costs of complying with the proposed prohibition of the discharge of materials used in or generated by pharmaceutical manufacturing processes.

10.0 TOC Limits as Alternative to COD Limits

EPA is aware of suggestions that, in some instances, the TOC (Total Organic Carbon) test may be an appropriate substitute for the COD test and that, therefore, TOC limits should be promulgated instead of or as an alternative to COD limits. Industrial commenters on analytical methods have indicated that the approved method for determining COD in wastewater does not completely correct for abnormally high chloride (a direct interferent) concentrations found in some wastewaters.

EPA solicits all influent and effluent TOC and COD concentration data points that are descriptive of the same wastewater stream but the Agency is especially interested in those concentration data that are descriptive of wastewaters with high chloride concentrations.

11.0 Wastewaters From Bioengineered Materials

The Agency recognizes that there has been considerable development of bioengineered materials that may be incorporated in pharmaceutical products. The Agency is concerned about the release of these bioengineered materials in pharmaceutical

wastewaters. EPA solicits comment and data that characterize wastewater from the development of bioengineered materials.

12.0 Source Reduction Activities

The Agency solicits information and data on any efforts (ongoing or planned) concerning source reduction activities at pharmaceutical manufacturing facilities, as discussed in Section IX of this preamble.

12.1 Pollution Prevention and Combustion Strategy

EPA solicits comments on the waste minimization and combustion strategy discussed in Section XII.B of this preamble as it may be applied in this industry. See also solicitation number 22 below.

13.0 Water-Based Tablet Coating Processes

EPA is aware that certain facilities engaging in subcategory D operations (compounding/mixing/formulating) have opportunities to make process changes that can result in lower wastewater discharges and air emissions of volatile pollutants. Specifically, facilities may utilize an aqueous-based tablet coating process as opposed to a volatile organic solvent-based tablet coating process. EPA realizes that this substitution is not feasible for all coating processes. Nonetheless, EPA solicits data from plants in the industry on any changes or substitutions made to solvent-based tablet coating processes.

14.0 Concentration Versus Percent Reduction and Mass-Based Limitations

The Agency today is proposing concentration-based effluent limitations and standards as the most appropriate basis for controlling the discharge of conventional, priority, and nonconventional pollutants from the pharmaceutical manufacturing industry. Industry representatives have commented that alternative formats for these limitations and standards controlling volatile pollutants may be appropriate, including percent removal with base concentrations as provided for in the HON.

14.1 Concentration-Based Format

The Agency solicits comment on the concentration-based format for limitations being proposed today.

14.2 Implementation of an Alternative Percent Reduction Limitation

The Agency solicits comment on alternative percent reduction-based limitations, as used for some of the existing effluent limitations and the

HON, and how this approach would be implemented. See solicitation number 32.4.

14.3 Implementation of a Mass-Based Limitation

The Agency solicits comment on alternative mass-based limitations and how this approach would be implemented.

15.0 In-Plant Limitations for Volatile Organic Pollutant Control

For PSES and PSNS, the Agency is proposing to require compliance monitoring in-plant for certain pollutants (e.g., chloroform, methylene chloride, and toluene) that due to dilution would be found at the end-of-pipe at levels below the current analytical limits of detection. The long-term average concentrations upon which the applicable standards are based are, for many pollutants, near the analytical limits of detection established for these pollutants in wastewater. The Agency is concerned that measurements made at end-of-pipe, after dilution with process and non-process wastewaters, will not adequately reflect the performance of the PSES or PSNS level treatment due to uncertainty associated with pollutant concentration measurements near established limits of detection. EPA has a similar concern for the proposed BAT technology for facilities with subcategory A and/or C operations and the NSPS technology for all manufacturing subcategories.

During development of these proposed regulations, industry representatives asserted that requiring compliance monitoring in-plant on internal streams may reduce their flexibility in compliance and require installation of specific in-plant treatment technologies. Based upon available data, the Agency believes that even if in-plant monitoring is required, pharmaceutical facilities will retain considerable flexibility in choosing specific compliance strategies that may be implemented at individual facilities, including available in-plant treatment technologies. EPA also believes in-plant limitations will enhance opportunities for recovery and reuse of solvents and may allow for the generation of "clean fuels," as described in section XI.C of this preamble.

15.1 Feasibility of End-of-Pipe Limits in Measuring Compliance

EPA solicits comments and data on whether requiring compliance monitoring at the end-of-pipe could practically or feasibly be used to determine whether the proposed BAT,

PSES, NSPS and PSNS limitations and standards are being met.

15.2 Feasibility of End-of-Pipe Limits in Measuring Technology Performance

EPA solicits comments and data on whether requiring compliance monitoring at the end-of-pipe could practically or feasibly be used to measure the performance of the process technologies that form the basis of EPA's proposed BAT, PSES, NSPS and PSNS regulation.

15.3 Extent That In-Plant Control Enhances Recovery/Reuse

The Agency solicits comments and specific supporting data on the extent to which recovery and reuse opportunities may be enhanced by in-plant control.

15.4 Compliance Strategy With In-Plant Monitoring Points

The Agency solicits comments on whether compliance strategies are either enhanced or limited by the use of in-plant monitoring points.

15.5 Air Emissions

The Agency solicits comment on the extent to which air emissions may be controlled by in-plant limits and standards for volatile organic pollutants based on steam stripping or steam stripping with distillation.

15.6 Minimum Concentration and Flow Thresholds

EPA is aware that it may not be efficient or cost effective for plants to steam strip or distill wastewater streams containing low concentrations of volatile organic pollutants. Consequently, EPA solicits suggestions for concentration and flow thresholds for identifying wastewater streams containing volatile organic pollutants which would be subject to in-plant steam stripping or steam stripping with distillation.

15.7 Setting In-Plant Limitations on Case-by-Case Basis

The Agency solicits comment on the burden imposed on permit writers to establish in-plant BAT limitations and NSPS on a case-by-case basis for the 45 volatile organic pollutants for which EPA is proposing to specify end-of-pipe limitations and standards. EPA also seeks comment on its proposal that the end-of-pipe BAT limitations and NSPS standards for particular pollutants would not apply if a permit writer finds in-plant limitations or standards to be necessary for those pollutants; EPA also seeks comment on the recommendation that the permit writer consult the appropriate PSES or PSNS table in

setting the necessary in-plant limitations and standards on a best professional judgment basis. EPA also seeks comment on the utility of relying on EPA's existing NPDES permit regulations to address issues associated with pollutants that are not detectable at the end of the pipe.

15.8 Deference to Clean Air Act Rulemaking

The Agency seeks comment on all aspects of EPA's policy determination in this proposal to defer to the Clean Air Act rulemaking for the pharmaceuticals industry with respect to the control of volatile air emissions from certain pharmaceutical wastestreams.

15.9 Comments on Steam Stripping With Distillation

The Agency requests comments and data on whether steam stripping with distillation should be the technology basis for effluent limitations and standards for volatile organic pollutants, particularly those that are difficult to strip, such as methanol and ethanol.

15.10 Comments on the Proposed End-of-Pipe Limits for Highly Strippable Volatile Organic Pollutants

The Agency solicits comments supported by data regarding whether it is appropriate to develop limitations requiring compliance monitoring at the end of the pipe for highly strippable volatile organic pollutants such as methylene chloride and chloroform.

16.0 WATER7 Model

In analyzing responses to the mass balance question (section 3-2 of the 308 questionnaire), EPA has determined that many of the loading estimates (i.e., to air, to water etc.) provided for individual pollutants were not accompanied with explanations of how the estimates were made. The Agency is concerned that the 308 mass balance responses may underestimate the amount of pollutant air emissions from wastewater and overestimate the amount of pollutant biodegradation and/or destruction. Consequently, EPA has used the WATER7 computer model in conjunction with other 308 response data to develop pollutant-by-pollutant air emission estimates. The WATER7 program was used previously to estimate air emissions from wastewater for the SOCMH HON (see 59 FR 19402).

16.1 Technical Validity of the WATER7 Model

EPA solicits comments on the technical validity of the WATER7 model and its use in estimating pollutant releases at pharmaceutical facilities.

16.2 Other Models for Estimating Air and Water Loadings

The Agency also welcomes suggestions regarding the use of other computer models for estimating air and water loadings at pharmaceutical plants.

17.1 Alternative Technologies to Steam Stripping or Steam Stripping With Distillation Technology

For volatile organic pollutants, EPA is proposing to base its BAT limitations for facilities with subcategory A and/or C operations and PSES limitations for all manufacturing subcategories on steam stripping technology. EPA also proposed to base NSPS and PSNS regulations for all manufacturing subcategories for those pollutants on in-plant steam stripping with distillation technology. The Agency believes that steam stripping technology is the best available technology and that steam stripping with distillation technology is the best demonstrated technology for removing volatile pollutants from wastewater that also offer the opportunity for recovery and recycle of solvents.

EPA solicits comments accompanied by data regarding other technologies designed to remove volatile organic pollutants from wastewater. Information on alternative technologies should be accompanied by influent and effluent data that demonstrate removal.

18.0 Materials of Construction for Steam Stripper and Distillation Columns

EPA has used stainless steel as its construction material in steam stripper and distillation column capital cost estimates. Nonetheless, the Agency recognizes that certain corrosive (low pH) streams may require the use of construction materials made of corrosion resistant alloys such as Hastalloy to allow long-term operation of steam strippers and distillation columns.

18.1 Process Wastewater Characteristics Requiring Special Alloys

The Agency solicits comments and data on the characteristics of any process wastewater streams that may require that steam strippers and/or distillation columns be constructed of highly specialized alloys such as Hastalloy.

18.2 Existing Materials of Construction

The Agency requests information regarding the construction materials used to build all the steam strippers and distillation units currently in-place within the industry.

19.0 Streams Containing Volatile Organic Pollutants That Also Contain Significant Amounts of Dissolved Solids

EPA wants to ensure that the final limitations and standards for volatile organics based on steam stripping or steam stripping with distillation technology adequately reflect the dissolved solids content of representative industry wastestreams. The Agency is aware that certain waste streams that contain large concentrations of certain inorganic salts may cause scaling problems within packed columns that may reduce column performance. Consequently, EPA solicits comments supported by data concerning the strippability of wastestreams containing high concentrations of inorganic salts (dissolved solids).

20.0 COD Removal Through Steam Stripping and Steam Stripping With Distillation

As indicated earlier in this preamble, the Agency does not have removal data for COD achievable through steam stripping and steam stripping with distillation technology.

20.1 COD Removal Data

EPA solicits any influent and effluent COD data across a steam stripper and/or distillation unit for any available time period. The COD influent and effluent data should also include influent stream characteristics data (i.e., organic constituent concentrations) if possible. EPA also solicits COD data for any facilities that also have a biological treatment system following a steam stripper or distillation unit for which COD data are available or may be gathered.

20.2 COD Regulation Beyond BPT

EPA is proposing BAT limitations and NSPS for COD for all manufacturing subcategories based on advanced biological treatment (the BPT-level technology). EPA is not proposing COD limitations and standards based on steam stripping or steam stripping with distillation because EPA is unable at this time to quantify the COD loading reductions attainable through those technologies in addition to advanced biological treatment. EPA solicits comments and data concerning whether BAT limitations and NSPS for COD based on in-plant steam stripping or steam stripping with distillation in addition to advanced biological treatment are necessary or appropriate for facilities with subcategory A and/or C operations. EPA also solicits comments and data on the advisability of adding granular activated carbon

adsorption technology to the steam stripping-based technologies for additional removal of COD. EPA also solicits comments and data concerning BAT limitations and NSPS for COD for facilities with subcategory B and D operations.

21.0 Clean Up of Steam Stripping and Distillation Overheads, i.e., Condensates

21.1 Additional Treatment Required for Clean Up

EPA is aware that the overhead materials recovered from steam stripping and distillation may need to be "cleaned up" prior to reuse. EPA solicits information on the technologies that are currently being used to purify overheads from steam stripping and distillation.

21.2 Costs of Overhead Recovery for Reuse

EPA solicits information and data regarding the costs of cleaning up or purifying overheads for reuse in manufacturing operations along with information on the cost of virgin solvent materials.

22.0 Clean Fuels

EPA is aware that some facilities use distillation/steam stripping overheads as boiler feed. The Agency solicits data and comment concerning the use of such overheads as "clean fuels" from plants which are using overheads as boiler feed and from plants which plan to do so in the future.

23.0 Regulation of Ammonia at BAT and PSES

EPA is proposing effluent limitations and standards controlling the discharge of the pollutant ammonia for facilities with subcategory A and/or C operations because it is a pollutant of concern and is discharged at treatable concentration levels. Data are available demonstrating that ammonia passes through POTWs, and that ammonia is not adequately treated at direct dischargers. The control technology basis for BAT ammonia limitations is incidental removal through in-plant steam stripping and advanced biological treatment upgraded for nitrification. The control technology basis for PSES ammonia limitations is removal through in-plant steam stripping. Industry representatives have commented that ammonia discharges from direct dischargers should be controlled through water quality standards. Industry representatives have also commented that the adoption of technology-based limitations and standards for ammonia would result in

significant cross-media transfers and energy use.

23.1 Degree to Which Ammonia Passes Through POTWs

EPA solicits comments and data on the degree to which ammonia generated by pharmaceutical manufacturing facilities passes through POTWs.

23.2 Degree to Which Ammonia is Treated at Direct Dischargers

EPA solicits comments and data on the degree to which ammonia is adequately treated at direct discharging facilities.

23.3 Achievability of the Proposed Ammonia Limitations

EPA solicits comments and data on the achievability of the Agency's proposed ammonia limitations.

23.4 Proposed Ammonia Control Technologies

EPA solicits comments on the underlying control technologies proposed for ammonia treatment.

23.5 Nutrient Balance of Downstream Biotreatment

EPA solicits comments on the extent to which ammonia removal may adversely affect the nutrient balance of process wastewaters treated in biological treatment systems.

23.6 Other Factors

EPA solicits comments on the costs, effluent reduction benefits, water quality benefits, and any other factors that may be related to the proposed ammonia limitations and standards.

24.0 Impact of Pharmaceutical Wastewaters on POTW Operations

EPA has received information and data indicating that pharmaceutical manufacturing process wastewaters discharged to POTWs contain significant concentrations of volatile organic pollutants. These concentrations can result in slug loads of volatile organic pollutants and other wastewater constituents that, in turn, may cause significant air emissions in the headworks of these POTWs and may be a threat to worker safety and health. The Agency's proposed PSES are intended to reduce the concentration of volatile organic pollutants in pharmaceutical discharges. EPA solicits comments and supporting data on these findings and on the question whether these objectives can be satisfied by assuring that discharges to the POTW sewer are near or at the level of detection.

24.1 PSES Removal of Volatile Organic Pollutants

The Agency solicits comments and data that address the extent to which EPA's proposed PSES may reduce the concentration of volatile organic pollutants in pharmaceutical plant discharges to POTWs.

24.2 Regulatory Approach

The Agency solicits comment on the appropriate regulatory approach for facilities that discharge pharmaceutical manufacturing wastewater to privately owned treatment works. The Agency specifically requests comment on whether such discharges are best regulated under today's proposed regulations, are best regulated under effluent limitations guidelines and standards for centralized waste treatment facilities, 40 CFR Part 437, or are best regulated on a case-by-case basis using best professional judgment.

24.3 Comments on the Finding of No Pass-Through for 33 Volatile Organic Pollutants Under PSES Co-Proposal (2)

The Agency solicits comments and data regarding its finding under PSES co-proposal (2) that the specified 33 volatile organic pollutants do not pass through.

24.4 Need for Pretreatment Standards for 33 Less Strippable Volatile Organic Pollutants

The Agency proposes as PSES and PSNS pass-through co-proposal (1) to establish PSES and PSNS for 33 less strippable volatile organic pollutants. Co-proposal (1) is supported by the Association of Metropolitan Sewerage Agencies, which in letter to EPA dated February 14, 1995, asserted that the promulgation of national pretreatment standards for these pollutants would be the most environmentally sound, timely and cost-effective method of addressing those pollutants. See Section IX.E.5.a. EPA solicits comments on EPA's two pass-through co-proposals and on the asserted benefits to POTWs associated with co-proposal (1).

Industry data supplied to the Agency indicate preliminarily that only 10 percent of the indirect sources account for 80 to 90 percent of the total discharge of these pollutants to POTWs and that problems associated with discharges to POTWs are specific and local. EPA solicits comments and supporting data on the extent to which indirect discharges present a national problem warranting regulation at the national, as opposed to local, level and whether mechanisms other than those considered as the technology basis for

PSES and PSNS are possible alternatives for addressing the problem.

24.5 Effect of Forthcoming Clean Air Rule

EPA is developing a separate rulemaking (under the requirements of Section 112 of the Clean Air Act) to address the air emissions from pharmaceutical plants, including the emissions of most of these 12 volatile organic pollutants. EPA's air rulemaking may complement this proposal so that standards set at the point of discharge to the POTW sewer may satisfy EPA's objectives in this rulemaking. EPA expects to propose these air emission standards next year. As a result, EPA is also considering whether to establish the limits for the 12 highly strippable organic pollutants at the point of discharge to the POTW sewer and solicits comments and supporting data on this question.

25.0 Pretreatment of Methanol

25.1 Biodegradation of Non-Halogenated Volatile Organic Pollutants Without Causing Air Emissions

Industry representatives have stated that EPA's pretreatment standards requiring removal of methanol and other non-halogenated volatile organic pollutants (e.g., acetone, ethanol, and isopropanol) are not necessary because these pollutants are adequately biodegraded by POTWs. Industry maintains that these pollutants have low predicted air emissions from industrial direct discharge systems and, at the lower temperatures and concentrations found in POTW systems, would have even lower potential to be emitted from POTWs.

EPA solicits comments and supporting data regarding the ability of POTWs to biodegrade non-halogenated volatile organic pollutants without significant air emissions.

25.2 BOD₅ Removal Efficiency at POTWs

Industry also asserts that removal of these non-halogenated volatile organic pollutants (a portion of which are measured as BOD₅) may have adverse impacts on the BOD₅ removal efficiency of biological treatment systems at POTWs receiving pharmaceutical manufacturing process wastewaters. EPA solicits comments and supporting data on whether pretreatment of these pollutants will adversely affect the BOD₅ removal efficiency of POTWs.

25.3 Financial Impact on POTWs

The industry has asserted that pretreatment of methanol and other non-halogenated volatile organic

pollutants by pharmaceutical manufacturing facilities will have an adverse financial impact on POTWs.

EPA solicits comments and supporting data on whether pretreatment for removal of these pollutants, and thereby reduced BOD₅ raw waste loads to POTWs, will have adverse financial impacts on POTW revenues.

26.0 Pass-Through of COD at POTWs

EPA will be conducting a POTW pass-through analysis for the pollutant COD because EPA is concerned that certain refractory organic waste materials from subcategory A and C operations measured as COD may pass-through the treatment afforded by POTWs.

26.1 Data on COD Pass-Through

EPA is soliciting data on COD removal (influent and effluent data) from POTWs that treat wastewater from pharmaceutical plants engaging in subcategory A and C operations.

26.2 Appropriate Procedure for Conducting the COD Pass-Through Analysis

EPA also solicits comments on the appropriate procedure for conducting a pass-through analysis for the pollutant COD.

27.0 Pretreatment Standards for Nonstrippable Organic Pollutants

27.1 Package Biotreatment for Five Nonstrippable Organic Pollutants

As noted in Section IX.E.5.a of this preamble, EPA has determined that five nonstrippable biodegradable organic pollutants (N,N dimethyl formamide, dimethyl sulfoxide, N,N-dimethyl acetamide, formaldehyde and ethylene glycol) pass through POTWs. EPA is considering developing pretreatment standards for these pollutants based on package biological treatment. EPA solicits comments and data regarding whether pretreatment standards based on package biological treatment for the five nonstrippable organic pollutants should be promulgated.

27.2 Other Treatment Technologies for Nonstrippable Organic Pollutants

EPA solicits data and information regarding the ability of other technologies to reduce wastewater concentrations of the five nonstrippable organic pollutants identified in the comment solicitation above.

27.3 POTW Pass Through for Acetonitrile and PEG 600

EPA solicits data and information concerning whether acetonitrile and

polyethylene glycol 600 pass through POTWs.

28.0 PSES for Additional Pollutants

Although today's proposed PSES would control 45 volatile organic pollutants (as well as cyanide and ammonia for subcategories A and C), the Agency is concerned that additional pollutants currently being discharged by pharmaceutical plants may either pass through POTWs or interfere with their operation.

Consequently, EPA solicits comments and data concerning other pollutants discharged by pharmaceutical plants in all manufacturing subcategories that may pass through and/or interfere with POTWs, such as sulfates and sulfide (hydrogen sulfide) which are capable of causing significant worker safety problems and corrosion.

29.0 Revision of BPT

EPA is proposing to revise the existing BPT effluent limitations, which are outdated and no longer represent the average of the best performers in the pharmaceutical manufacturing industry. In developing the proposed revised BPT effluent limitations, EPA has identified the average of the best performers with advanced biological treatment.

29.1 Advanced Biological Treatment

EPA solicits comments and data with respect to whether EPA has appropriately selected advanced biological treatment as the technology basis for the proposed BPT conventional pollutant limitations.

29.2 Methodology Used to Select Best Performers

EPA solicits comments on the methodology used to select the best performing facilities with advanced biological treatment and to develop the limitations based on performance data from these facilities.

29.3 Statutory Authority and Other Factors

EPA solicits comments and data with respect to the authority under the Clean Water Act to revise BPT, and on costs, effluent reduction benefits, water quality benefits, and any other factors that may be related to the proposed BPT revisions.

30.0 Revision of BCT

EPA is proposing to revise the existing BCT effluent limitations that were promulgated in July 1986 (51 FR 24974). EPA identified no technologies that achieve greater removals of conventional pollutants than those associated with the proposed revised

BPT limitations that are also cost-reasonable.

30.1 Proposed Baseline for BCT Cost Test

EPA solicits comments on the baseline used for this proposal (i.e., revised BPT limits being proposed today) beyond which candidate technologies were identified, and the alternative baseline identified (i.e., existing BPT limitations).

30.2 Candidate Technologies for BCT

EPA solicits comments on the candidate technologies considered for BCT in this analysis and any others not identified that may be appropriate.

30.3 BCT Results

EPA solicits comments on the finding that none of the candidate BCT technologies beyond BPT were cost-reasonable.

30.4 Other Factors

EPA solicits comments with respect to costs, effluent reduction benefits, and any other factors that may be related to the proposed BCT revisions.

31.0 Applicability and Scope of Best Management Practices

Section 304(e) of the CWA gives the Administrator the authority to publish regulations to control plant site runoff, spillage or leaks, sludge or waste disposal, and drainage from raw material storage that the Administrator determines are associated with or ancillary to the industrial manufacturing or treatment processes of the regulated point source category and that she (he) determines may contribute significant amounts of pollutants to waters of the United States. Examples of BMP regulations include the requirement that dikes be constructed in process areas and required employee training in spill prevention and control.

31.1 Establishment of BMPs

EPA solicits comments regarding whether BMP regulations should be established for the pharmaceutical manufacturing industry.

31.2 BMPs and Costs

The Agency also solicits suggestions on possible BMPs to be prescribed by regulation, accompanied by facility implementation cost estimates that may be appropriate for this industrial category.

31.3 Suggested Specific BMPs

The Agency solicits comments on the suggested specific BMPs presented in Appendix B of the Technical Development Document.

32.0 MACT Standards Versus Effluent Guidelines

The proposed BAT and PSES effluent limitations guidelines will control volatile organic pollutants of which 22 are hazardous air pollutants (HAPs), that are released to the environment primarily in wastewater discharges and air emissions. The mass of HAPs being controlled by the effluent limitations guidelines and standards is about 40 percent of the total mass of volatile organic pollutants being controlled. It is the Agency's intent for both the effluent guidelines being proposed today and the MACT standards to be proposed at a later date that upon promulgation the in-plant technology basis of both rules will be applicable to essentially the same high concentration low volume process wastewater streams in which the bulk of the volatile organic pollutants are contained.

Industry representatives commented that air emissions from pharmaceutical manufacturing facilities should be controlled by a NESHAP rulemaking rather than by BAT limitations and PSES. Industry representatives also commented that the Agency should integrate the development of these two rules, which now are progressing on separate schedules. Industry representatives commented further that the effluent guidelines should include the same elements of flexibility (e.g., allow for demonstration of equivalence of biological treatment to steam stripping) and format of the limitations as included in the HON (e.g., percent removal). Industry representatives also indicated that the HON will allow for emission-suppressed transport of volatile organic pollutant-containing wastewaters to central treatment facilities.

32.1 *Should the Water and Air Regulations Be Integrated*

In view of these preliminary concerns, the Agency solicits comments and data with respect to whether it is necessary or appropriate for the two rules to be integrated and, if so, how.

32.2 *List of Organic Pollutants Covered*

EPA solicits comments on whether it is necessary or appropriate for the two rules to cover the same list of volatile organic pollutants.

32.3 *Steam Stripping Design and Operating Parameters*

EPA solicits comments on whether the design and operating parameters for steam stripping technology as applied in the two rules should be the same and, if so, how (within the constraints of the governing statutes).

32.4 *Percent Removal Standard With a Base Concentration*

EPA solicits comments on whether EPA should adopt, as an alternative to the proposed concentration-based limitations and standards, effluent limitations guidelines and standards based on percent removal standards, as proposed in the HON for the Specialty Organic Chemical Manufacturing Industry (SOCMI). See solicitation numbers 14.0–14.3.

32.5 *Central Treatment for Volatiles Removal*

EPA solicits comments on whether central treatment (i.e., steam stripping or an equivalent technology prior to end-of-pipe biological treatment) is or should be an acceptable compliance approach for the effluent guidelines.

32.6 *Alternate Limitations for End-of-Pipe Biological Treatment*

EPA solicits comments on whether the effluent guidelines should include alternative limitations which would allow for end-of-pipe biological treatment of hard-piped volatile organic pollutants (in place of in-plant steam stripping or steam stripping with distillation technology).

32.7 *Control of Air Emissions Using Alternate Limitations*

EPA solicits comments on whether an alternative approach (as described in comment number 32.6) would present the same control of air emissions as achieved by in-plant steam stripping and steam stripping with distillation technology.

32.8 *Energy Use for and Air Emissions From Generation of Steam Used for Steam Stripping and Steam Stripping with Distillation*

EPA solicits comments and data on the increase in energy required to generate steam used for steam stripping and distillation, and on the increase in air emissions created by steam generation facilities (industrial boilers).

32.9 *Comments on Evaluating the Record of This Rulemaking in the Context of the MACT Rule*

The Agency requests comments on whether it is appropriate for the Office of Air and Radiation to evaluate the basis for the proposed effluent limitations and standards as part of its development of MACT standards for the pharmaceutical manufacturing industry.

33.0 Analytical Methods

A complete discussion of the new analytical methods being proposed in conjunction with these proposed

regulations may be found in section 18 of the Technical Development Document.

33.1 *Analytical Methods Proposed Today*

The methods being proposed today involve the use of isotope dilution gas chromatography/mass spectrometry (GC/MS), derivatization followed by high pressure liquid chromatography (HPLC), and GC followed by detection in an electrochemical cell optimized for nitrogen containing compounds (GC/ELCD). EPA solicits comments with respect to these techniques (see discussion in Section IX of this preamble, and the supporting compendium of analytical methods entitled "Analytical Methods for the Determination of Pollutants in Pharmaceutical Manufacturing Industry Wastewater;" see Section II of this preamble) and any suggestions regarding alternative techniques as well.

33.2 *Limitations Set at the Minimum Level of the Method*

EPA solicits comments on those limitations whose long-term average basis is equal to the minimum level established for the limited pollutant.

33.3 *Statistical Methods for Establishing Limitations*

EPA solicits alternative statistical methodologies for developing limitations based on all non-detect data which may be more appropriate than the statistical methodology employed by EPA.

33.4 *Analytical Methods for Alcohols*

EPA has proposed analytical methods for quantifying various low-molecular weight alcohols (e.g., methanol and ethanol) in wastewater. See "Analytical Methods for the Determination of Pollutants in Pharmaceutical Wastewater", EPA 821-R-95-015. EPA invites comments on the proposed methods for determining alcohols in wastewater from industrial laboratories, public sector laboratories and individual researchers familiar with similar analytical methods.

33.5 *Matrix Interferences and Analytical Methods*

EPA is interested in identifying solutions to matrix interference problems connected with the analysis of pharmaceutical manufacturing industry wastewater streams. EPA is also interested in any extraction, concentration or other analytical techniques that may offer solutions to matrix interference problems.

33.6 *Analytical Method for the Determination of Polyethylene Glycol 600 in Wastewater*

EPA has determined that GC/MS methods have not been found to be useful in the determination of polyethylene glycol 600 in wastewater. EPA invites suggestions concerning the analysis of this pollutant in wastewater.

33.7 *COD Determinations in Samples With High Chloride Content*

EPA is aware that the standard method determinations of COD in samples with high chloride content (e.g., brackish wastewater) need to be pretreated to remove chloride prior to the oxidation step in the COD determination. EPA requests comments regarding the techniques used to remove chlorides prior to the oxidation step and their adequacy in preventing interference with the COD determinations. EPA also solicits data and information with respect to any analytical method studies involving COD determinations in wastewaters with high chloride concentrations.

34.0 **Surface Impoundments**

EPA is concerned about the transfer of volatile organic pollutants from surface impoundments located at pharmaceutical manufacturing facilities to groundwater and air. EPA solicits comment and data on the monitoring of surface impoundments, including leachate data and air emissions data.

35.0 **Regulatory Impact Analysis**

EPA solicits comments concerning the methodology employed to estimate costs and benefits in the Regulatory Impact Analysis developed for these regulations and the conclusions EPA reached by applying those methodologies.

36.0 **Economic Impact Analysis**

EPA solicits comments on the methodology employed to measure the economic impacts of the proposed regulations.

36.1 *Definition of Small Entities*

The Agency solicits comment on the definition of small entity used in this analysis, the analytical procedures for assessing impacts on small entities, and the opportunities to minimize the impacts on small entities, as described in the Economic Impact Analysis and Regulatory Flexibility Analysis of Proposed Effluent Guidelines for the Pharmaceutical Manufacturing Industry.

37.0 **Use of Bulk Parameters to Represent Pollutants of Concern**

EPA solicits comments and data on the use of bulk parameters such as COD

to represent the presence and treatability of pollutants of concern, such as the broad range of organic compounds present in pharmaceutical manufacturing process wastewaters, particularly chemical synthesis process wastewaters. See also solicitation numbers 10.0, 20.0, 26.0, 27.0, and 28.0.

38.0 **Reducing Monitoring Requirements**

The Agency solicits comment on ways to reduce the monitoring requirements associated with the proposed rulemaking.

38.1 *Subcategory D Facilities*

The Agency is aware that many facilities with subcategory D operations do not use or generate the pollutants for which regulations are being proposed today. Consequently, these facilities should not be required to monitor for these pollutants. EPA solicits comment on any appropriate mechanism for reducing monitoring requirements for these facilities.

38.2 *Pollutants Not Used or Generated*

Similarly, facilities with operations in other subcategories may not use or generate specific pollutants for which regulations are being proposed. EPA solicits comment on any appropriate mechanism for reducing monitoring requirements for these pollutants at such facilities.

38.3 *Use of Alternate Analytical Methods*

EPA also solicits comments on whether circumstances may exist under which it may be appropriate to allow facilities to use analytical methods for organic pollutants other than those used to generate data upon which this proposal is based. Such circumstances may include "screening" to confirm the absence of pollutants where solvents are not used in pharmaceutical manufacturing processes (i.e., subcategory D, mixing/ compounding/ formulating). These alternate methods might include Methods 624 and 625 as alternatives to Methods 1624 and 1625.

39.0 **Privately Owned Treatment Plants**

EPA solicits comment on the issue whether part 439 should apply to process wastewater pollutants introduced into privately owned treatment works.

List of Subjects in 40 CFR Part 439

Environmental Protection Air pollution control, pharmaceutical manufacturing Pollution prevention, Wastewater treatment.

Dated: February 28, 1995.

Carol M. Browner,
Administrator.

For the reasons set out in the preamble, title 40, chapter I, part 439 of the Code of Federal Regulations is proposed to be amended as follows:

PART 439—PHARMACEUTICAL MANUFACTURING POINT SOURCE CATEGORY

1. The authority citation for part 439 is revised to read as follows:

Authority: Sections 301, 304, 306, 307, and 501 of the Clean Water Act, (33 U.S.C. 1311, 1314, 1316, 1317, and 1361).

2. The Table of Contents for part 439 is amended by adding §§ 439.3 and 439.4 and the entire table of contents is published for the convenience of the reader.

Sec.
439.0 Applicability.
439.1 General definitions.
439.2 Monitoring requirements.
439.3 Dilution prohibition.
439.4 [Reserved]

Subpart A—Fermentation Subcategory

439.10 Applicability; description of the fermentation products subcategory.
439.11 Specialized definitions.
439.12 Effluent limitations representing the degree of effluent reduction attainable by the application of best practicable control technology currently available (BPT).
439.13 Effluent limitations representing the degree of effluent reduction attainable by the best conventional pollutant control technology (BCT).
439.14 Effluent limitations representing the degree of effluent reduction attainable by the application of best available technology economically achievable (BAT).
439.15 New source performance standards (NSPS).
439.16 Pretreatment standards for existing sources (PSES).
439.17 Pretreatment standards for new sources (PSNS).
439.18 [Reserved]

Subpart B—Extraction Subcategory

439.20 Applicability; description of the extraction products subcategory.
439.21 Specialized definitions.
439.22 Effluent limitations representing the degree of effluent reduction attainable by the application of best practicable control technology currently available (BPT).
439.23 Effluent limitations representing the degree of effluent reduction attainable by the best conventional pollutant control technology (BCT).
439.24 Effluent limitations representing the degree of effluent reduction attainable by the application of best available technology economically achievable (BAT).

- 439.25 New source performance standards (NSPS).
 439.26 Pretreatment standards for existing sources (PSES).
 439.27 Pretreatment standards for new sources (PSNS).
 439.28 [Reserved]

Subpart C—Chemical Synthesis Subcategory

- 439.30 Applicability; description of the chemical synthesis products subcategory.
 439.31 Specialized definitions.
 439.32 Effluent limitations representing the degree of effluent reduction attainable by the application of best practicable control technology currently available (BPT).
 439.33 Effluent limitations representing the degree of effluent reduction attainable by the best conventional pollutant control technology (BCT).
 439.34 Effluent limitations representing the degree of effluent reduction attainable by the application of best available technology economically achievable (BAT).
 439.35 New source performance standards (NSPS).
 439.36 Pretreatment standards for existing sources (PSES).
 439.37 Pretreatment standards for new sources (PSNS).
 439.38 [Reserved]

Subpart D—Mixing, Compounding and Formulating Subcategory

- 439.40 Applicability; description of the mixing, compounding and formulating subcategory.
 439.41 Specialized definitions.
 439.42 Effluent limitations representing the degree of effluent reduction attainable by the application of best practicable control technology currently available (BPT).
 439.43 Effluent limitations representing the degree of effluent reduction attainable by the best conventional pollutant control technology (BCT).
 439.44 Effluent limitations representing the degree of effluent reduction attainable by the application of best available technology economically achievable (BAT).
 439.45 New source performance standards (NSPS).
 439.46 Pretreatment standards for existing sources (PSES).

- 439.47 Pretreatment standards for new sources (PSNS).
 439.48 [Reserved]

Subpart E—Research Subcategory

- 439.50 Applicability; description of the research subcategory.
 439.51 Specialized definitions.
 439.52 Effluent limitations representing the degree of effluent reduction attainable by the application of best practicable control technology currently available (BPT).
 439.53 Effluent limitations representing the degree of effluent reduction attainable by the best conventional pollutant control technology (BCT). [Reserved]
 439.54 Effluent limitations representing the degree of effluent reduction attainable by the application of best available technology economically achievable (BAT). [Reserved]
 439.55 New source performance standards (NSPS). [Reserved]
 439.56 Pretreatment standards for existing sources (PSES). [Reserved]
 439.57 Pretreatment standards for new sources (PSNS). [Reserved]
 439.58 [Reserved]

3. Sections 439.0 through 439.2 are revised and §§ 439.3 and 439.4 are added to read as follows:

General Provisions

§ 439.0 Applicability.

This part applies to any pharmaceutical manufacturing facility that discharges or may discharge process wastewater pollutants to the waters of the United States, or that introduces or may introduce process wastewater pollutants into a publicly owned treatment works. This part does not apply to process wastewater pollutants introduced into privately owned treatment works.

§ 439.1 General definitions.

In addition to the definitions set forth in 40 CFR part 401, the following definitions shall apply to this part:

(a) *Annual average*. The mean concentration, mass loading or production-normalized mass loading of a pollutant over a period of 365 consecutive days (or such other period of time determined by the permitting

authority to be sufficiently long to encompass expected variability of the concentration, mass loading, or production-normalized mass loading at the relevant point of measurement).

(b) *Bench-scale operation*. Laboratory testing of materials, methods, or processes on a small scale, such as on a laboratory worktable.

(c) *Chemical oxygen demand (COD)*. A bulk parameter that measures the total oxygen-consuming capacity of wastewater. This parameter is a measure of materials in water or wastewater that are biodegradable and materials that are resistant (refractory) to biodegradation. Refractory compounds slowly exert demand on downstream receiving water resources. Certain of the compounds measured by this parameter have been found to have adverse effects, either singly or in combination. It is expressed as the amount of oxygen consumed by a chemical oxidant in a specific test.

(d) *Conventional pollutants*. The pollutants identified in Section 304(a)(4) of the CWA and the regulations thereunder, 40 CFR 401.16 (i.e., biochemical oxygen demand (BOD₅), total suspended solids (TSS), oil and grease, pH, and fecal coliform).

(e) *End-of-pipe effluent*. Final plan effluent discharged to waters of the United States or to a POTW.

(f) *In-plant monitoring points*. (1) For regulated organic pollutants, monitoring point(s) prior to dilution by non-process wastewater, commingling with other process wastewaters not containing the regulated organic pollutants at treatable levels, and any conveyance, equalization, or other wastewater treatment units that are open to the atmosphere.

(2) For cyanide, monitoring point(s) prior to dilution or mixing with any noncyanide-bearing wastewater.

(g) *Minimum level*. The level at which an analytical system gives recognizable signals and an acceptable calibration point. The following minimum levels (for water samples only) and analytical methods apply to pollutants in this part:

Pollutant	Method	Minimum level micrograms per liter (µg/L)
Acetone	1624B	50
Acetonitrile	1666, 1671	5,000
Ammonia (aqueous)	350.1, 350.2, 350.3	30
n-Amyl Acetate	1666	5
Amyl Alcohol	1666	500
Aniline	1665	2
Benzene	1624B	10
BOD ₅	405.1	(^a)
2-Butanone	1624B	50
n-Butyl Acetate	1666	5
n-Butyl Alcohol	1666	500

Pollutant	Method	Minimum level micrograms per liter (µg/L)
<i>tert</i> -Butyl Alcohol	1666	100
Chemical Oxygen Demand (COD)	410.1, 410.2, 410.3, 410.4	(^a)
Chlorobenzene	1624B	10
Chloroform	1624B	10
Chloromethane	1624B	50
Cyanide (Total)	335.1, 335.2, 335.3	(^a)
Cyclohexane	1666	5
1,2-Dichlorobenzene	1625B	10
1,2-Dichloroethane	1624B	10
Diethylamine	1666, 1671	50,000
Diethyl Ether	1624B	50
N,N-Diethylacetamide	1665	50
N,N-Dimethylaniline	1665	10
Dimethylamine	1666, 1671	50,000
N,N-Dimethylformamide	1665	5
Dimethylsulfurxide	1666, 1671	20,000
1,4-Dioxane	1624B	50
Ethanol	1666, 1671(^b)	3,180
Ethyl Acetate	1666	10
Ethylene Glycol	1666, 1671	100,000
Formaldehyde	1667	50
Formamide	1666, 1671	100,000
Furfural	1666, 1677	50
n-Heptane	1666	10
n-Hexane	1666	10
Isobutyraldehyde	1666, 1667	10
Isopropanol	1666	200
Isopropyl Acetate	1666	10
Isopropyl Ether	1666	5
Methanol	1666, 1671(^a)	3,180
Methylamine	1666, 1671	50,000
Methyl Cellosolve	1666, 1671	20,000
Methylene Chloride	1624B	10
Methyl Formate	1666	100
Methyl Isobutyl Ketone (MIBK)	1666	10
2-Methylpyridine	1624B, 1665	5
Petroleum Naptha (as n-pentane)	1666	10
Phenol	1625	10
Polyethylene Glucol 600	1673	1,000
n-Propanol	1666, 1671(^b)	3,180
Pyridine	1665	5
Tetrahydrofuran	1666	20
Toluene	1624	10
Trichlorofluoromethane	1666	10
Triethylamine	1666, 1671	50,000
TSS	160.2	(^a)
m,p-Xylene	1666	10
o-Xylene	1666	5

(^a)—As specified in 40 CFR Part 136.

(^b)—Method 1671 is modified ASTM Method D3695–88.

(h) *New source*. As defined in EPA's regulations at 40 CFR 122.2 and 122.29.

(i) *Nonconventional pollutants*. Pollutants that are neither conventional pollutants nor toxic pollutants.

(j) *Non-detect (ND) value*. A concentration-based measurement reported below the minimum level (see paragraph (g) of this section) that can be reliably measured by the analytical method for the pollutant.

(k) *Pilot-scale operation*. The trial operation of processing equipment, which is the intermediate stage between laboratory experimentation and full-scale operation in the development of a new process or product.

(l) *POTW*. Publicly owned treatment works, as defined at 40 CFR 403.3(o).

(m) *Process wastewater*. Any water that, during manufacturing or processing, comes into direct contact with or results from the production or use of any raw material, intermediate product, finished product, byproduct, or waste product. Process wastewater includes surface runoff from the immediate process area that has the potential to become contaminated.

(1) For the purposes of this part, the following materials are excluded from the definition of process wastewater, and the discharge of such materials must be regulated separately.

(i) Trimethyl silanol;

(ii) Any active anti-microbial materials;

(iii) Wastewater from imperfect fermentation batches; and

(iv) Process area spills.

(2) For purposes of this part, the following waters and wastewaters are excluded from the definition of process wastewater: noncontact cooling water, utility wastewaters, general site surface runoff, groundwater (e.g., contaminated groundwaters from on-site or off-site groundwater remediation projects), and other nonprocess water generated on site. The discharge of such waters and

wastewaters must be regulated separately.

(n) *Toxic pollutants*. The pollutants designated by EPA as toxic in 40 CFR 401.15.

(o) *Xylenes*. The sum of o-xylene, p-xylene, and m-xylene.

§ 439.2 Monitoring requirements.

Permit compliance monitoring is required for each regulated pollutant generated or used at a pharmaceutical manufacturing facility. Routine

compliance monitoring is not required for regulated pollutants not generated or used at the facility. Except for cyanide, for which a separate procedure is established in subparts A and C, determination that regulated pollutants are not generated or used should be based on a review of all raw materials used, and an assessment of all chemical processes used, considering resulting products and by-products. The determination that a regulated pollutant

is not generated or used must be confirmed by annual chemical analyses of wastewater from each monitoring location. Such confirmation is provided by an analytical measurement of a non-detect value. Compliance monitoring for all regulated pollutants generated or used is required at each of the monitoring locations specified in this part for those pollutants or at such locations specified pursuant to 40 CFR 122.45.

CAS No.	Pollutant	Monitoring frequency (frequency per week)
67-64-1	Acetone	1
75-05-8	Acetonitrile	1
1336-21-6	Ammonia	1
628-63-7	n-Amyl Acetate	1
71-41-0	Amyl Alcohol	1
62-53-3	Aniline	1
71-43-2	Benzene	1
78-93-3	2-Butanone	1
123-86-4	n-Butyl Acetate	1
71-36-3	n-Butyl Alcohol	1
75-65-0	tert-Butyl Alcohol	1
C-004-(r)	Chemical Oxygen Demand (COD)	7
108-90-7	Chloabenzene	1
67-66-3	Chloroform	1
74-87-3	Chloromethane	1
57-12-5	Cyanide, Total	(b)1
110-82-7	Cyclohexane	1
95-50-1	1,2-Dichlorobenzene	1
107-06-2	1,2-Dichloroethane	1
109-89-7	Diethylamine	1
60-29-7	Diethyl ether	1
127-19-5	N,N-Dimethylacetamide	1
121-69-7	N,N-Dimethylaniline	1
124-40-3	Dimethylamine	1
68-12-2	N,N-Dimethylformamide	1
67-68-5	Dimethylsulfoxide	1
123-91-1	1,4-Dioxane	1
64-17-5	Ethanol	1
141-78-6	Ethyl acetate	1
107-21-1	Ethylene glycol	1
50-00-1	Formaldehyde	1
75-12-7	Formamide	1
98-01-1	Furfural	1
142-82-5	n-Heptane	1
110-54-3	n-Hexane	1
78-84-2	Isobutyraldehyde	1
67-63-0	Isopropanol	1
108-21-4	Isopropyl acetate	1
108-20-3	Isopropyl ether	1
67-56-1	Methanol	1
74-89-5	Methylamine	1
109-86-4	Methyl Cellosolve	1
75-09-2	Methylene Chloride	1
107-31-3	Methyl formate	1
108-10-1	Methyl Isobutyl Ketone	1
109-06-8	2-Methylpyridine	1
8030-30-6	Petroleum Naphtha	1
108-95-2	Phenol	1
25322-68-3	Polyethylene Glycol 600	1
71-23-8	n-Propanol	1
110-86-1	Pyridine	1
109-99-9	Tetrahydrofuran	1
108-88-3	Toluene	1
75-69-4	Trichlorodluoromethane	1
121-44-8	Triethylamine	1
(c)	Xylenes	1
C-002-(a)	BOD ₅	7

CAS No.	Pollutant	Monitoring frequency (frequency per week)
C-009-(a)	TSS	7

(a) These are synthetic CASRN's designed for use with the Environmental Monitoring Methods Index (EMMI).

(b) Monitoring frequency for cyanide is once per treated batch.

(c) M-Xylene 108-38-3, o-Xylene 95-47-6, p-Xylene 106-42-3.

§ 439.3 Dilution prohibition.

Dilution may not be practiced to meet the effluent limitations and standards specified in this part.

§ 439.4 [Reserved]

Subpart A—Fermentation Subcategory

4. Sections 439.10 through 439.14 are revised to read as follows:

§ 439.10 Applicability; description of the fermentation subcategory; prohibition.

(a) The provisions of this subpart are applicable to discharges resulting from the manufacture of pharmaceuticals by fermentation. Fermentation operations are defined as process operations that utilize a chemical change induced by a living organism or enzyme, specifically, bacteria, or the microorganisms occurring in unicellular plants such as yeast, molds, or fungi to produce a specified product. Fermentation operations include pilot-scale research operations not covered by the provisions of subpart E, Research Subcategory.

(b) The discharge of nonprocess wastewater and materials excluded from the definition of process wastewater at § 439.1 is not covered by this subpart. Discharge of such nonprocess wastewater and excluded materials into publicly owned treatment works or waters of the United States by a source subject to this subpart without an NPDES permit or individual control mechanism authorizing such discharge is prohibited.

§ 439.11 Specialized definitions.

For the purpose of this subpart:

(a) Except as provided in paragraph (b) of this section, the general definitions, abbreviations, and methods of analysis set forth in 40 CFR part 401 and § 439.1 shall apply to this subpart.

(b) The term "product" shall mean pharmaceutical products derived from fermentation processes.

§ 439.12 Effluent limitations representing the degree of effluent reduction 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, any existing point source subject to this subpart must achieve the following effluent limitations representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available.

(1) Subpart A (For In-Plant Monitoring Points).

Pollutant or pollutant property	BPT effluent limitations micrograms per liter (µg/L)	
	Maximum for any one day	Monthly average
Cyanide (Total)	766	406

(2) Subpart A (For End-of-Pipe Effluent).

Pollutant or pollutant property	BPT effluent limitations milligrams per liter (mg/L)	
	Maximum for any one day	Monthly average
BOD ₅	137	58
TSS	318	110
COD	1100	628

(3) The pH shall be within the range of 6.0–9.0 standard units.

(b) Permittees not using or generating cyanide are deemed to comply with the monitoring requirements specified in paragraph (a) of this section for cyanide if they certify to the permit issuing authority that they are not using or generating this pollutant.

§ 439.13 Effluent limitations representing the degree of effluent reduction attainable by the application of the best conventional pollutant control technology (BCT).

Except as provided in 40 CFR 125.30 through 125.32, any existing point source subject to this subpart must achieve the following effluent limitations representing the degree of effluent reduction attainable by the application of the best conventional pollutant control technology: The limitations shall be the same as those specified for the conventional pollutants BOD₅ and TSS in § 439.12 for the best practicable control technology currently available.

§ 439.14 Effluent limitations representing the degree of effluent reduction attainable by the application of best available technology economically achievable (BAT).

(a) Except as provided in 40 CFR 125.30 through 125.32, any existing point source subject to this subpart must achieve the following effluent limitations representing the degree of effluent reduction attainable by the application of the best available technology economically achievable.

(1) Subpart A (For In-Plant Monitoring Points).

Pollutant or pollutant property	BAT effluent limitations micrograms per liter (µg/L)	
	Maximum for any one day	Monthly average
Cyanide (Total)	766	406

(2) Subpart A (For End-of-Pipe Effluent). The limitations in the following table do not apply for any pollutant(s) for which the permit writer finds it necessary to specify in-plant monitoring requirements pursuant to 40 CFR 122.44(i) and 122.45(h). Limitations for those pollutant(s) would be established on a best professional judgment basis pursuant to 40 CFR 125.3.

Pollutant or pollutant property	BAT effluent limitations micrograms per liter (µNDg/L)	
	Maximum for any one day	Monthly average
Acetone	ND	ND
Acetonitrile	ND	ND
Ammonia	4,850	3,230
n-Amyl Acetate	105	45
Amyl Alcohol	668	ND
Aniline	10	10
Benzene	ND	ND
2-Butanone (MEK)	202	86
n-Butyl Acetate	87	37
n-Butyl Alcohol	ND	ND
tert-Butyl Alcohol	668	284
Chemical Oxygen Demand (COD)	1,100,000	628,000
Chlorobenzene	ND	ND
Chloroform	ND	ND
Chloromethane	ND	ND
Cyclohexane	ND	ND
o-Dichlorobenzene	ND	ND
1,2-Dichloroethane	100	35
Diethylamine	ND	ND
Diethyl Ether	574	244
Dimethylamine	ND	ND
N,N-Dimethylacetamide	ND	ND
N,N-Dimethylaniline	50	50
N,N-Dimethylformamide	45	19
Dimethyl Sulfoxide	ND	ND
1,4-Dioxane	220	94
Ethanol	ND	ND
Ethyl Acetate	105	45
Ethylene Glycol	ND	ND
Formaldehyde	1,480	623
Formamide	ND	ND
Furfural	2,670	1,140
n-Heptane	ND	ND
n-Hexane	ND	ND
Isobutyraldehyde	1,370	581
Isopropanol	ND	ND
Isopropyl Acetate	87	37
Isopropyl Ether	574	244
Methanol	ND	ND
Methylamine	ND	ND
Methyl Cellosolve	ND	ND
Methyl Formate	105	ND
Methylene Chloride	ND	ND
Methyl Isobutyl Ketone (MIBK)	ND	ND
2-Methylpyridine	50	50
Petroleum Naphtha	ND	ND
Phenol	25	14
Polyethylene Glycol 600	4,870	2,070
n-Propanol	ND	ND
Pyridine	10	10
Tetrahydrofuran	910	264
Toluene	ND	ND
Trichlorofluoromethane	ND	ND
Triethylamine	ND	ND
Xylenes	ND	ND

(b) Permittees not using or generating cyanide are deemed to comply with the monitoring requirements specified in paragraph (a) of this section for cyanide if they certify to the permit issuing authority that they are not using or generating this pollutant.

5. Section 439.15 is amended by revising paragraph (a) introductory text and paragraph (b) and by adding paragraph (c) to read as follows:

§ 439.15 New source performance standards (NSPS).

(a) Any new source subject to this subpart that was a "new source" under 40 CFR 122.29 prior to [promulgation date of the final rule] must achieve the following new source performance standards until the expiration of the applicable time period specified in 40 CFR 122.29(d)(1), after which the source must achieve the effluent limitations

specified in §§ 439.12, 439.13, and 439.14.

* * * * *

(b) Except as provided in paragraph (a) of this section, any new source subject to this subpart must achieve the following new source performance standards.

(1) Subpart A (For In-Plant Monitoring Points).

Pollutant or pollutant property	New source performance standards micrograms per liter (µg/L)	
	Maximum for any one day	Monthly average
Cyanide (Total)	766	406

(2) Subpart A (For End-of Pipe Effluent). The standards in the following table do not apply for any pollutant(s) for which the permit writer finds it necessary to specify in-plant monitoring requirements pursuant to 40 CFR 122.44(i) and 122.45(h). Standards for those pollutant(s) would be established on a best professional judgment basis pursuant to 40 CFR 125.3.

Pollutant or pollutant property	New source performance standards micrograms per liter (µg/L)	
	Maximum for any one day	Monthly average
Acetone	ND	ND
Acetonitrile	ND	ND
Ammonia	4,850	3,230
n-Amyl Acetate	14	6
Amyl Alcohol	ND	ND
Aniline	10	4
Benzene	ND	ND
2-Butanone (MEK)	144	61
n-Butyl Acetate	11	ND
n-Butyl Alcohol	ND	ND
tert-Butyl Alcohol	ND	ND
Chlorobenzene	ND	ND
Chloroform	ND	ND
Chloromethane	ND	ND
Cyclohexane	ND	ND
o-Dichlorobenzene	ND	ND
1,2-Dichloroethane	13	ND
Diethylamine	ND	ND
Diethyl Ether	74	ND
Dimethylamine	ND	ND
N,N-Dimethylacetamide	ND	ND
N,N-Dimethylaniline	50	45
N,N-Dimethylformamide	45	19
Dimethyl Sulfoxide	ND	ND
1,4-Dioxane	ND	ND
Ethanol	ND	ND
Ethyl Acetate	14	ND
Ethylene Glycol	ND	ND
Formaldehyde	1,480	623
Formamide	ND	ND
Furfural	53	ND
n-Heptane	ND	ND
n-Hexane	ND	ND
Isobutyraldehyde	304	129
Isopropanol	ND	ND
Isopropyl Acetate	11	ND
Isopropyl Ether	74	32
Methanol	ND	ND
Methylamine	ND	ND
Methyl Cellosolve	ND	ND
Methyl Formate	ND	ND
Methylene Chloride	ND	ND
Methyl Isobutyl Ketone (MIBK)	ND	ND
2-Methylpyridine	50	45
Petroleum Naphtha	ND	ND
Phenol	25	14
Polyethylene Glycol 600	4,870	2,070
n-Propanol	ND	ND
Pyridine	10	10
Tetrahydrofuran	910	264
Toluene	ND	ND
Trichlorofluoromethane	ND	ND
Triethylamine	ND	ND
Xylenes	ND	ND

(3) Subpart A For End-of-Pipe Effluent).

Pollutant or pollutant property	New source performance standards milligrams per liter (mg/L)	
	Maximum for any one day	Monthly average
BOD ₅	62	29
COD	781	538
TSS	87	43
pH	(^a)	(^a)

(^a) Within the range of 6.0 to 9.0 standard units.

(c) Permittees not using or generating cyanide are deemed to comply with the monitoring requirements specified in paragraph (a) of this section for cyanide if they certify to the permit issuing authority that they are not using or generating this pollutant.

6. Section 439.16 is revised to read as follows:

§ 439.16 Pretreatment standards for existing sources (PSES).

(a) Except as provided in 40 CFR 403.7 and 403.13, any existing source subject to this subpart that introduces

pollutants into a publicly owned treatment works must comply with 40 CFR part 403 by [date 3 years from the promulgation date of the final rule] and achieve the following pretreatment standards for existing sources.

(1) Subpart A (For In-Plant Monitoring Points).

Pollutant or pollutant property	Pretreatment standards for existing sources micrograms per liter (µg/L)	
	Maximum for any one day	Monthly average
Benzene	796	268
Chlorobenzene	796	268
Chloroform	ND	ND
Chloromethane	796	268
Cyanide	766	406
Cyclohexane	796	268
n-Heptane	796	268
n-Hexane	796	268
Methyl Cellosolve	ND	ND
Methylene Chloride	809	279
Toluene	198	148
Trichlorofluoromethane	796	268
Xylenes	796	268

(2) Subpart A (For End-of-Pipe Monitoring Points).

[**Note:** With respect to pollutants in this table, EPA proposes pretreatment standards for existing sources only for ammonia under co-proposal (2).]

Pollutant or pollutant property	Pretreatment standards for existing sources micrograms per liter (µg/L)	
	Maximum for any one day	Monthly average
Acetone	31,400	9,690
Ammonia	12,900	10,900
n-Amyl Acetate	23,900	8,050
Amyl Alcohol	607,000	205,000
Aniline	10,900,000	3,690,000
2-Butanone (MEK)	1,440,000	430,000
n-Butyl Acetate	23,900	8,050
n-Butyl Alcohol	10,900,000	3,690,000
tert-Butyl Alcohol	607,000	205,000
o-Dichlorobenzene	23,900	8,050
1,2-Dichloroethane	23,900	8,050
Diethylamine	ND	ND
Diethyl Ether	23,900	8,050
Dimethylamine	607,000	205,000
N,N-Dimethylaniline	607,000	205,000
1,4-Dioxane	10,900,000	3,690,000
Ethanol	2,200,000	784,000
Ethyl Acetate	23,900	8,050
Formamide	607,000	205,000
Furfural	607,000	205,000
Isobutyraldehyde	23,900	8,050

Pollutant or pollutant property	Pretreatment standards for existing sources micrograms per liter (µg/L)	
	Maximum for any one day	Monthly average
Isopropanol	597,000	198,000
Isopropyl Acetate	23,900	8,050
Isopropyl Ether	23,900	8,050
Methanol	11,700,000	3,800,000
Methylamine	607,000	205,000
Methyl Formate	23,900	8,050
Methyl Isobutyl Ketone (MIBK)	23,900	8,050
2-Methylpyridine	607,000	205,000
Petroleum Naphtha	10,900,000	3,690,000
n-Propanol	2,790,000	941,000
Pyridine	1,000	1,000
Tetrahydrofuran	9,210	3,360
Triethylamine	ND	ND

(b) Indirect dischargers not using or generating cyanide are deemed to comply with the monitoring requirements specified in paragraph (a) of this section for cyanide if they certify to the control authority that they are not using or generating this pollutant.

7. Section 439.17 is amended by revising paragraph (a) introductory text and paragraph (b) and by adding paragraph (c) to read as follows:

§ 439.17 Pretreatment standards for new sources (PSNS).

(a) Any new source subject to this subpart that was a "new source" under 40 CFR 122.29 prior to [promulgation date of the final rule] must achieve the following pretreatment standards for new sources until the expiration of the applicable time period specified in 40 CFR 122.29(d)(1), after which the source must achieve the standards specified in § 439.16.

* * * * *

(b) Except as provided in 40 CFR 403.7 and paragraph (a) of this section, any new source subject to this subpart that introduces pollutants into a publicly owned treatment works must comply with 40 CFR part 403 and achieve the following pretreatment standards for new sources.

(1) Subpart A (For In-Plant Monitoring).

[Note: With respect to pollutants in this table, EPA does not propose pretreatment standards for new sources for pollutants with an asterisk (*) under co-proposal (2).]

Pollutant or pollutant property	Pretreatment standards for new sources micrograms per liter (µg/L)	
	Maximum for any one day	Monthly average
Acetone *	1,190	600
Amyl Alcohol *	8,690	3,220
Benzene	573	212
n-Butyl Alcohol *	8,690	3,220
tert-Butyl Alcohol *	8,690	3,220
Chlorobenzene	573	212
Chloroform	ND	ND
Chloromethane	573	212
Cyanide	766	406
Cyclohexane	573	212
Diethylamine *	ND	ND
Diethyl Ether *	2,230	826
Dimethylamine *	ND	ND
Ethanol *	8,690	3,220
Formamide *	ND	ND
n-Heptane	573	212
n-Hexane	573	212
Isopropanol *	8,690	3,220
Methanol *	8,320	ND
Methylamine *	ND	ND
Methyl Cellosolve	ND	ND
Methylene Chloride	809	279
Methyl Formate *	2,230	826
n-Propanol *	8,690	3,220
Toluene	184	135
Trichlorofluoromethane	573	212
Triethylamine *	ND	ND
Xylenes	573	212

(2) Subpart A (For End-of-Pipe Monitoring Points).

[Note: With respect to pollutants in this table, EPA does not propose pretreatment standards for new sources for pollutants with an asterisk (*) under co-proposal (2).]

Pollutant or pollutant property	Pretreatment standards for new sources micrograms per liter (µg/L)	
	Maximum for any one day	Monthly average
Ammonia	12,900	10,900
n-Amyl Acetate*	2,230	826
Aniline*	8,690	3,220
2-Butanone (MEK)*	161,000	57,900
n-Butyl Acetate*	2,230	826
o-Dichlorobenzene*	2,230	826
1,2-Dichloroethane*	2,230	826
N,N-Dimethylaniline*	8,690	3,220
1,4-Dioxane*	8,690	3,220
Ethyl Acetate*	2,230	826
Furfural*	8,690	3,220
Isobutyraldehyde*	2,230	826
Isopropyl Acetate*	2,230	826
Isopropyl Ether*	2,230	826
Methyl Isobutyl Ketone (MIBK)*	2,230	826
2-Methylpyridine*	8,690	3,220
Petroleum Naphtha*	8,690	3,220
Pyridine*	1,000	1,000
Tetrahydrofuran*	9,210	3,360

(c) Indirect dischargers not using or generating cyanide are deemed to comply with the monitoring requirements specified in paragraph (a) of this section for cyanide if they certify to the control authority that they are not using or generating this pollutant.

§ 439.18 [Reserved]

Subpart B—Extraction Subcategory

8. Sections 439.20 through 439.24 are revised to read as follows:

§ 439.20 Applicability; description of the extraction subcategory; prohibition.

(a) The provisions of this subpart are applicable to discharges resulting from the manufacture of pharmaceutical products by biological and natural extraction operations. Biological and natural extraction operations are defined as process operations that utilize the chemical and physical extraction of pharmaceutically active ingredients from natural sources such as plant roots and leaves, animal glands, and parasitic fungi. Biological and natural extraction operations include pilot-scale research operations not covered by the provisions of subpart E, Research Subcategory.

(b) The discharge of nonprocess wastewater and materials excluded from the definition of process wastewater at § 439.1 is not covered by this subpart. Discharge of such nonprocess wastewater and excluded materials into publicly owned treatment works or waters of the United States by a source subject to this subpart without an

NPDES permit or individual control mechanism authorizing such discharge is prohibited.

§ 439.21 Specialized definitions.

(a) Except as provided paragraph (b) of this section, the general definitions, abbreviations, and methods of analysis set forth in 40 CFR part 401 and § 439.1 shall apply to this subpart.

(b) The term “product” shall mean any biological and natural extraction product. This subcategory shall include blood fractions, vaccines, serums, animal bile derivatives, endocrine products, and isolation of medicinal products, such as alkaloids, from botanical drugs and herbs.

§ 439.22 Effluent limitations representing the degree of effluent reduction 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, any existing point source subject to this subpart must achieve the following effluent limitations representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available.

(1) Subpart B (For End-of-Pipe Effluent).

Pollutant or pollutant parameter	BPT effluent limitations milligrams per liter (mg/L)	
	Maximum for any one day	Monthly average
BOD ₅	37	11
TSS	80	27
COD	145	60

(2) The pH shall be within the range of 6.0–9.0 standard units.

(b) [Reserved]

§ 439.23 Effluent limitations representing the degree of effluent reduction attainable by the application of the best conventional pollutant control technology (BCT).

Except as provided in 40 CFR 125.30 through 125.32, any existing point source subject to this subpart must achieve the following effluent limitations representing the degree of effluent reduction attainable by the application of the best conventional pollutant control technology: The limitations shall be the same as those specified for conventional pollutants BOD₅ and TSS in § 439.22 for the best practicable control technology currently available.

§ 439.24 Effluent limitations representing the degree of effluent reduction attainable by the application of best available technology economically achievable (BAT).

(a) Except as provided in 40 CFR 125.30 through 125.32, any existing point source subject to this subpart must achieve the following effluent limitations representing the degree of

effluent reduction attainable by the application of the best available technology economically achievable.

(1) Subpart B (For End-of-Pipe Effluent).

Pollutant or pollutant property	BAT effluent limitations micrograms per Liter (µg/L)	
	Maximum for any one day	Monthly average
Acetone	413	178
Acetonitrile	ND	ND
n-Amyl Acetate	3,000	1,280
Amyl Alcohol	3,980	1,690
Aniline	10	10
Benzene	40	17
2-Butanone (MEK)	202	86
n-Butyl Acetate	500	500
n-Butyl Alcohol	ND	ND
tert-Butyl Alcohol	3,980	1,690
Chemical Oxygen Demand (COD)	145,000	59,900
Chlorobenzene	ND	ND
Chloroform	22	13
Chloromethane	206	87
Cyclohexane	ND	ND
o-Dichlorobenzene	ND	ND
1,2-Dichloroethane	438	152
Diethylamine	ND	ND
Diethyl Ether	4,870	2,070
N,N-Dimethylacetamide	ND	ND
Dimethylamine	ND	ND
N,N-Dimethylaniline	50	50
N,N-Dimethylformamide	45	19
Dimethyl Sulfoxide	ND	ND
1,4-Dioxane	220	94
Ethanol	ND	ND
Ethyl Acetate	3,000	1,280
Ethylene Glycol	ND	ND
Formaldehyde	1,480	623
Formamide	ND	ND
Furfural	3,000	1,280
n-Heptane	ND	ND
n-Hexane	ND	ND
Isobutyraldehyde	1,370	581
Isopropanol	1,120	476
Isopropyl Acetate	500	500
Isopropyl Ether	4,870	2,070
Methanol	6,660	ND
Methylamine	ND	ND
Methyl Cellosolve	ND	ND
Methylene Chloride	1,420	357
Methyl Formate	3,000	1,280
Methyl Isobutyl Ketone (MIBK)	119	51
2-Methylpyridine	50	50
Petroleum Naphtha	40	17
Phenol	25	14
Polyethylene Glycol 600	4,870	2,070
n-Propanol	3,980	ND
Pyridine	10	10
Tetrahydrofuran	15,000	4,350
Toluene	40	17
Trichlorofluoromethane	599	322
Triethylamine	ND	ND
Xylenes	ND	ND

(2) [Reserved]

(b) [Reserved]

9. Section 439.25 is amended by revising paragraph (a) introductory text and paragraph (b) to read as follows:

§ 439.25 New source performance standards (NSPS).

(a) Any new source subject to this subpart that was a “new source” under 40 CFR 122.29 prior to [promulgation date of the final rule] must achieve the

following new source performance standards until the expiration of the applicable time period specified in 40 CFR 122.29(d)(1), after which the source must achieve the effluent limitations

specified in §§ 439.22, 439.23, and 439.24.

* * * * *

(b) Except as provided in paragraph (a) of this section any new source subject to this subpart must achieve the

following new source performance standards.

(1) Subpart B (For End-of-Pipe Effluent) The standards in the following table do not apply for any pollutant(s) for which the permit writer finds it

necessary to specify in-plant monitoring requirements pursuant to 40 CFR 122.44(i) and 122.45(h). Standards for those pollutant(s) would be established on a best professional judgment basis pursuant to 40 CFR 125.3.

Pollutant or pollutant property	New source performance standards micrograms per liter (µg/L)	
	Maximum for any one day	Monthly average
Acetone	ND	ND
Acetonitrile	ND	ND
Ammonia	4,850	3,230
n-Amyl Acetate	14	6
Amyl Alcohol	ND	ND
Aniline104 Benzene	ND	10/4
2-Butanone (MEK)	144	61
n-Butyl Acetate	11	ND
n-Butyl Alcohol	ND	ND
tert-Butyl Alcohol	ND	ND
Chlorobenzene	ND	ND
Chloroform	ND	ND
Chloromethane	ND	ND
Cyclohexane	ND	ND
o-Dichlorobenzene	ND	ND
1,2-Dichloroethane	13	ND
Diethylamine	ND	ND
Diethyl Ether	74	ND
Dimethylamine	ND	ND
N,N-Dimethylacetamide	ND	ND
N,N-Dimethylaniline	50	45
N,N-Dimethylformamide	45	19
Dimethyl Sulfoxide	ND	ND
1,4-Dioxane	ND	ND
Ethanol	ND	ND
Ethyl Acetate	14	ND
Ethylene Glycol	ND	ND
Formaldehyde	1,480	623
Formamide	ND	ND
Furfural	53	ND
n-Heptane	ND	ND
n-Hexane	ND	ND
Isobutyraldehyde	304	129
Isopropanol	ND	ND
Isopropyl Acetate	11	ND
Isopropyl Ether	74	32
Methanol	ND	ND
Methylamine	ND	ND
Methyl Cellosolve	ND	ND
Methyl Formate	ND	ND
Methylene Chloride	ND	ND
Methyl Isobutyl Ketone (MIBK)	ND	ND
2-Methylpyridine	50	45
Petroleum Naphtha	ND	ND
Phenol	25	14
Polyethylene Glycol 600	4,870	2,070
n-Propanol	ND	ND
Pyridine	10	10
Tetrahydrofuran	910	264
Toluene	ND	ND
Trichlorofluoromethane	ND	ND
Triethylamine	ND	ND
Xylenes	ND	ND

(2) Subpart B (For End-of-Pipe Effluent).

Pollutant or pollutant parameter	New source performance standards milligrams per liter (mg/L)		Pollutant or pollutant parameter	New source performance standards milligrams per liter (mg/L)	
	Maximum for any one day	Monthly average		Maximum for any one day	Monthly average
BOD ₅	34	10	pH	(a)	(a)
COD	60	24	(a) Within the range of 6.0 to 9.0 standard units.		
TSS	40	12	10. Section 439.26 is revised to read as follows:		

§ 439.26 Pretreatment standards for existing sources (PSES).

(a) Except as provided in 40 CFR 403.7 and 403.13, any existing source subject to this subpart that introduces pollutants into a publicly owned treatment works must comply with 40 CFR part 403 and by [date 3 years from the promulgation date of the final rule] achieve the following pretreatment standards for existing sources.

(1) Subpart B (For In-Plant Monitoring Points).

Pollutant or pollutant property	Pretreatment standards for existing sources micrograms per liter (µg/L)	
	Maximum for any one day	Monthly average
Benzene	796	268
Chlorobenzene	796	268
Chloroform	ND	ND
Chloromethane	796	268
Cyclohexane	796	268
n-Heptane	796	268
n-Hexane	796	268
Methyl Cellosolve	ND	ND
Methylene Chloride	809	279
Toluene	198	148
Trichlorofluoromethane	796	268
Xylenes	796	268

(2) Subpart B (For End-of-Pipe Monitoring Points).

(Note: Under co-proposal (2), EPA does not propose pretreatment standards for existing sources for these pollutants.)

Pollutant or pollutant property	Pretreatment standards for existing sources micrograms per liter (µg/L)	
	Maximum for any one day	Monthly average
Acetone	31,400	9,690
n-Amyl Acetate	23,900	8,050
Amyl Alcohol	607,000	205,000
Aniline	10,900,000	3,690,000
2-Butanone (MEK)	1,440,000	430,000
n-Butyl Acetate	23,900	8,050
n-Butyl Alcohol	10,900,000	3,690,000
tert-Butyl Alcohol	607,000	205,000
o-Dichlorobenzene	23,900	8,050
1,2-Dichloroethane	23,900	8,050
Diethylamine	ND	ND
Diethyl Ether	23,900	8,050
Dimethylamine	607,000	205,000
N,N-Dimethylaniline	607,000	205,000
1,4-Dioxane	10,900,000	3,690,000
Ethanol	2,200,000	784,000
Ethyl Acetate	23,900	8,050
Formamide	607,000	205,000
Furfural	607,000	205,000
Isobutyraldehyde	23,900	8,050
Isopropanol	597,000	198,000
Isopropyl Acetate	23,900	8,050
Isopropyl Ether	23,900	8,050
Methanol	11,700,000	3,800,000
Methylamine	607,000	205,000
Methyl Formate	23,900	8,050
Methyl Isobutyl Ketone (MIBK)	23,900	8,050
2-Methylpyridine	607,000	205,000
Petroleum Naphtha	10,900,000	3,690,000
n-Propanol	2,790,000	941,000
Pyridine	1,000	1,000

Pollutant or pollutant property	Pretreatment standards for existing sources micrograms per liter (µg/L)	
	Maximum for any one day	Monthly average
Tetrahydrofuran	9,210	3,360
Triethylamine	ND	ND

(b) [Reserved]

11. Section 439.27 is amended by revising paragraph (a) introductory text and paragraph (b) to read as follows:

§ 439.27 Pretreatment standards for new sources (PSNS).

(a) Any new source subject to this subpart that was a “new source” under 40 CFR 122.29 prior to [promulgation date of the final rule] must achieve the

following pretreatment standards for new sources until the expiration of the applicable time period specified in 40 CFR 122.29(d)(1), after which the source must achieve the standards specified in § 439.26.

* * * * *

(b) Except as provided in 40 CFR 403.7 and paragraph (a) of this section, any new source subject to this subpart

that introduces pollutants into a publicly owned treatment works must comply with 40 CFR part 403 and achieve the following pretreatment standards for new sources.

(1) Subpart B (For In-Plant Monitoring Points).

[Note: With respect to pollutants in this table, EPA does not propose pretreatment standards for new sources for pollutants with an asterisk (*) under co-proposal (2).]

Pollutant or pollutant property	Pretreatment standards for new sources micrograms per liter (µg/L)	
	Maximum for any one day	Monthly average
Acetone*	1,190	600
Amyl Alcohol*	8,690	3,220
Benzene	573	212
n-Butyl Alcohol*	8,690	3,220
tert-Butyl Alcohol*	8,690	3,220
Chlorobenzene	573	212
Chloroform	ND	ND
Chloromethane	573	212
Cyclohexane	573	212
Diethylamine*	ND	ND
Diethyl Ether*	2,230	826
Dimethylamine*	ND	ND
Ethanol*	8,690	3,220
Formamide*	ND	ND
n-Heptane	573	212
n-Hexane	573	212
Isopropanol*	8,690	3,220
Methanol*	8,320	ND
Methylamine*	ND	ND
Methyl Cellosolve	ND	ND
Methylene Chloride	809	279
Methyl Formate*	2,230	826
n-Propanol*	8,690	3,220
Toluene	184	135
Trichlorofluoromethane	573	212
Triethylamine*	ND	ND
Xylenes	573	212

(2) Subpart B (For End-of-Pipe Monitoring Points).

[Note: With respect to pollutants in this table, EPA does not propose pretreatment standards for new sources for pollutants with an asterisk (*) under co-proposal (2).]

Pollutant or pollutant property	Pretreatment standards for new sources micrograms per liter (µg/L)	
	Maximum for any one day	Monthly average
n-Amyl Acetate*	2,230	826
Aniline*	8,690	3,220
2-Butanone (MEK)*	161,000	57,900
n-Butyl Acetate*	2,230	826
o-Dichlorobenzene*	2,230	826
1,2-Dichloroethane*	2,230	826

Pollutant or pollutant property	Pretreatment standards for new sources micrograms per liter (µg/L)	
	Maximum for any one day	Monthly average
N,N-Dimethylaniline*	8,690	3,220
1,4-Dioxane*	8,690	3,220
Ethyl Acetate*	2,230	826
Furfural*	8,690	3,220
Isobutyraldehyde*	2,230	826
Isopropyl Acetate*	2,230	826
Isopropyl Ether*	2,230	826
Methyl Isobutyl Ketone (MIBK)*	2,230	826
2-Methylpyridine*	8,690	3,220
Petroleum Naphtha*	8,690	3,220
Pyridine*	1,000	1,000
Tetrahydrofuran*	9,210	3,360

§ 439.28 [Reserved]

Subpart C—Chemical Synthesis Subcategory

12. Sections 439.30 through 439.34 are revised to read as follows:

§ 439.30 Applicability; description of the chemical synthesis subcategory; prohibition.

(a) The provisions of this subpart are applicable to discharges resulting from the manufacture of pharmaceutical products by chemical synthesis operations. Chemical synthesis is defined as the process(es) of using a chemical reaction or series of chemical reactions to produce a specified product. Chemical synthesis operations include pilot-scale research operations not covered by the provisions of subpart E, Research Subcategory.

(b) The discharge of non-process wastewater and materials excluded from the definition of process wastewater at § 439.1 is not covered by this subpart. Discharge of such non-process wastewater and excluded materials into publicly owned treatment works or waters of the United States by a source subject to this subpart without an NPDES permit or individual control mechanism authorizing such discharge is prohibited.

§ 439.31 Specialized definitions.

For the purpose of this subpart:

(a) Except as provided in paragraph (b) of this section, the general definitions, abbreviations, and methods of analysis set forth in 40 CFR part 401 and § 439.1 shall apply to this subpart.

(b) The term “product” shall mean any pharmaceutical product derived from chemical synthesis processes.

§ 439.32 Effluent limitations representing the degree of effluent reduction 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, any existing point source subject to this subpart must achieve the following effluent limitations representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available.

(1) Subpart C (For In-Plant Monitoring Points).

Pollutant or pollutant property	BPT effluent limitations micrograms per liter (µg/L)	
	Maximum for any one day	Monthly average
Cyanide (Total)	766	406

(2) Subpart C (For End-of-Pipe Effluent).

Pollutant or pollutant property	BPT effluent limitations micrograms per liter (mg/L)	
	Maximum for any one day	Monthly average
BOD ₅	137	58
TSS	318	110
COD	1100	628

3) The pH shall be within the range of 6.0–9.0 standard units.

(b) Permittees not using or generating cyanide are deemed to comply with the monitoring requirements specified in paragraph (a) of this section for cyanide if they certify to the permit issuing authority that they are not using or generating this pollutant.

§ 439.33 Effluent limitations representing the degree of effluent reduction attainable by the application of the best conventional pollutant control technology (BCT).

Except as provided in 40 CFR 125.30 through 125.32, any existing point source subject to this subpart must achieve the following effluent limitations representing the degree of effluent reduction attainable by the application of the best conventional pollutant control technology: The limitations shall be the same as those specified for conventional pollutants BOD₅ and TSS in § 439.32 for the best practicable control technology currently available.

§ 439.34 Effluent limitations representing the degree of effluent reduction attainable by the application of best available technology economically achievable (BAT).

(a) Except as provided in 40 CFR 125.30 through 125.32, any existing point source subject to this subpart must achieve the following effluent limitations representing the degree of effluent reduction attainable by the application of the best available technology economically achievable.

(1) Subpart C (For In-Plant Monitoring Points)

Pollutant or pollutant property	BAT effluent limitations micrograms per liter (µg/L)	
	Maximum for any one day	Monthly average
Cyanide (Total)	766	406

(2) Subpart C (For End-of-Pipe Effluent). The limitations in the following table do not apply for any pollutant(s) for which the permit writer finds it necessary to specify in-plant monitoring requirements pursuant to 40 CFR 122.44(i) and 122.45(h). Limitations for those pollutant(s) would be established on a best professional

judgment basis pursuant to 40 CFR 125.3.

Pollutant or pollutant property	BAT effluent limitations micrograms per liter (µg/L)	
	Maximum for any one day	Monthly average
Acetone	ND	ND
Acetonitrile	ND	ND
Ammonia	4,850	3,230
n-Amyl Acetate	105	45
Amyl Alcohol	668	ND
Aniline	10	10
Benzene	ND	ND
2-Butanone (MEK)	202	86
n-Butyl Acetate	87	37
n-Butyl Alcohol	ND	ND
tert-Butyl Alcohol	668	284
Chemical Oxygen Demand (COD)	1,100,000	628,000
Chlorobenzene	ND	ND
Chloroform	ND	ND
Chloromethane	ND	ND
Cyclohexane	ND	ND
o-Dichlorobenzene	ND	ND
1,2-Dichloroethane	100	35
Diethylamine	ND	ND
Diethyl Ether	574	244
Dimethylamine	ND	ND
N,N-Dimethylacetamide	ND	ND
N,N-Dimethylaniline	50	50
N,N-Dimethylformamide	45	19
Dimethyl Sulfoxide	ND	ND
1,4-Dioxane	220	94
Ethanol	ND	ND
Ethyl Acetate	105	45
Ethylene Glycol	ND	ND
Formaldehyde	1,480	623
Formamide	ND	ND
Furfural	2,670	1,140
n-Heptane	ND	ND
n-Hexane	ND	ND
Isobutyraldehyde	1,370	581
Isopropanol	ND	ND
Isopropyl Acetate	87	37
Isopropyl Ether	574	244
Methanol	ND	ND
Methylamine	ND	ND
Methyl Cellosolve	ND	ND
Methyl Formate	105	ND
Methylene Chloride	ND	ND
Methyl Isobutyl Ketone (MIBK)	ND	ND
2-Methylpyridine	50	50
Petroleum Naphtha	ND	ND
Phenol	25	14
Polyethylene glycol 600	4,870	2,070
n-Propanol	ND	ND
Pyridine	10	10
Tetrahydrofuran	910	264
Toluene	ND	ND
Trichlorofluoromethane	ND	ND
Triethylamine	ND	ND
Xylenes	ND	ND

(b) Permittees not using or generating cyanide are deemed to comply with the monitoring requirements specified in paragraph (a) of this section for cyanide if they certify to the permit issuing authority that they are not using or generating this pollutant.

13. Section 439.35 is amended by revising paragraph (a) introductory text and paragraph (b) and by adding paragraph (c) to read as follows:

§ 439.35 New source performance standards (NSPS).

(a) Any new source subject to this subpart that was a "new source" under

40 CFR 122.29 prior to [promulgation date of the final rule] must achieve the following new source performance standards until the expiration of the applicable time period specified in 40 CFR 122.29(d)(1), after which the source must achieve the effluent limitations

specified in §§ 439.32, 439.33, and 439.34.

* * * * *

(b) Except as provided in paragraph (a) of this section, any new source subject to this subpart must achieve the following new source performance standards.

(1) Subpart C (For In-Plant Monitoring Points).

Pollutant or pollutant property	New source performance standards micrograms per liter (µg/L)	
	Maximum for any one day	Monthly average
Cyanide (Total)	766	406

(2) Subpart C (For End-of-Pipe Effluent). The standards in the following table do not apply for any pollutant(s) for which the permit writer finds it necessary to specify in-plant monitoring requirements pursuant to 40 CFR 122.44(i) and 122.45(h). Standards for those pollutant(s) would be established on a best professional judgment basis pursuant to 40 CFR 125.3.

Pollutant or pollutant property	New source performance standards micrograms per liter (µg/L)	
	Maximum for any one day	Monthly average
Acetone	ND	ND
Acetonitrile	ND	ND
Ammonia	4,850	3,230
n-Amyl Acetate	14	6
Amyl Alcohol	ND	ND
Aniline	10	4
Benzene	ND	ND
2-Butanone (MEK)	144	61
n-Butyl Acetate	11	ND
n-Butyl Alcohol	ND	ND
tert-Butyl Alcohol	ND	ND
Chlorobenzene	ND	ND
Chloroform	ND	ND
Chloromethane	ND	ND
Cyclohexane	ND	ND
o-Dichlorobenzene	ND	ND
1,2-Dichloroethane	13	ND
Diethylamine	ND	ND
Diethyl Ether	74	ND
Dimethylamine	ND	ND
N,N-Dimethylacetamide	ND	ND
N,N-Dimethylaniline	50	45
N,N-Dimethylformamide	45	19
Dimethyl Sulfoxide	ND	ND
1,4-Dioxane	ND	ND
Ethanol	ND	ND
Ethyl Acetate	14	ND
Ethylene Glycol	ND	ND
Formaldehyde	1,480	623
Formamide	ND	ND
Furfural	53	ND
n-Heptane	ND	ND
n-Hexane	ND	ND
Isobutyraldehyde	304	129
Isopropanol	ND	ND
Isopropyl Acetate	11	ND
Isopropyl Ether	74	32
Methanol	ND	ND
Methylamine	ND	ND
Methyl Cellosolve	ND	ND
Methyl Formate	ND	ND
Methylene Chloride	ND	ND
Methyl Isobutyl Ketone (MIBK)	ND	ND
2-Methylpyridine	50	45
Petroleum Naphtha	ND	ND
Phenol	25	14
Polyethylene Glycol 600	4,870	2,070
n-Propanol	ND	ND
Pyridine	10	10
Tetrahydrofuran	910	264
Toluene	ND	ND
Trichlorofluoromethane	ND	ND
Triethylamine	ND	ND
Xylenes	ND	ND

(3) Subpart C (For End-of-Pipe Effluent).

Pollutant or pollutant property	New source performance standards milligrams per liter (mg/L)	
	Maximum for any one day	Monthly average
BOD ₅	62	29
COD	781	538
TSS	87	43
pH	(^a)	(^a)

(^a) Within the range of 6.0 to 9.0 standard units.

(c) Permittees not using or generating cyanide are deemed to comply with the monitoring requirements specified in paragraph (a) of this section for cyanide if they certify to the permit issuing authority that they are not using or generating this pollutant.

14. Section 439.36 is revised to read as follows:

§ 439.36 Pretreatment standards for existing sources (PSES).

(a) Except as provided in 40 CFR 403.7 and 403.13, any existing source subject to this subpart that introduces pollutants into a publicly owned

treatment works must comply with 40 CFR part 403 and by [date 3 years from the promulgation date of the final rule] achieve the following pretreatment standards for existing sources.

(1) Subpart C (For In-Plant Monitoring Points).

Pollutant or pollutant property	Pretreatment standards for existing sources micrograms per liter (µg/L)	
	Maximum for any one day	Monthly average
Benzene	796	268
Chlorobenzene	796	268
Chloroform	ND	ND
Chloromethane	796	268
Cyanide	766	406
Cyclohexane	796	268
n-Heptane	796	268
n-Hexane	796	268
Methyl Cellosolve	ND	ND
Methylene Chloride	809	279
Toluene	198	148
Trichlorofluoromethane	796	268
Xylenes	796	268

(2) Subpart C (For End-of-Pipe Monitoring Points).

[Note: With respect to the pollutants in this table, EPA proposes pretreatment standards for existing sources only for ammonia under co-proposal (2).]

Pollutant or pollutant property	Pretreatment standards for existing sources micrograms per liter (µg/L)	
	Maximum for any one day	Monthly average
Acetone	31,400	9,690
Ammonia	12,900	10,900
n-Amyl Acetate	23,900	8,050
Amyl Alcohol	607,000	205,000
Aniline	10,900,000	3,690,000
2-Butanone (MEK)	1,440,000	430,000
n-Butyl Acetate	23,900	8,050
n-Butyl Alcohol	10,900,000	3,690,000
tert-Butyl Alcohol	607,000	205,000
o-Dichlorobenzene	23,900	8,050
1,2-Dichloroethane	23,900	8,050
Diethylamine	ND	ND
Diethyl Ether	23,900	8,050
Dimethylamine	607,000	205,000
N,N-Dimethylaniline	607,000	205,000
1,4-Dioxane	10,900,000	3,690,000
Ethanol	2,200,000	784,000
Ethyl Acetate	23,900	8,050
Formamide	607,000	205,000
Furfural	607,000	205,000
Isobutyraldehyde	23,900	8,050
Isopropanol	597,000	198,000
Isopropyl Acetate	23,900	8,050

Pollutant or pollutant property	Pretreatment standards for existing sources micrograms per liter (µg/L)	
	Maximum for any one day	Monthly average
Isopropyl Ether	23,900	8,050
Methanol	11,700,000	3,800,000
Methylamine	607,000	205,000
Methyl Formate	23,900	8,050
Methyl Isobutyl Ketone (MIBK)	23,900	8,050
2-Methylpyridine	607,000	205,000
Petroleum Naphtha	10,900,000	3,690,000
n-Propanol	2,790,000	941,000
Pyridine	1,000	1,000
Tetrahydrofuran	9,210	3,360
Triethylamine	ND	ND

(b) Indirect dischargers not using or generating cyanide are deemed to comply with the monitoring requirements specified in paragraph (a) of this section for cyanide if they certify to the control authority that they are not using or generating this pollutant.

15. Section 439.37 is amended by revising paragraph (a) introductory text and paragraph (b) and by adding paragraph (c) to read as follows:

§ 439.37 Pretreatment standards for new sources (PSNS).

(a) Any new source subject to this subpart that was a "new source" under 40 CFR 122.29 prior to [promulgation date of the final rule] must achieve the following pretreatment standards for new sources until the expiration of the applicable time period specified in 40 CFR 122.29(d)(1), after which the source

must achieve the standards specified in § 439.36.

* * * * *

(b) Except as provided in 40 CFR 403.7 and paragraph (a) of this section, any new source subject to this subpart that introduces pollutants into a publicly owned treatment works must comply with 40 CFR part 403 and achieve the following pretreatment standards for new sources.

(1) Subpart C (For In-Plant Monitoring Points).

[**Note:** With respect to pollutants in this table, EPA does not propose pretreatment standards for new sources for pollutants with an asterisk (*) under co-proposal (2).]

Pollutant or pollutant property	Pretreatment standards for new sources micrograms per liter (µg/L)	
	Maximum for any one day	Monthly average
Acetone*	1,190	600
Amyl Alcohol*	8,690	3,220
Benzene	573	212
n-Butyl Alcohol*	8,690	3,220
tert-Butyl Alcohol*	8,690	3,220
Chlorobenzene	573	212
Chloroform	ND	ND
Chloromethane	573	212
Cyanide	766	406
Cyclohexane	573	212
Diethylamine*	ND	ND
Diethyl Ether*	2,230	826
Dimethylamine*	ND	ND
Ethanol*	8,690	3,220
Formamide*	ND	ND
n-Heptane	573	212
n-Hexane	573	212
Isopropanol*	8,690	3,220
Methanol*	8,320	ND
Methylamine*	ND	ND
Methyl Cellosolve	ND	ND
Methylene Chloride	809	279
Methyl Formate*	2,230	826
n-Propanol*	8,690	3,220
Toluene	184	135
Trichlorofluoromethane	573	212
Triethylamine*	ND	ND
Xylenes	573	212

(2) Subpart C (For End-of-Pipe Monitoring Points).

[Note: With respect to pollutants in this table, EPA does not propose pretreatment standards for new sources for pollutants with an asterisk (*) under co-proposal (2).]

Pollutant or pollutant property	Pretreatment standards for new sources micrograms per liter (µg/L)	
	Maximum for any one day	Monthly average
Ammonia	12,900	10,900
n-Amyl Acetate*	2,230	826
Aniline*	8,690	3,220
2-Butanone (MEK)*	161,000	57,900
n-Butyl Acetate*	2,230	826
o-Dichlorobenzene*	2,230	826
1,2-Dichloroethane*	2,230	826
N,N-Dimethylaniline*	8,690	3,220
1,4-Dioxane*	8,690	3,220
Ethyl Acetate*	2,230	826
Furfural*	8,690	3,220
Isobutyraldehyde*	2,230	826
Isopropyl Acetate*	2,230	826
Isopropyl Ether*	2,230	826
Methyl Isobutyl Ketone (MIBK)*	2,230	826
2-Methylpyridine*	8,690	3,220
Petroleum Naphtha*	8,690	3,220
Pyridine*	1,000	1,000
Tetrahydrofuran*	9,210	3,360

(c) Indirect dischargers not using or generating cyanide are deemed to comply with the monitoring requirements specified in paragraph (a) of this section for cyanide if they certify to the control authority that they are not using or generating this pollutant.

§ 439.38 [Reserved]

Subpart D—Mixing, Compounding and Formulating Subcategory

16. Sections 439.40 through 439.44 are revised to read as follows:

§ 439.40 Applicability; description of the mixing, compounding and formulating subcategory; prohibition.

(a) The provisions of this subpart are applicable to discharges resulting from the mixing, compounding and formulating operations of pharmaceutical products. Mixing, compounding, and formulating operations are defined as processes through which pharmaceutical products are put in dosage forms. Mixing, compounding, and formulating operations include pilot-scale research operations not covered by the provisions of subpart E, Research Subcategory.

(b) The discharge of non-process wastewaters and materials excluded from the definition of process wastewater at § 439.1 is not covered by this subpart. Discharge of such non-process wastewater and excluded materials into publicly owned treatment works or waters of the United States, by a source subject to this subpart, without

an NPDES permit or individual control mechanism authorizing such discharge is prohibited.

§ 439.41 Specialized definitions.

For the purpose of this subpart:

(a) Except as provided below, the general definitions, abbreviations, and methods of analysis set forth in 40 CFR part 401 and § 439.1 shall apply to this subpart.

(b) The term “product” shall mean products from plants that blend, mix, compound, and formulate pharmaceutical ingredients. Pharmaceutical preparations for human and veterinary use such as ampules, tablets, capsules, vials, ointments, medicinal powders, solutions, and suspensions are included.

§ 439.42 Effluent limitations representing the degree of effluent reduction 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, any existing point source subject to this subpart must achieve the following effluent limitations representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available.

(1) Subpart D (For End-of-Pipe Effluent).

Pollutant or pollutant parameter	BPT effluent limitations milligrams per liter (mg/L)	
	Maximum for any one day	Monthly average
BOD ₅	37	11
TSS	80	27
COD	145	60

(2) The pH shall be within the range of 6.0–9.0 standard units.

(b) [Reserved]

§ 439.43 Effluent limitations representing the degree of effluent reduction attainable by the application of the best conventional pollutant control technology (BCT).

Except as provided in 40 CFR 125.30 through 125.32, any existing point source subject to this subpart must achieve the following effluent limitations representing the degree of effluent reduction attainable by the application of the best conventional pollutant control technology. The limitations shall be the same as those specified for conventional pollutants BOD₅ and TSS in § 439.42 for the best practicable control technology currently available.

§ 439.44 Effluent limitations representing the degree of effluent reduction attainable by the application of best available technology economically achievable (BAT).

(a) Except as provided in 40 CFR 125.30 through 125.32, any existing point source subject to this subpart must achieve the following effluent limitations representing the degree of

effluent reduction attainable by the

application of the best available
technology economically achievable.(1) Subpart D (For End-of-Pipe
Effluent).

Pollutant or pollutant property	BAT effluent limitations micrograms per liter (µg/L)	
	Maximum for any one day	Monthly average
Acetone	413	178
Acetonitrile	ND	ND
n-Amyl Acetate	3,000	1,280
Amyl Alcohol	3,980	1,690
Aniline	10	10
Benzene	40	17
2-Butanone (MEK)	202	86
n-Butyl Acetate	500	500
n-Butyl Alcohol	ND	ND
tert-Butyl Alcohol	3,980	1,690
Chemical Oxygen Demand (COD)	145,000	59,900
Chlorobenzene	ND	ND
Chloroform	22	13
Chloromethane	206	87
Cyclohexane	ND	ND
o-Dichlorobenzene	ND	ND
1,2-Dichloroethane	438	152
Diethylamine	ND	ND
Diethyl Ether	4,870	2,070
N,N-Dimethylacetamide	ND	ND
Dimethylamine	ND	ND
N,N-Dimethylaniline	50	50
N,N-Dimethylformamide	45	19
Dimethyl Sulfoxide	ND	ND
1,4-Dioxane	220	94
Ethanol	ND	ND
Ethyl Acetate	3,000	1,280
Ethylene Glycol	ND	ND
Formaldehyde	1,480	623
Formamide	ND	ND
Furfural	3,000	1,280
n-Heptane	ND	ND
n-Hexane	ND	ND
Isobutyraldehyde	1,370	581
Isopropanol	1,120	476
Isopropyl Acetate	500	500
Isopropyl Ether	4,870	2,070
Methanol	6,660	ND
Methylamine	ND	ND
Methyl Cellosolve	ND	ND
Methylene Chloride	1,420	357
Methyl Formate	3,000	1,280
Methyl Isobutyl Ketone (MIBK)	119	51
2-Methylpyridine	50	50
Petroleum Naphtha	40	17
Phenol	25	14
Polyethylene Glycol 600	4,870	2,070
n-Propanol	3,980	ND
Pyridine	10	10
Tetrahydrofuran	15,000	4,350
Toluene	40	17
Trichlorofluoromethane	599	322
Triethylamine	ND	ND
Xylenes	ND	ND

(2) [Reserved]

(b) [Reserved]

17. Section 439.45 is amended by
revising paragraph (a) introductory text
and paragraph (b) to read as follows:

**§ 439.45 New source performance
standards (NSPS).**

(a) Any new source subject to this
subpart that was a "new source" under

40 CFR 122.29 prior to [promulgation
date of the final rule] must achieve the
following new source performance
standards until the expiration of the
applicable time period specified in 40
CFR 122.29(d)(1), after which the source
must achieve the effluent limitations

specified in §§ 439.42, 439.43, and
439.44.

* * * * *

(b) Except as provided in paragraph
(a) of this section, any new source
subject to this subpart must achieve the
following new source performance
standards.

(1) Subpart D (For End-of-Pipe Monitoring Points). The standards in the following table do not apply for any pollutant(s) for which the permit writer finds it necessary to specify in-plant monitoring requirements pursuant to 40 CFR 122.44(i) and 122.45(h). Standards for those pollutant(s) would be established on a best professional judgment basis pursuant to 40 CFR 125.3.

Pollutant or pollutant property	New source performance standards micrograms per liter (µg/L)	
	Maximum for any one day	Monthly average
Acetone	ND	ND
Acetonitrile	ND	ND
Ammonia	4,850	3,230
n-Amyl Acetate	14	6
Amyl Alcohol	ND	ND
Aniline	10	4
Benzene	ND	ND
2-Butanone (MEK)	144	61
n-Butyl Acetate	11	ND
n-Butyl Alcohol	ND	ND
tert-Butyl Alcohol	ND	ND
Chlorobenzene	ND	ND
Chloroform	ND	ND
Chloromethane	ND	ND
Cyclohexane	ND	ND
o-Dichlorobenzene	ND	ND
1,2-Dichloroethane	13	ND
Diethylamine	ND	ND
Diethyl Ether	74	ND
Dimethylamine	ND	ND
N,N-Dimethylacetamide	ND	ND
N,N-Dimethylaniline	50	45
N,N-Dimethylformamide	45	19
Dimethyl Sulfoxide	ND	ND
1,4-Dioxane	ND	ND
Ethanol	ND	ND
Ethyl Acetate	14	ND
Ethylene Glycol	ND	ND
Formaldehyde	1,480	623
Formamide	ND	ND
Furfural	53	ND
n-Heptane	ND	ND
n-Hexane	ND	ND
Isobutyraldehyde	304	129
Isopropanol	ND	ND
Isopropyl Acetate	11	ND
Isopropyl Ether	74	32
Methanol	ND	ND
Methylamine	ND	ND
Methyl Cellosolve	ND	ND
Methyl Formate	ND	ND
Methylene Chloride	ND	ND
Methyl Isobutyl Ketone (MIBK)	ND	ND
2-Methylpyridine	50	45
Petroleum Naphtha	ND	ND
Phenol	25	14
Polyethylene Glycol 600	4,870	2,070
n-Propanol	ND	ND
Pyridine	10	10
Tetrahydrofuran	910	264
Toluene	ND	ND
Trichlorofluoromethane	ND	ND
Triethylamine	ND	ND
Xylenes	ND	ND

(2) Subpart D (For End-of-Pipe Effluent).

Pollutant or pollutant property	New source performance standards milligrams per liter (mg/L)	
	Maximum for any one day	Monthly average
BOD ₅	34	10

Pollutant or pollutant property	New source performance standards milligrams per liter (mg/L)	
	Maximum for any one day	Monthly average
COD	60	24
TSS	40	12
pH	(^a)	(^a)

(^a) Within the range of 6.0–9.0 standard units.

18. Section 439.46 is revised to read as follows:

§ 439.46 Pretreatment standards for existing sources (PSES).

(a) Except as provided in 40 CFR 403.7 and 403.13, any existing source subject to this subpart that introduces pollutants into a publicly owned treatment works must comply with 40 CFR part 403 and by [date 3 years from the promulgation date of the final rule] achieve the following pretreatment standards for existing sources.

(1) Subpart D (For In-Plant Monitoring Points).

Pollutant or pollutant property	Pretreatment standards for existing sources micrograms per liter (µg/L)	
	Maximum for any one day	Monthly average
Benzene	796	268
Chlorobenzene	796	268
Chloroform	ND	ND
Chloromethane	796	268
Cyclohexane	796	268
n-Heptane	796	268
n-Hexane	796	268
Methyl Cellosolve	ND	ND
Methylene Chloride	809	279
Toluene	198	148
Trichlorofluoromethane	796	268
Xylenes	796	268

(2) Subpart D (For End-of-Pipe Monitoring Points).

[**Note:** Under co-proposal (2), EPA does not propose pretreatment standards for existing sources for these pollutants.]

Pollutant or pollutant property	Pretreatment standards for existing sources micrograms per liter (µg/L)	
	Maximum for any one day	Monthly average
Acetone	31,400	9,690
n-Amyl Acetate	23,900	8,050
Amyl Alcohol	607,000	205,000
Aniline	10,900,000	3,690,000
2-Butanone (MEK)	1,440,000	430,000
n-Butyl Acetate	23,900	8,050
n-Butyl Alcohol	10,900,000	3,690,000
tert-Butyl Alcohol	607,000	205,000
o-Dichlorobenzene	23,900	8,050
1,2-Dichloroethane	23,900	8,050
Diethylamine	ND	ND
Diethyl Ether	23,900	8,050
Dimethylamine	607,000	205,000
N,N-Dimethylaniline	607,000	205,000
1,4-Dioxane	10,900,000	3,690,000
Ethanol	2,200,000	784,000
Ethyl Acetate	23,900	8,050
Formamide	607,000	205,000
Furfural	607,000	205,000
Isobutyraldehyde	23,900	8,050
Isopropanol	597,000	198,000
Isopropyl Acetate	23,900	8,050
Isopropyl Ether	23,900	8,050
Methanol	11,700,000	3,800,000
Methylamine	607,000	205,000
Methyl Formate	23,900	8,050

Pollutant or pollutant property	Pretreatment standards for existing sources micrograms per liter (µg/L)	
	Maximum for any one day	Monthly average
Methyl Isobutyl Ketone (MIBK)	23,900	8,050
2-Methylpyridine	607,000	205,000
Petroleum Naphtha	10,900,000	3,690,000
n-Propanol	2,790,000	941,000
Pyridine	1,000	1,000
Tetrahydrofuran	9,210	3,360
Triethylamine	ND	ND

(b) [Reserved]

19. Section 439.47 is amended by revising paragraph (a) introductory text and paragraph (b) to read as follows:

§ 439.47 Pretreatment standards for new sources (PSNS).

(a) Any new source subject to this subpart that was a "new source" under 40 CFR 122.29 prior to [promulgation date of the final rule] must achieve the

following pretreatment standards for new sources until the expiration of the applicable time period specified in 40 CFR 122.29(d)(1), after which the source must achieve the standards specified in § 439.46.

* * * * *

(b) Except as provided in 40 CFR 403.7 and paragraph (a) of this section, any new source subject to this subpart

that introduces pollutants into a publicly owned treatment works must comply with 40 CFR part 403 and achieve the following pretreatment standards for new sources.

(1) Subpart D (For In-Plant Monitoring Points).

[**Note:** With respect to pollutants in this table, EPA does not propose pretreatment standards for new sources for pollutants with an asterisk (*) under co-proposal (2).]

Pollutant or pollutant property	Pretreatment standards for new sources micrograms per liter (µg/L)	
	Maximum for any one day	Monthly average
Acetone*	1,190	600
Amyl Alcohol*	8,690	3,220
Benzene	573	212
n-Butyl Alcohol*	8,690	3,220
tert-Butyl Alcohol*	8,690	3,220
Chlorobenzene	573	212
Chloroform	ND	ND
Chloromethane	573	212
Cyclohexane	573	212
Diethylamine*	ND	ND
Diethyl Ether*	2,230	826
Dimethylamine*	ND	ND
Ethanol*	8,690	3,220
Formamide*	ND	ND
n-Heptane	573	212
n-Hexane	573	212
Isopropanol*	8,690	3,220
Methanol*	8,320	ND
Methylamine*	ND	ND
Methyl Cellosolve	ND	ND
Methylene Chloride	809	279
Methyl Formate*	2,230	826
n-Propanol*	8,690	3,220
Toluene	184	135
Trichlorofluoromethane	573	212
Triethylamine*	ND	ND
Xylenes	573	212

(2) Subpart D (For End-of-Pipe Monitoring Points).

[**Note:** With respect to pollutants in this table, EPA does not propose pretreatment standards for new sources for pollutants with an asterisk (*) under co-proposal (2).]

Pollutant or pollutant property	Pretreatment standards for new sources micrograms per liter (µg/L)	
	Maximum for any one day	Monthly average
n-Amyl Acetate*	2,230	826

Pollutant or pollutant property	Pretreatment standards for new sources micrograms per liter (µg/L)	
	Maximum for any one day	Monthly average
Aniline*	8,690	3,220
2-Butanone (MEK)*	161,000	57,900
n-Butyl Acetate*	2,230	826
o-Dichlorobenzene*	2,230	826
1,2-Dichloroethane*	2,230	826
N,N-Dimethylaniline*	8,690	3,220
1,4-Dioxane*	8,690	3,220
Ethyl Acetate*	2,230	826
Furfural*	8,690	3,220
Isobutyraldehyde*	2,230	826
Isopropyl Acetate*	2,230	826
Isopropyl Ether*	2,230	826
Methyl Isobutyl Ketone (MIBK)*	2,230	826
2-Methylpyridine*	8,690	3,220
Petroleum Naphtha*	8,690	3,220
Pyridine*	1,000	1,000
Tetrahydrofuran*	9,210	3,360

§ 439.48 [Reserved]**Subpart E—Research Subcategory**

20. Sections 439.50 through 439.52 are revised to read as follows:

§ 439.50 Applicability; description of the research subcategory; prohibition.

(a) The provisions of this subpart are applicable to discharges resulting from bench-scale pharmaceutical research operations and product development activities. This subpart does not apply to pilot- or full-scale operations that generate wastewaters using fermentation, extraction, chemical synthesis, or mixing, compounding and formulating. Such operations are covered under subparts A, B, C, and D, respectively.

(b) The discharge of non-process wastewaters and materials excluded from the definition of process wastewater at § 439.1 is not covered by this subpart. Discharges of such non-process wastewater and excluded materials into publicly owned treatment works or waters of the United States, by a source subject to this subpart without an NPDES permit or individual control mechanism authorizing such discharge is prohibited.

§ 439.51 Specialized definitions.

For the purpose of this subpart:

(a) Except as provided below, the general definitions, abbreviations, and methods of analysis set forth in 40 CFR part 401 and § 439.1 shall apply to this subpart.

(b) The term “product” shall mean any product or service resulting from pharmaceutical research, which includes microbiological, biological, and chemical operations.

§ 439.52 Effluent limitations representing the degree of effluent reduction 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, any existing point source subject to this subpart must achieve the following effluent limitations representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available.

(1) The allowable discharge for the pollutant parameters BOD₅ and COD shall be expressed in mass per unit time and shall represent the specified wastewater treatment efficiency in terms of a residual discharge associated with an influent to the waste treatment plant corresponding to the maximum production period for a given pharmaceutical plant as defined in paragraph (a)(4) of this section.

(2) The allowable effluent discharge limitation for the daily average mass of BOD₅ in any calendar month shall specifically not reflect not less than 90 percent reduction in the long term daily average raw waste content of BOD₅ multiplied by a variability factor of 3.0. However, a plant shall not be required to attain a 30-day average BOD₅ effluent limitation of less than the equivalent of 45 mg/L.

(3) The allowable effluent discharge limitation for the daily average mass of COD in any calendar month shall specifically not reflect not less than 74 percent reduction in the long term daily average raw waste content of COD multiplied by a variability factor of 2.2. However, a plant shall not be required to attain a 30-day average COD effluent

limitation of less than the equivalent of 220 mg/L.

(4) The long term daily average raw waste load for the pollutant parameters BOD₅ and COD is defined as the average daily mass of each pollutant influent to the wastewater treatment system over a 12 consecutive month period within the most recent 36 months, which shall include the greatest production effort.

(5) To assure equity in regulation of discharges from sources covered by this subpart of the point source category, calculation of raw waste loads of BOD₅ and COD for the purpose of determining NPDES permit limitations (i.e., the base numbers to which the percent reductions are applied) shall exclude any waste load associated with solvents in those raw waste loads, except the residual amounts of solvents remaining after the practice of solvent recovery and/or separate disposal or reuse. These practices of removal, disposal, or reuse include recovery of solvents from waste streams and incineration of concentrated solvent waste streams (including tar still bottoms). This subpart does not prohibit inclusion of such wastes in the raw waste loads in fact, nor does it mandate any specific practice, but rather describes the rationale for determining permit conditions. These limits may be achieved by any one of several programs and practices or a combination thereof.

(6) The allowable effluent discharge limitation for the daily average mass of TSS in any calendar month shall be 1.7 times the BOD₅ limitation determined in paragraph (a)(2) of this section.

(7) The pH shall be within the range of 6.0–9.0 standard units.

(b) [Reserved]

439.53 Effluent limitations representing the degree of effluent reduction attainable by the best conventional pollutant control technology (BCT). [Reserved]

439.54 Effluent limitations representing the degree of effluent reduction attainable by the application of best available technology economically achievable (BAT). [Reserved]

439.55 New source performance standards (NSPS). [Reserved]

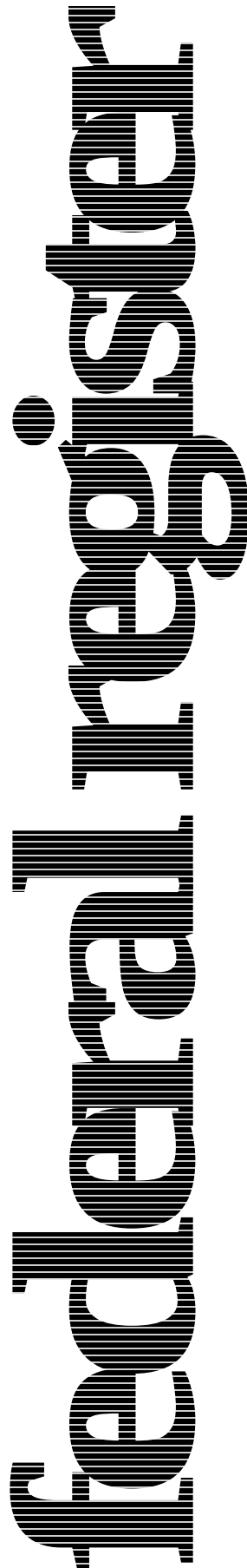
439.56 Pretreatment standards for existing sources (PSES). [Reserved]

439.57 Pretreatment standards for new sources (PSNS). [Reserved]

439.58 [Reserved]

[FR Doc. 95-5663 Filed 5-1-95; 8:45 am]

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Tuesday
May 2, 1995

Part III

Environmental Protection Agency

40 CFR Part 82

Motor Vehicle Air Conditioners and
Protection of Stratospheric Ozone; Final
Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 82

[FRL-5199-4]

Motor Vehicle Air Conditioners and Protection of Stratospheric Ozone

AGENCY: Environmental Protection Agency.

ACTION: Supplemental final rule.

SUMMARY: On July 14, 1992, EPA published a final rule in the **Federal Register** establishing the standards and requirements regarding the servicing of motor vehicle air conditioners and restrictions on the sale of small containers of class I or class II substances pursuant to section 609 of the Clean Air Act as amended (Act). The rule requires that only approved refrigerant recovery/recycling equipment be used to perform service for consideration on motor vehicle air conditioners. Two types of equipment could be approved: Equipment that recovers refrigerant and recycles it on-site, and equipment that only recovers refrigerant. The refrigerant from recover-only equipment may be recycled on-site or sent off-site for reclamation. The Agency established a standard for recover/recycle equipment (appendix A), but reserved finalizing the standard for recover-only equipment.

Today's final rule establishes a standard for approval of recover-only equipment that extracts CFC-12 from motor vehicle air conditioners. This standard follows closely the Society of Automotive Engineers (SAE) Standards J1989: Recommended Service Procedure for the Containment of R-12, and J2209: CFC-12 (R-12) Extraction Equipment for Mobile Automotive Air-conditioning Systems. Because automotive technicians have previously been required to use only recover/recycle equipment for which an Agency standard had been established, today's rule permits these technicians additional flexibility in determining how to meet Section 609 requirements.

This final rule also updates the purity standard for off-site reclamation, by changing the standard from ARI 700-88 to ARI 700-93.

By promoting the reclamation of refrigerants from motor vehicle air conditioners, this final rule will help to lower the risk of depletion of the stratospheric ozone layer, thus diminishing potentially harmful effects to human health and the environment, including increased incidences of certain skin cancers and cataracts.

DATES: This final rule is effective June 1, 1995, except that the changes to § 82.32(e)(2) will become effective on July 3, 1995, unless EPA has received by June 1, 1995, adverse comment. Should EPA receive such notice, EPA will publish one subsequent action in the **Federal Register** to withdraw the changes to § 82.32(e)(2), and will publish another action proposing this action and requesting comments.

Judicial review of this action is available only by the filing of a petition for review in the United States Circuit Court of Appeals for the District of Columbia Circuit within 60 days of publication.

ADDRESSES: Comments and materials supporting this rulemaking are contained in Public Docket No. A-91-41 in room M-1500, Waterside Mall (Ground Floor), U.S. Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460. The docket may be inspected from 8:30 a.m. until 5:30 p.m., Monday through Friday. A reasonable fee may be charged for copying docket materials. Those wishing to submit adverse comments on the portion of this action relating to the adoption of the ARI 700-1993 standard should contact Christine Dibble, Program Implementation Branch, Stratospheric Protection Division, Office of Atmospheric Programs, Office of Air and Radiation (6205-J), 401 M Street, SW., Washington, DC 20460 Docket #A-91-41 IV-D (202) 233-9147.

FOR FURTHER INFORMATION CONTACT: Christine Dibble, Stratospheric Protection Division, Office of Atmospheric Programs, Office of Air and Radiation (6205-J), 401 M Street SW., Washington, DC 20460. (202) 233-9147. The Ozone Information Hotline at 1-800-296-1996 can also be contacted for further information.

SUPPLEMENTARY INFORMATION: The contents of today's preamble are listed in the following outline:

- I. Background
- II. Summary of Public Participation
- III. Summary and Response to Major Public Comments
- IV. Summary of Today's Final Rule
 - A. Adoption of Standard Based on ARI 700-1993 in Definition of "Properly Using" and in Appendix B
 - B. Standard for Recover-Only Equipment
 - C. Substantially Identical Equipment
 - D. Approved Independent Standards Testing Organizations
 - E. Technician Training and Certification
- V. Summary of Supporting Analyses
 - A. Executive Order 12866
 - B. Regulatory Flexibility Analysis
 - C. Paperwork Reduction Act

I. Background

Title VI of the Act is designed to protect the stratospheric ozone layer. Section 609 of the Act requires the Administrator to promulgate regulations establishing standards and requirements regarding the servicing of motor vehicle air conditioners. On July 14, 1992, the Agency published the final rule implementing this section. In that rule, the Agency defined "approved refrigerant recycling equipment" as equipment certified by the Administrator or by an independent standards testing organization approved by the Agency as meeting the standards set forth in appendix A in the rule. Refrigeration recycling equipment was also considered approved if it was purchased before September 4, 1991, and is substantially identical to the certified equipment. Only equipment certified as meeting the standards or meeting the criteria for substantially identical equipment are approved for use in the servicing of motor vehicle air conditioners under section 609 of the Act.

Underwriters Laboratories (UL) and ETL Testing Laboratories (ETL) are the approved independent standards testing organizations that currently certify equipment using the standards that appear in appendix A of the rule. These standards apply to recover/recycle equipment that extracts CFC-12 refrigerant from a motor vehicle air conditioner and cleans the refrigerant on-site (recover/recycle equipment). The regulatory standards, based on those developed by the SAE, cover service procedures for recovering CFC-12 (SAE J1989, issued in October 1989), test procedures to evaluate recover/recycle equipment (SAE J1990, issued in October 1989 and revised in March 1992) and a purity standard for recycled CFC-12 refrigerant (SAE J1991, issued in October 1989).

Although appendix A set forth the standards appropriate for recover/recycle equipment, EPA has until now not established a standard which would apply to certification of equipment that extracts but does not recycle refrigerant (recover-only equipment). Under the current regulation, the refrigerant from these recover-only machines would typically be sent off-site for purification, but it may be recycled on-site in a recover/recycle machine to the SAE J1991 standard of purity. In addition, refrigerant may be extracted using the recover-only equipment and subsequently recycled off-site by equipment owned by the person who owns both the recover-only equipment

and owns or operates the establishment at which the refrigerant was extracted.

Appendix B of the rule was reserved for the standards for recover-only equipment. EPA proposed appendix B in a supplemental notice published April 22, 1992 (57 FR 14763). The proposed standard closely resembled a proposed SAE standard, SAE J2209: CFC-12 Extraction Equipment for Mobile Automotive Air-conditioning Systems, with the Agency's editorial comments included in the standard in brackets. This final rule adopts the final version of this SAE standard, with minor changes. In addition, EPA is adopting for recover-only equipment the recommended service procedure for the containment of CFC-12 described in SAE J1989 and already set forth in appendix A. In today's rule, that portion of appendix A based on SAE J1989 has been incorporated into appendix B in order to make clear that those service procedures apply when operating recover-only equipment.

For both recover/recycle equipment and recover-only equipment, the definition of "properly using" set forth in 40 CFR 82.32(e) applies. This final rule revises the requirements for Agency approval of independent standards testing organizations to include certification of recover-only equipment in compliance with the standards in appendix B. The criteria for approval of technician training and certification programs are also revised to reflect the use of recover-only equipment. The discussion in this preamble clarifies how the inclusion of standards for recover-only equipment will affect the certification of technicians, the Agency's approval of technician certification programs, and the Agency's approval of independent standards testing organizations.

II. Summary of Public Participation

A public hearing on the proposed supplemental rule was held on May 12, 1992. Only one person presented oral comments on the proposed requirements, also submitting written testimony to the Agency. A transcript of the hearing is contained in the public docket.

The Agency received a total of 10 letters on the supplemental proposed rule.

III. Summary and Response to Major Public Comments

Comments to this rule were submitted between April 22, 1992 and May 22, 1992. The remarks of several commenters were addressed in the July 14, 1992 final rule (57 FR 31241). For example, several commenters urged the

Agency to state more explicitly the circumstances in which refrigerant may be recycled off-site (*i.e.*, if the recycle equipment is owned by the person who also owns both the recover-only equipment and the establishment at which the refrigerant was recovered). These circumstances were explicitly discussed when EPA adopted the definition of "properly using" in the July 14, 1992 final rule (57 FR 31241).

One commenter urged the Agency not to adopt a recover-only equipment standard. This commenter argued that recover-only equipment increases the risk of contamination of the entire recycled refrigerant pool because it could lead to intermixing of refrigerant types and failure to purify the recovered refrigerant prior to recycling. EPA believes the use of recover-only equipment will, in conjunction with recover/recycle equipment, afford more cost-effective compliance options for smaller service facilities that may choose not to purchase the more expensive recover/recycle equipment, but instead to send all recovered refrigerant to off-site reclaimers. In addition, larger service facilities and fleet owners may purchase the less expensive recover-only equipment for use in conjunction with their recover/recycle equipment during peak air conditioning service months. By adopting this standard, the Agency believes that facilities are likely to recover ozone-depleting chemicals that might have otherwise been improperly vented. Moreover, EPA believes that the adoption of the appendix B standards will effectively safeguard against contamination of the refrigerant supply. For example, the standard specifies that the equipment discharge or transfer fitting on recover-only equipment shall be unique in order to prevent the unintentional use of extracted CFC-12 used for recharging prior to recycling or reclamation.

The remainder of the comments remarked upon the adoption of SAE J2209 standard as the basis of appendix B, or upon specific provisions of appendix B. The adoption of the J2209 standard for recover-only equipment in appendix B parallels the adoption of the J1990 standard for recover/recycle equipment in appendix A. The J1991-based standard set forth in appendix A establishes a standard for recycled refrigerant and consequently would not apply to recover-only equipment. As discussed above, the J1989-based standard in appendix A has been incorporated by reference in appendix B.

The standard for recover-only equipment proposed by EPA differed

slightly from the then-current draft of J2209, with the Agency's editorial comments included in the appendix B proposed standard in brackets. These editorial comments clarified some terms, inserted missing words and corrected other typographical errors in the J2209 draft. The final version of SAE J2209, which eliminated these errors, has been almost wholly incorporated into today's rulemaking as appendix B.

The significant differences between the draft version of the J2209 standard as set forth in the proposed appendix B, and the final version of this standard as set forth in today's rule, are as follows. First, the proposed appendix B stated that portable refillable containers of recovered refrigerant must be marked with the words "Dirty Refrigerant—Do Not Use Without Recycling." In the final version of J2209, and in this final rule, the container marking must read "Dirty R-12—Do Not Use, Must Be Reprocessed." This change illuminates the fact that refrigerant may either be recycled on-site using recover/recycle equipment, or may be reclaimed off-site to the ARI 700 standard.

In addition, unlike the draft version of J2209, the final J2209 standard and today's final rule: (1) Require that recover-only equipment be preconditioned with standard contaminated CFC-12 before starting the test cycle; (2) designate the temperature of the preconditioning; and (3) specify the operation of the sample method fixture. These additions were incorporated into the final version of J2209 and into appendix B in order to remain consistent with, and as stringent as, SAE J1990. Section 609(b)(2)(a) of the Act states that standards developed by the Administrator shall, as a minimum, be as stringent as SAE J1990 in effect as of November 15, 1990.

The standard reproduced here is almost identical to the final SAE standard submitted to the Agency in June, 1992, except that references to ARI standard 700-88 have been changed to 700-93. SAE intends to make this change in J2209 shortly. In addition, updates or revisions to SAE publications referenced in the standard will not automatically be incorporated by reference.

One commenter urged that EPA adopt ARI standard 740 rather than SAE J2209 as the basis of appendix B because complying with the more stringent J2209 standard would increase the cost of recover-only equipment, so that small businesses would face greater difficulties meeting Section 609 requirements. The standard adopted today in appendix B is as stringent as SAE J1990 regarding the procedure for

extracting refrigerant and separating lubricant from refrigerant. Unlike SAE J2209, ARI standard 740 is not designed to address the servicing of mobile automotive air-conditioning systems, and does not meet the statutory requirement of being as rigorous in all respects as J1990. Unlike J1990 and J2209, ARI 740 does not establish an oil separation requirement or require that a contaminated CFC-12 sample be processed to verify oil separation.

One commenter remarked that sections 6.2 and 6.2.1 of J2209 should not be adopted into appendix B because these sections, which describe the preconditioning of the equipment with a standard contaminated CFC-12 sample, apply only to recycle equipment and not to recover-only equipment. These provisions not only apply to measuring the efficiency with which a unit cleans the refrigerant for recycling, but also to measuring how much lubricant has been removed from the air-conditioning system during the recovery process, so that technicians may determine how much lubricant to replace prior to the completion of servicing. This determination should be made whenever any refrigerant is recovered, whether from a recover-recycle unit or a recover-only unit.

In addition, the language contained in Sections 6.2 and 6.2.1 is almost identical to the language of J1990, Sections 8.3 and 8.4.1. Since today's standard must at a minimum be as stringent as SAE J1990, these provisions should be contained in appendix B. The Agency believes that the proper determination of how well a particular model of equipment extracts refrigerant depends in part on testing the model with a contaminated sample. Noncondensable gases in particular may affect extraction efficiency. In addition, the Agency desires to further consistency between industry standards such as J2209 and Agency regulations.

A commenter remarked that the reference in section 6.3.3 of appendix B to the use of overfill protection based on a tank's volume should be based on weight rather than volume, because many tank filling operations recognize that weight is a better control to prevent overfilling a tank. The Agency has decided to base its overfill protection method on volume since both the Department of Transportation specifications for shipments and packagings and the American Society of Mechanical Engineers do so.

One commenter argued that the Agency should consider a six-month grace period which would allow owners of uncertified equipment to use older recover-only equipment while ordering

and installing recover-only equipment that would comply with this rule. The Agency believes that the provisions set forth in today's rule governing substantially identical equipment, combined with the extended time frame between the publication of the proposal and the publication of this final rule, and the adoption of standard closely modeled on a consensus SAE standard, sufficiently address these lead time concerns. Equipment owners have had a significant time period to purchase equipment that should meet the standards to be adopted today.

Finally, two commenters objected to the provision set forth in section 6.7 of appendix B requiring that the equipment be able to separate the lubricant from recovered refrigerant and accurately indicate the amount removed from the system. These commenters claimed that this was a redundant requirement, and was not needed to determine the amount of oil to be replaced. EPA has included this provision in appendix B because it promotes consistency between the Agency requirements and the industry standard, as set forth in SAE J2209; because it promotes consistency in operating recover-only and recover/recycle equipment (i.e., the technician will know that oil separation and measurement is a component in operating both types of machines); and because, by helping to prevent overcharging the vehicle system with lubricant, section 6.7 provides the technician with every opportunity to complete compressor lubrication properly.

IV. Summary of Today's Final Rule

A. Adoption of Standard Based on ARI 700-1993 in Definition of "Properly Using" and in Appendix B

Section 82.32(e) provides in the definition of "properly using" that "(r)efrigerant from reclamation facilities that is used for the purpose of recharging motor vehicle air conditioners must be at or above the standard of purity developed by the Air-conditioning and Refrigeration Institute (ARI 700-88) * * * in effect as of November 15, 1990." Today's rulemaking changes the definition of "properly using" to refer to ARI 700-1993, which is an updated version of ARI 700-88. In addition, references to the ARI 700 standard in appendix B, the Standard for Recover Equipment, are to ARI 700-93 rather than ARI 700-88.

EPA believes that ARI 700-1993 should substitute for ARI 700-1988 in order for section 609 regulations to remain consistent with other provisions

of the Clean Air Act regulations and with industry standards. The direct final rule amending the Refrigerant Recycling Regulations published on August 19, 1994 (59 FR 42949) and effective on October 18, 1994 requires that persons reclaiming refrigerant for sale to a new owner must return refrigerant to a standard of purity based on ARI 700-1993. In addition, the Society of Automotive Engineers is in the process of revising all of its air-conditioning standards and recommended practices to reference current ARI specifications for fluorocarbon refrigerants. SAE will soon revise its J2209 standard, the basis for appendix B.

Whereas ARI 700-1988 allowed 0.5 as the maximum percentage by weight of "other refrigerants", ARI 700-1993 allows 0.50 as the maximum percentage by weight of "all other organic impurities, including other refrigerants," effectively tightening the standard. Changes in ARI 700-1993 that do not affect the automotive industry include adding purity standards for eleven additional refrigerants, and increasing liquid phase contaminant water levels for certain refrigerants not used in automobile air conditioners.

EPA is substituting the ARI 700-1993 standard for ARI 700-1988 as a direct final rule, recognizing that the Agency did not propose the substitution in the April 22, 1992 proposal of this rulemaking. This substitution predominantly affects the activities of refrigerant reclaimers, who were similarly affected by the substitution of ARI 700-93 for ARI 700-88 in the direct final rule amending the Refrigerant Recycling Regulations published on August 18, 1994 (59 FR 42949). Commenters to that rule overwhelmingly agreed that the changes to the ARI standard were both appropriate and necessary.

As discussed above, this portion of today's rule will become effective on July 3, 1995, unless EPA is has received by June 1, 1995 adverse comment. Should EPA receive such notice, EPA will publish one subsequent action in the **Federal Register** to withdraw the portion of this final action, and will publish another action proposing this action and requesting comments. In that event, following a public comment period and the opportunity for a public hearing, the Agency will draft the final regulation to be published in the **Federal Register**.

B. Standard for Recover-Only Equipment

Section 82.36(a) of the regulations specifies that equipment that recovers and recycles refrigerant must meet the

standards set forth in appendix A. Today's rulemaking adds a provision that equipment that extracts refrigerant for recycling on-site or for reclamation off-site must meet the SAE J2209 standards set forth in appendix B, the Standard for Recover Equipment.

The standard adopted today contains specifications for labeling recover equipment once it is certified; safety requirements; requirements that the equipment manufacturer must provide operating instructions; and a functional description of the equipment, including hose and fitting specifications, overfill protection requirements and additional storage tank requirements. The standard requires that the container for used refrigerant be gray with a yellow top and be marked in black print "DIRTY REFRIGERANT—DO NOT USE, MUST BE REPROCESSED." The standard states that the recovery equipment must be able to separate lubricant from recovered refrigerant and to indicate accurately the amount removed from the air-conditioning system in order to assure that the proper amount of lubricant can be returned to the system. It should be noted that EPA's labeling rule published on February 11, 1993 (58 FR 8136) requires that containers containing class I or II substances that enter into interstate commerce are required to bear a specific warning label. Such containers that are sent for off-site recycling or reclamation are entered into interstate commerce and thus require labeling.

The Act states that standards developed by the Administrator shall, as a minimum, be as stringent as SAE J1990 in effect as of the date of November 15, 1990. The standard proposed today is equally as stringent as SAE J1990 regarding the procedure for extracting refrigerant and separating lubricant from refrigerant. It offers a further specification on extraction efficiency (referring to 102 mm of mercury versus the more general statement regarding removal "to a vacuum"). Procedures and requirements regarding unintentional releases of refrigerant during the extraction process are equivalent to SAE J1990, and because recover-only equipment does not purge non-condensable gases from the refrigerant collected, no CFC-12 is released in the process.

Refrigerant removed from motor vehicle air conditioners with recover-only equipment must be either recycled on-site to the SAE J1991 standard of purity or sent off-site to a reclamation facility for purification to ARI 700-93, a higher standard of purity than SAE J1991. Under the provisions of the July 14, 1992 final rule, refrigerant may also

be sent off-site for recycling but only if the equipment used to recycle the refrigerant is owned by the person who owns both the recover-only equipment and owns or operates the establishment at which the refrigerant was extracted. Requirements concerning reclamation facilities and their ability to ensure that refrigerant meets the ARI 700-93 standard of purity were addressed in the direct final rule amending 40 CFR 82.164, published on August 19, 1994 (59 FR 42949).

The standard adopted today as appendix B represents a consensus of the Interior Climate Control Committee of SAE. This committee is made up of automotive industry experts, equipment and supply manufacturers, and chemical producers. SAE prepared the standards (SAE J1990, SAE J1991) later adopted by EPA in appendix A and the Agency believes that the standard set forth in today's rulemaking as appendix B is consistent with the specifications required in those standards for recovery. The Agency believes that the appendix B standard is appropriate for recovery because it achieves environmental protection through efficient recovery of refrigerant and protects automobile equipment through lubricant removal indication.

C. Substantially Identical Equipment

Section 82.36(b) of the regulations states that equipment purchased before the proposal of the standards for refrigerant recycling equipment in appendix A (i.e., before September 4, 1991) shall be considered certified if it is "substantially identical" to equipment approved under § 82.36(a). Until now, this provision has effectively applied only to recover/recycle equipment, because only recover/recycle equipment has been approved by the Agency.

Today's rulemaking applies the Act's "substantially identical" provision to recover-only equipment as well. Recover-only equipment shall be considered approved if it is substantially identical to recover-only equipment approved under § 82.36(a) and if it was purchased prior to the date of proposal of this rulemaking (i.e., April 22, 1992). EPA's regulations do not define "substantially identical," but a manufacturer or owner may request a determination from EPA on this point.

The Agency's views on implementation of the "substantially identical" provision are discussed in some detail in the September 4, 1991 Notice. In general, EPA proposes to follow the same strict approach in implementing this provision for recover-only equipment as for recover/recycle

equipment. The Agency is aware that although some recover-only machines have been sold, until mid-1992, manufacturers of these machines did not have the opportunity to have machines certified because the proposed standard had not been developed. Recover-only equipment that is certified to meet the standard in appendix B will be considered "approved refrigerant recycling equipment." Where the models sold in the past are the same as models that are approved, this equipment will be considered substantially identical. In situations where the models sold were not the same as the approved model, EPA will consult with approved independent standards testing organizations to evaluate the previously sold equipment. EPA will use these organizations' test data and any additional information submitted by the manufacturer, such as process diagrams and lists of components, in the evaluation. EPA will maintain a list of equipment determined to be substantially identical. An essential criterion for evaluation is that equipment removes refrigerant as efficiently as the SAE J2209 standard and separates lubricant from refrigerant. The Agency is also interested in ensuring safety in operation of the equipment.

Should manufacturers consider the possibility of retrofit kits to bring the pre-certification models up to the performance standard of certified models, EPA would require that the retrofit kits be certified by an approved independent standards testing organization and that equipment owners indicate in their certification to the Agency (as discussed in the September 4, 1991 proposal) that they have retrofitted equipment.

EPA is aware of some cases in which equipment purchased before the publication of the proposal to today's rule was produced by manufacturers that have not yet received a certification on any model or by manufacturers that no longer make equipment. In situations where equipment was purchased without certification and no model by that manufacturer achieves certification, EPA will evaluate the equipment on a model-by-model basis before making a substantially identical determination. Owners of the equipment, if they cannot contact manufacturers to determine the status of equipment, must submit process flowsheets and lists of components, and EPA reserves the right to inspect the equipment and request samples of refrigerant if necessary. The address for submittal of information is: MVACs Recycling Program Manager, Stratospheric Protection Division,

(6205J), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460, Attention: Substantially Identical Equipment Review. EPA will maintain a strict interpretation of the substantially identical clause in order to protect the air-conditioning units and the integrity of the recycling program. As a result, the Agency does not anticipate that many types of recover-only machines will qualify as substantially identical through this evaluation procedure.

D. Approved Independent Standards Testing Organizations

Section 82.38 establishes the criteria for approval of testing laboratories or organizations to certify whether equipment governed by the regulations meets the standards set forth in the regulations. Under the original final rule, approved organizations would determine whether recover/recycle equipment met the standards set forth in appendix A to the rule, which was based on SAE J1990 and 1991. Today's rulemaking will expand that provision so that approved organizations will be able to determine whether recover-only equipment meets the standards set forth in appendix B to the rule.

Because the Agency received written requests from both UL and ETL requesting that they be approved to certify recover-only equipment, and because the application materials received by the Agency from UL on October 21, 1991, and from ETL on November 27, 1991 demonstrate that both organizations have met the criteria set forth in § 82.38(b) with respect to recover-only equipment, the Agency has approved UL and ETL to certify recover-only equipment, effective as of the effective date of this rulemaking.

EPA encourages applications from other facilities that are capable of testing equipment to the necessary standards. Organizations must demonstrate that they have the experience and the appropriate equipment to perform testing. The EPA will maintain a list of approved independent standards testing organizations available upon request at the address set forth in § 82.38. The Agency reserves the right to revoke approval if the testing organization violates any of the requirements contained in § 82.38.

E. Technician Training and Certification

Section 82.40 established the standards for programs approved to train and certify technicians. The standards cover training, the subject material that must be covered by each program, and minimum test administration procedures. Summaries

of reviews of programs must be submitted every two years and programs must offer technicians proof of certification upon successful completion of the test.

At this time, 23 organizations have been approved by EPA to train and certify technicians in the use of recover-recycle equipment. Ten of these organizations train and certify their employees, while the remaining train members of the general public. While EPA's approval of these organizations has been limited to recover-recycle equipment, the Agency believes that for purposes of training and certification conducted prior to June 1, 1995, these organizations should also be considered as approved for purposes of recover-only equipment. As discussed below, recover-only equipment and the recovery aspects of recover-recycle equipment are very similar, and the procedures for extracting refrigerant are very similar for both types of equipment. Retraining and recertifying of technicians already certified to use recover-recycle equipment would therefore produce only a limited environmental benefit. In addition, such retraining and recertification would impose a large burden on the technicians and the organizations that certify them. For these reasons, EPA intends at this time to approve the 23 organizations noted above for training and certification of technicians in the use of recover-only equipment conducted prior to June 1, 1995.

EPA will also approve organizations for future training and certification of technicians for the use of recover-only equipment on the condition that each organization certify in writing to the Agency that its training materials discuss the standard set forth in Appendix B, and that its testing materials include questions concerning that standard. Each organization that submits such a certification shall be approved upon the date which is the later of (i) the effective date of this rule (i.e., June 1, 1995), or (ii) the receipt by the Agency of such a certification. Organizations that do not submit such a certification will not be approved to train and certify future technicians for the use of recovery-only equipment.

As noted above, the prior training and testing of previously approved technicians for recover-recycle equipment adequately and sufficiently covers the standards set forth in appendix B because of the large overlap between the text of the standard based on SAE J1990 contained in appendix A and the standard based on SAE J2209 contained in appendix B. In both appendix A and appendix B, the

following provisions are identical or nearly identical: safety requirements; requirement that the manufacturer must provide operating instructions; requirement that the equipment must ensure the refrigerant recovery by reducing system pressure below atmospheric to a minimum of 102 mm of mercury; the preconditioning of the equipment with a contaminated sample; the composition of that contaminated sample; the requirement that the equipment must be certified by UL or an equivalent certifying laboratory; the requirement that the label on the equipment must state that it has been design certified to meet applicable SAE standards; and the additional storage tank requirements.

Where the SAE J1990-based standards in appendix A differ from the SAE J2209-based standards in appendix B, they differ largely because appendix A contains many provisions which relate to the recycle portion of the equipment operation and which are thus not applicable to appendix B. For example, appendix A describes requirements for the recycling test cycle and for the quantitative determination of moisture, lubricant, and noncondensable gas in that cycle.

In addition, SAE J2209 contains one provision which applies to recover-only but not to recover/recycle equipment. Section 3.5 of J2209 states that the label on the equipment must be processed to ARI 700-88 specifications before reuse in a mobile air-conditioning system. The Agency recognizes that refrigerant may be transferred on-site to recover/recycle equipment and processed to the standards set forth in appendix A, rather than be transferred off-site to a reclamation facility for processing to the ARI 700 standard. However, since the final SAE J2209 standard, including the textual requirements for the equipment label, was issued over two years prior to the date of this rule, the Agency has determined not to require the inclusion of any language on the label which would be inconsistent with SAE requirements.

A review of SAE J2209 indicates it contains two provisions which relate to the recovery of refrigerant for which there are no equivalent provisions in SAE J1990. First, section 3.2 of SAE J2209 requires that the equipment discharge or transfer fitting shall be unique. SAE did not consider this requirement until after the publication of the final version of J1990. Second, section 6.1 of SAE J2209 requires that the unit must have a device that assures that refrigerant has been recovered so that outgassing is prevented. Although there is no equivalent to this provision

in SAE J1990, J1989 requires safeguards to prevent outgassing.

VI. Summary of Supporting Analyses

A. Executive Order 12866

Under Executive Order 12866 (58 FR 51735, October 4, 1993), the Agency must determine whether this regulatory action is "significant" and therefore subject to OMB review and the requirements of the Executive Order. The 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 and materially affect 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 entitlement, 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.

It has been determined by OMB and EPA that this supplemental final rule is not a "significant regulatory action" under the terms of Executive Order 12866 and is therefore not subject to OMB review under the Executive Order. The Agency prepared an analysis to assess the impact of the proposed regulation (see Costs and Benefits of MACs Recycling, May 24, 1991) which covers both recover/recycle equipment and recover-only equipment, and is available for review in the public docket for this rulemaking.

B. Regulatory Flexibility Analysis

The Regulatory Flexibility Act, 5 U.S.C. 601-612, requires that Federal agencies examine the impacts of their regulations on small entities. Under 5 U.S.C. 604(a), whenever an agency is required to publish a general notice of proposed rulemaking, it must prepare and make available for public comment an initial regulatory flexibility analysis (RFA). Such an analysis is not required if the head of an agency certifies that a rule will not have a significant economic impact on a substantial number of small entities, pursuant to 5 U.S.C. 605(b).

The Agency performed an initial regulatory flexibility analysis for the July 14, 1992 final rule that this rule supplements. No additional RFA need be prepared for this supplemental final

rule because the changes being made today to that final rule do not alter the original analysis.

C. Paperwork Reduction Act

This supplemental final rule has no new information requirements subject to the Paperwork Reduction Act.

List of Subjects for 40 CFR Part 82

Environmental protection, Chlorofluorocarbons, Motor vehicle air-conditioning, Recover-only equipment, Stratospheric ozone layer.

Dated: April 24, 1995.

Carol M. Browner,
Administrator.

For the reasons set out in the preamble, EPA is hereby amending 40 CFR part 82 as follows:

PART 82—PROTECTION OF STRATOSPHERIC OZONE

1. The authority citation for part 82 continues to read as follows:

Authority: 42 U.S.C. 7414, 7601, 7671, and 7671h.

2. Section 82.32 is amended by redesignating the first four sentences of paragraph (e) as paragraph (e)(1), and redesignating the last four sentences of paragraph (e) as paragraph (e)(2), and by revising the first sentences of newly redesignated paragraphs (e)(1) and (e)(2) to read as follows:

§ 82.32 Definitions.

* * * * *

(e) (1) Properly using means using equipment in conformity with Recommended Service Procedures and Recommended Practices for the Containment of R-12 (CFC-12) set forth in appendix A or appendix B to this subpart, as applicable.

(2) Refrigerant from reclamation facilities that is used for the purpose of recharging motor vehicle air conditioners must be at or above the standard of purity developed by the Air-conditioning and Refrigeration Institute (ARI 700-93) (which is codified at 40 CFR part 82, subpart F, appendix A, and is available at 4301 North Fairfax Drive, Suite 425, Arlington, Virginia 22203).

* * * * *

3. Section 82.36 is amended by revising paragraphs (a)(2) and (b) to read as follows:

§ 82.36 Approved refrigerant recycling equipment.

(a) (1) * * *

(2) Equipment that recovers and recycles the refrigerant must meet the standards set forth in appendix A to this subpart (Recommended Service

Procedure for the Containment of R-12, Extraction and Recycle Equipment for Mobile Automotive Air-Conditioning Systems, and Standard of Purity for Use in Mobile Air-Conditioning Systems). Equipment that recovers refrigerant for recycling on-site or for reclamation off-site must meet the standards set forth in appendix B to this subpart (Recommended Service Procedure for the Containment of R-12, Extraction Equipment for Mobile Automotive Air-Conditioning Systems).

(b) Refrigerant recycling equipment purchased before September 4, 1991 that recovers and recycles refrigerant, and refrigerant recycling equipment purchased before April 22, 1992 that recovers refrigerant for recycling on-site or reclamation off-site, that has not been certified under paragraph (a) of this section, shall be considered approved if the equipment is substantially identical to equipment certified under paragraph (a) of this section. Equipment manufacturers or owners may request a determination by the Administrator by submitting an application and supporting documents that indicate that the equipment is substantially identical to approved equipment to: MVACs Recycling Program Manager, Stratospheric Protection Division (6205J), U.S. Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460, Attn: Substantially Identical Equipment Review. Supporting documents must include process flow sheets, lists of components and any other information that would indicate that the equipment is capable of processing the refrigerant to the standards in appendix A or appendix B to this subpart, as applicable. Authorized representatives of the Administrator may inspect equipment for which approval is being sought and request samples of refrigerant that has been extracted and/or recycled using the equipment. Equipment that fails to meet appropriate standards will not be considered approved.

* * * * *

4. Section 82.38 is amended by revising paragraphs (a) and (b)(1)(iii) to read as follows:

§ 82.38 Approved independent standards testing organizations.

(a) Any independent standards testing organization may apply for approval by the Administrator to certify equipment as meeting the standards in appendix A and appendix B to this subpart, as applicable. This application shall be sent to: MVACs Recycling Program Manager, Stratospheric Protection Division (6205J), U.S. Environmental

Protection Agency, 401 M Street, SW., Washington, DC 20460.

(b) * * *

(1) * * * (i) * * *

(ii) * * *

(iii) Thorough knowledge of the standards as they appear in appendix A and appendix B of this subpart, as applicable; and

* * * * *

5. Section 82.40 is amended by revising paragraph (a)(2)(i) to read as follows:

§ 82.40 Technician training and certification.

(a) * * *

(2) * * *

(i) The standards established for the service and repair of motor vehicle air conditioners as set forth in appendix A and appendix B to this subpart. These standards relate to the recommended service procedures for the containment of refrigerant, extraction equipment, extraction and recycle equipment, and the standard of purity for refrigerant in motor vehicle air conditioners.

* * * * *

6. Section 82.42 is amended by revising the last sentence of paragraph (a)(1)(iii) to read as follows:

§ 82.42 Certification, recordkeeping and public notification requirements.

(a) * * *

(1) * * *

(iii) * * * The certification should be sent to: MVACs Recycling Program Manager, Stratospheric Protection Division, (6205J), U.S. Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460.

* * * * *

7. Appendix B is added to subpart B to read as follows:

Appendix B to Subpart B—Standard for Recover Equipment

SAE J1989, Recommended Service Procedure for the Containment of R-12, as set forth under Appendix A, also applies to this Appendix B.

SAE J2209, issued June, 1992.

SAE Recommended Practice: CFC-12 (R-12) Extraction Equipment for Mobile Automotive Air-Conditioning Systems

Foreword

CFCs deplete the stratospheric ozone layer that protects the earth against harmful ultraviolet radiation. To reduce the emissions of CFCs, the 1990 Clean Air Act requires recycle of CFC-12 (R-12) used in mobile air-conditioning systems to eliminate system venting during service operations. SAE J1990 establishes equipment specifications for on-site recovery and reuse of CFCs in mobile air-conditioning systems. Establishing extraction equipment specifications for CFC-12 will

provide service facilities with equipment to assure that venting of refrigerant will not occur.

1. Scope

The purpose of this document is to provide equipment specifications for CFC-12 (R-12) recovery for recycling on-site or for transport off-site to a refrigerant reclamation facility that will process it to ARI (Air-Conditioning and Refrigeration Institute) standard 700-93 as a minimum. It is not acceptable that the refrigerant removed from a mobile air-conditioning system, with this equipment, be directly returned to a mobile air-conditioning system.

This information applies to equipment used to service automobiles, light trucks, and other vehicles with similar CFC-12 systems.

2. References

2. Applicable Documents—The following documents form a part of this specification to the extent specified herein.

2.1.1 SAE Publications—Available from SAE, 400 Commonwealth Drive, Warrendale, PA 15096-0001.

SAE J639—Vehicle Service Coupling
SAE J1990—Extraction and Recycle Equipment for Mobile Automotive Air-Conditioning Systems
SAE J2196—Service Hose for Automotive Air-Conditioning

2.1.2 ARI Publications—Available from Air-Conditioning and Refrigeration Institute, 1501 Wilson Boulevard, Sixth Floor, Arlington, VA 22209.

ARI 700-93—Specifications for Fluorocarbon Refrigerants

2.1.3 CGA Publications—Available from CGA, Crystal Gateway #1, Suite 501, 1235 Jefferson Davis Highway, Arlington, VA 22202.

CGA S-1.1—Pressure Relief Device Standard Part 1—Cylinders for Compressed Gases

2.1.4 DOT Specifications—Available from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402.

49 CFR, Section 173.304—Shippers—General Requirements for Shipments and Packagings

2.1.5 UL Publications—Available from Underwriters Laboratories, 333 Pfingsten Road, Northbrook, IL 60062-2096.

UL 1769—Cylinder Valves

3. Specifications and General Description

3.1 The equipment must be able to extract CFC-12 from a mobile air-conditioning system.

3.2 The equipment discharge or transfer fitting shall be unique to prevent the unintentional use of extracted CFC-12 to be used for recharging auto air conditioners.

3.3 The equipment shall be suitable for use in an automotive service garage environment as defined in 6.8.

3.4 Equipment Certification—The equipment must be certified by Underwriters Laboratories or an equivalent certifying laboratory to meet this standard.

3.5 Label Requirements—The equipment shall have a label "Design Certified by (company name) to meet SAE J2209 for use

with CFC-12. The refrigerant from this equipment must be processed to ARI 700-93 specifications before reuse in a mobile air-conditioning system." The minimum letter size shall be bold type 3mm in height.

4. Safety Requirements

4.1 The equipment must comply with applicable federal, state and local requirements on equipment related to the handling of R-12 material. Safety precautions or notices or labels related to the safe operation of the equipment shall also be prominently displayed on the equipment and should also state "CAUTION—SHOULD BE OPERATED BY CERTIFIED PERSONNEL." The safety identification shall be located on the front near the controls.

4.2 The equipment must comply with applicable safety standards for electrical and mechanical requirements.

5. Operating Instructions

5.1 The equipment manufacturer must provide operating instructions, necessary maintenance procedures and source information for replacement parts and repair.

5.2 The equipment must prominently display the manufacturer's name, address and any items that require maintenance or replacement that affect the proper operation of the equipment. Operation manuals must cover information for complete maintenance of the equipment to assure proper operation.

6. Functional Description

6.1 The equipment must be capable of ensuring recovery of the CFC-12 from the system being serviced, by reducing the system pressure to a minimum of 102 mm of mercury below atmospheric. To prevent system delayed outgassing, the unit must have a device that assures that the refrigerant has been recovered from the air-conditioning system.

6.1.1 Testing laboratory certification of the equipment capability is required which shall process contaminated refrigerant samples at specific temperatures.

6.2 The equipment must be preconditioned with 13.6 kg of the standard contaminated CFC-12 at an ambient of 21°C before starting the test cycle. Sample amounts are not to exceed 1.13 kg with sample amounts to be repeated every 5 minutes. The sample method fixture defined in Figure 1 of appendix A shall be operated at 24°C. Contaminated CFC-12 samples shall be processed at ambient temperatures of 10 and 49°C.

6.2.1 Contaminated CFC-12 sample.

6.2.2 Standard contaminated CFC-12 refrigerant, 13.6 Kg sample size, shall consist of liquid CFC-12 with 100 ppm (by weight) moisture at 21°C and 45,000 ppm (by weight) mineral oil 525 suspension nominal and 770 ppm (by weight) of noncondensable gases (air).

6.3 Portable refillable containers used in conjunction with this equipment must meet applicable DOT standards.

6.3.1 The container color must be gray with yellow top to identify that it contains used CFC-12 refrigerant. It must be permanently marked on the outside surface in black print at least 20 mm high "DIRTY R-12—DO NOT USE, MUST BE REPROCESSED".

6.3.2 The portable refillable container shall have a SAE 3/8 inch flare male thread connection as identified in SAE J639 CFC-12 High Pressure Charging Valve Figure 2.

6.3.3 During operation the equipment shall provide overfill protection to assure that the storage container liquid fill does not exceed 80% of the tank's rated volume at 21°C per DOT standard, CFR Title 49, section 173.304 and the American Society of Mechanical Engineers.

6.4 Additional Storage Tank Requirements.

6.4.1 The cylinder valve shall comply with the standard for cylinder valves, UL 1769.

6.4.2 The pressure relief device shall comply with the pressure relief device standard part 1, CGA pamphlet S-1.1.

6.4.3 The container assembly shall be marked to indicate the first retest date, which shall be 5 years after date of manufacture. The marking shall indicate that retest must be performed every subsequent five years.

The marking shall be in letters at least 6 mm high.

6.5 All flexible hoses must meet SAE J2196 standard for service hoses.

6.6 Service hoses must have shutoff devices located within 30 cm of the connection point to the system being serviced to minimize introduction of noncondensable gases into the recovery equipment during connection and the release of the refrigerant during disconnection.

6.7 The equipment must be able to separate the lubricant from the recovered refrigerant and accurately indicate the amount removed from the system during processing in 30 ml units.

6.7.1 The purpose of indicating the amount of lubricant removed is to ensure that a proper amount is returned to the mobile air-conditioning system for compressor lubrication.

6.7.2 Refrigerant dissolved in this lubricant must be accounted for to prevent

system lubricant overcharge of the mobile air-conditioning system.

6.7.3 Only new lubricant, as identified by the system manufacturer, should be replaced in the mobile air-conditioning system.

6.7.4 Removed lubricant from the system and/or the equipment shall be disposed of in accordance with applicable federal, state and local procedures and regulations.

6.8 The equipment must be capable of continuous operation in ambient temperatures of 10°C to 49°C and comply with 6.1.

6.9 The equipment should be compatible with leak detection material that may be present in the mobile air-conditioning system.

7.0 For test validation, the equipment is to be operated according to the manufacturer's instructions.

[FR Doc. 95-10622 Filed 5-1-95; 8:45 am]

BILLING CODE 6560-50-P

REGISTERED

Tuesday
May 2, 1995

Part IV

**Department of
Housing and Urban
Development**

**Funding Availability; Application
Submission for Applicants in Oklahoma
City Area for Certain NOFAs; Notice**

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of the Assistant Secretary for Public and Indian Housing

[Docket No. N-95-3915; FR-3910-N-01]

PIH Notices of Funding Availability (NOFAs); Notice of Extension of Application Due Date and Location of Application Submission for Applicants in Oklahoma City Area for Certain NOFAs

AGENCY: Office of the Assistant Secretary for Public and Indian Housing, HUD.

ACTION: Notices of Funding Availability (NOFA) for Fiscal Year 1995; Notice of Extension of Application Due Date and Location of Application for Applicants in Oklahoma City Area for Certain PIH NOFAs.

SUMMARY: This notice sets forth a list of notices of funding availability (NOFAs) recently published by HUD's Office of Public and Indian Housing, and identifies where applications should be submitted in lieu of submission to HUD's Oklahoma State Office in Oklahoma City, Oklahoma. This notice also extends the application due date for certain NOFAs. The revised application submission locations and, where applicable, revised submission dates are applicable only to applicants within the Oklahoma State/Southern Plains Service Areas. All other applicants must rely on submission locations and submission dates published in the underlying NOFAs.

DATES: See **SUPPLEMENTARY INFORMATION** section of this notice.

FOR FURTHER INFORMATION CONTACT:

Please contact the person listed in the individual NOFA for which an application is to be submitted. For general information about this notice, contact Cheryl Teninga, Director, Field Operations Staff, Office of Public and Indian Housing, Department of Housing and Urban Development, Room 4120, 451 Seventh Street, SW, Washington, DC 20410-5000, telephone 708-4016. Hearing- or speech-impaired persons may use the Telecommunications Devices for the Deaf (TDD) by contacting the Federal Information Relay Service on 1-800-877-TDDY (1-800-877-8339) or (202) 708-9300. (Other than the "800" TDD number, telephone numbers are not toll-free.)

SUPPLEMENTARY INFORMATION: Due to the tragic event that occurred in Oklahoma City, Oklahoma, on April 19, 1995, which resulted in the destruction of the Alfred Murrah Federal Building in

Oklahoma City, Oklahoma, the location for the submission of applications in response to certain NOFAs, applications that would have been submitted to HUD's Oklahoma State Office in Oklahoma City, Oklahoma, must be submitted to other HUD offices. In addition, application due dates for certain NOFAs will be extended for applicants that would have been required to submit their applications to HUD's Oklahoma State Office in Oklahoma City.

HUD, however, assures the public, especially HUD's customers and clients in the Oklahoma State Office area that HUD will maintain an office in Oklahoma City. Additionally, HUD will not bypass the involvement of staff from the Oklahoma State Office, with whom applicants are familiar and have established a good working relationship. The other HUD offices to which applications are being directed will assist the Oklahoma office staff with processing of applications until the HUD Oklahoma State Office is fully operational in Oklahoma City. Available Oklahoma State Office will be involved in the NOFA processing in coordination with the offices that are providing assistance.

Accordingly, this notice sets forth a list of NOFAs recently published by HUD's Office of Public and Indian Housing. The notice identifies where applications should be submitted, and also extends the application due date for certain NOFAs. The NOFAs are listed in the order of publication. Application due dates that are extended are identified as extended.

With the exception of possible new application *due dates*, and a new location for submission of applications, all other information applicable to a particular NOFA remains as set forth in the published NOFA (as may have been amended by any subsequent technical correction or clarification). Please note that the unchanged information includes the time at which applications are due to the applicable HUD Office, and the manner in which applications are to be submitted.

Note: The revised application submission locations set forth in this notice, and where applicable, revised submission dates are applicable only to applicants within the Oklahoma State/Southern Plains Service Areas. All other applicants must rely on submission locations and submission dates published in the underlying NOFAs.

Subject to the limitations set forth in this notice, applicants within the Oklahoma State/Southern Plains Service area should submit applications under the following NOFAs to the location

identified, and by the due date set forth below.

1. NOFA for Public and Indian Housing Family Investment Centers

[Docket No. N-95-3714; FR 3832-N-01, published February 15, 1995, at 60 FR 8900]

Application Due Date: June 29, 1995*

[*Reflects extended due date]

Submit application to: HUD Colorado State Office, Public Housing, First Interstate Tower North, 633-17th Street, Denver, CO 80202-3607, ATTN: OKC

For Native American Programs submit application to: HUD Eastern/Woodlands Office of Native American Programs, Metcalfe Federal Building, 77 West Jackson Boulevard, Chicago, IL 60604-3507

2. NOFA for Community Development Block Grant Program for Indian Tribes and Alaska Native Villages. [Docket No. N-95-3870; FR-3798-N-01, published February 24, 1995 at 60 FR 10452]

Application Due Date: May 30, 1995*

[*Reflects extended due date]

Submit application to: HUD Northern Plains Office of Native American Programs, First Interstate Tower North, 633 17th Street, Denver, Colorado 80202-3607

3. NOFA for Service Coordinators for Public Housing Agencies

[Docket No. N-95-3854; FR-3785-N-01, published February 27, 1995, at 60 FR 10274]

Application Due Date: May 2, 1995*

[*Reflects extended due date¹]

Submit application to: HUD Colorado State Office, Public Housing, First Interstate Tower North, 633-17th Street, Denver, CO 80202-3607, ATTN: OKC

4. NOFA for Public and Indian Housing Tenant Opportunities Program Technical Assistance [Docket No. N-95-3847; FR-3828-N-01, published March 1, 1995, at 60 FR 11222]

Application Due Date: May 19, 1995*

[*Reflects extended due date]

Submit application to: HUD Colorado State Office, Public Housing, First Interstate Tower North, 633-17th Street, Denver, CO 80202-3607, ATTN: OKC

For Native American Programs submit application to: HUD Eastern/Woodlands Office of Native American Programs, Metcalfe Federal Building, 77 West Jackson Boulevard, Chicago, IL 60604-3507

5. NOFA for the Rental Voucher Program and Rental Certificate Program

[Docket No. N-95-3874; FR-3849-N-01, published March 3, 1995 at 60 FR 12036]

There were six subprogram areas. Each subprogram had its own application due date:

a. Fair Share Allocations

Application Due Date: May 16, 1995*

¹ Only two housing authorities located in the Oklahoma State/Southern Plains Service area would have submitted their applications to the Oklahoma State Office under this NOFA. These authorities have advised HUD that a May 2, 1995 application due date can be met.

[* Reflects extended due date]

Submit application to: HUD Texas State Office, Public Housing, P.O. Box 2905, Fort Worth, TX 76113-2905, ATTN: Bill Canales—OKC

For Native American Programs submit application to: HUD Northern Plains Office of Native American Programs, First Interstate Tower North, 633 17th Street, Denver, Colorado 80202-3607

b. Section 8 Counseling

Application Due Date: May 16, 1995*

[* Reflects extended due date]

Submit application to: HUD Texas State Office, Public Housing, P.O. Box 2905, Fort Worth, TX 76113-2905, ATTN: Bill Canales—OKC

For Native American Programs submit application to: HUD Northern Plains Office of Native American Programs, First Interstate Tower North, 633 17th Street, Denver, Colorado 80202-3607

c. Funding for Family Unification

Application Due Date: May 17, 1995

Submit application to: HUD Texas State Office, Public Housing, P.O. Box 2905, Fort Worth, TX 76113-2905, ATTN: Bill Canales—OKC

For Native American Programs submit application to: HUD Northern Plains Office of Native American Programs, First Interstate Tower North, 633 17th Street, Denver, Colorado 80202-3607

d. Funding for FSS Service Coordinators

Application Due Date: May 17, 1995

Submit application to: HUD Texas State Office, Public Housing, P.O. Box 2905, Fort Worth, TX 76113-2905, ATTN: Bill Canales—OKC

For Native American Programs submit application to: HUD Northern Plains Office of Native American Programs, First

Interstate Tower North, 633 17th Street, Denver, Colorado 80202-3607

e. Funding for Mainstream Housing

Application Due Date: June 1, 1995

Submit application to: HUD Texas State Office, Public Housing, P.O. Box 2905, Fort Worth, TX 76113-2905, ATTN: Bill Canales—OKC

For Native American Programs submit application to: HUD Northern Plains Office of Native American Programs, First Interstate Tower North, 633 17th Street, Denver, Colorado 80202-3607

f. Funding for Persons With AIDs

Application Due Date: June 1, 1995

Submit application to: HUD Texas State Office, Public Housing, P.O. Box 2905, Fort Worth, TX 76113-2905, ATTN: Bill Canales—OKC

For Native American Programs submit application to: HUD Northern Plains Office of Native American Programs, First Interstate Tower North, 633 17th Street, Denver, Colorado,, 80202-3607

g. Funding for Homeless Families

Application Due Date: June 1, 1995

Submit application to: HUD Texas State Office, Public Housing, P.O. Box 2905, Fort Worth, TX 76113-2905, ATTN: Bill Canales—OKC

For Native American Programs submit application to: HUD Northern Plains Office of Native American Programs, First Interstate Tower North, 633 17th Street, Denver, Colorado 80202-3607

6. *NOFA for Comprehensive Improvement Assistance Program (CIAP)*

[Docket No. N-95-3867; FR 3774-N-02; published on March 17, 1995, at 60 FR 14538]

Application Due Date: May 30, 1995*
[*Reflects extended due date]

Submit application to: HUD Texas State Office, Public Housing, P.O. Box 2905, Fort Worth, TX 76113-2905, ATTN: Bill Canales—OKC

For Native American Programs submit application to: HUD Northern Plains Office of Native American Programs, First Interstate Tower North, 633 17th Street, Denver, Colorado 80202-3607

7. *NOFA for Lead-Based Paint (LBP) Risk Assessments*

[Docket No. N-95-3778; FR-3875-N-01; published March 30, 1995, at 60 FR 16560]

Application Due Date: June 13, 1995*
[*Reflects extended due date]

Submit application to: HUD Texas State Office, Public Housing, P.O. Box 2905, Fort Worth, TX 76113-2905, ATTN: Bill Canales—OKC

For Native American Programs submit application to: HUD Northern Plains Office of Native American Programs, First Interstate Tower North, 633 17th Street, Denver, Colorado 80202-3607

8. *NOFA for Emergency Shelter Grants Set-Aside for Indian Tribes and Alaskan Native Villages*

[Docket No. N-95-3893; FR-3879-N-01, published April 11, 1995, at 60 FR 18524]

Application Due Date: June 9, 1995*
[*Reflects extended due date]

Submit application to: HUD Northern Plains Office of Native American Programs First Interstate Tower North, 633 17th Street, Denver, Colorado 80202-3607

Dated: April 28, 1995.

Joseph Shuldiner,

Assistant Secretary for Public and Indian Housing.

[FR Doc. 95-10884 Filed 4-28-95; 1:54 pm]

BILLING CODE 4210-33-P

Executive Order

Tuesday
May 2, 1995

Part V

The President

Proclamation 6793—Small Business Week

Presidential Documents

Title 3—

Proclamation 6793 of April 28, 1995

The President

Small Business Week, 1995

By the President of the United States of America

A Proclamation

At the heart of our free enterprise system are the Nation's 21.5 million small businesses. They are the engine of our economy, keeping America competitive in domestic and global markets. These businesses demonstrate by their achievements and success that the promise of the American Dream is within the grasp of every one of our citizens.

America's small business entrepreneurs are risk-takers, venturing into new and often uncertain territory. As a Nation, we are indebted to these bold men and women. With unparalleled commitment and determination, they keep us at the forefront of innovation and help fuel our economy.

During the past decade, more than 600,000 new firms have been created annually. Indeed, just last year, more small businesses were created than at any time in our country's history. Through much of this period, small businesses generated most of the Nation's new jobs. Today, they employ almost 60 percent of the country's private work force.

Growing numbers of women and minorities are empowering themselves through small business ownership, taking risks, and pursuing their entrepreneurial ambitions. New programs are teaching business ownership skills to our youth. And our Administration's Reinventing Government initiative—building a government that works better and costs less—will help sustain this entrepreneurial spirit for generations to come.

As we approach a new era of economic opportunity, our Nation's small business owners continue to inspire us by their example. On behalf of all Americans, I thank these hardworking citizens across the country for helping to keep the American Dream alive.

NOW, THEREFORE, I, WILLIAM J. CLINTON, President of the United States of America, by virtue of the authority vested in me by the Constitution and laws of the United States, do hereby proclaim April 30 through May 6, 1995, as "Small Business Week." I ask all Americans to join me in saluting the small business owners of our Nation during this week with appropriate events and ceremonies.

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



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Tuesday, May 2, 1995

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